In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-972V

Filed: January 24, 2018

PAUL MONDELLO,	*	To Be Published
Petitioner,	*	
v.	*	Ruling on Entitlement on Remand; Vaccine Act Entitlement; Hepatitis A Vaccine; Aseptic Meningitis; Seizures.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Verne E. Paradie, Jr., Paradie Sherman, et al., Lewiston, ME, for petitioner.
Darryl Wishard, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT ON REMAND[1]

Roth, Special Master:

On September 30, 2015, Paul Mondello ("petitioner" or "Mr. Mondello") timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] ("Vaccine Act" or "Program"). The petition alleges that Mr. Mondello suffers from a seizure disorder caused by the hepatitis A vaccination he received on November 15, 2013. Petition at ¶¶ 2, 15. The petition further alleges that Mr. Mondello's injuries persisted for more than six months. *Id*. at ¶ 12.

Petitioner's claim was denied by the undersigned after petitioner filed a Motion for Ruling on the Record. *Mondello v. Sec'y of HHS*, No. 15-972V (Fed. Cl. Spec Mstr. Nov. 15, 2016). Petitioner filed a Motion for Review and the Court of Federal Claims remanded the decision, ordering reconsideration of the evidence. *Mondello v. Sec'y of HHS*, 132 Fed. Cl. 316 (2017).

[1] Because this published ruling contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' 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)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, I agree that the identified material fits within the requirements of that provision, I will delete such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

In accordance with the Court of Federal Claims' order, the undersigned has reviewed all of the evidence after remand. The Motion for Ruling on the Record was filed on an underdeveloped record; therefore, the undersigned heard testimony from the petitioner and his treating neurologist. Respondent filed an expert report in response to the oral opinions of petitioner's neurologist, Dr. Bourque. Now that petitioner's record is more developed, he has provided preponderant evidence that supports the *Althen* prongs. Therefore, petitioner is entitled to compensation.

I. Procedural History

A. Office of Special Masters

The petition was filed on November 3, 2015. ECF No. 1. The medical record was completed on December 26, 2015. ECF No. 19. On January 11, 2016, respondent filed his Rule 4(c) report recommending against compensation. Resp. Rpt., ECF No. 20. In his report, respondent stated that petitioner had failed to satisfy the causation standards for an off-Table case as articulated in *Althen v. Sec'y of Health and Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005). Respondent stated that "the more likely cause of petitioner's seizure onset was the resultant side effect of his first dose of cyproheptadine." Resp. Rpt. at 6.

This case was initially assigned to Special Master Hamilton-Fieldman, but reassigned to me on January 14, 2016. ECF No. 21. Following a status conference on January 28, 2016, petitioner was ordered to retain an expert. Scheduling Order, ECF No. 23. On April 17, 2016, petitioner filed medical records from Dr. Bourque, petitioner's treating neurologist, as Pet. Ex. 9, along with a status report ("Pet. S.R."), in which petitioner stated that "Dr. Bourque's latest record and opinions establish that the vaccination was a substantial factor in bringing about his current condition." Pet. S.R., ECF No. 26, at 1.

A status conference was held on May 19, 2016, to discuss petitioner's need for an expert report which complied with "the *Althen* criteria required to prove causation in the program." Scheduling Order, ECF No. 27, at 1. On July 18, 2016, petitioner filed a status report stating "he does not intend on submitting an expert report and instead, anticipates filing a Motion for Ruling on the Record." Pet. S.R., ECF No. 31, at 1. On August 1, 2016, petitioner filed a motion for a ruling on the record along with the Twinrix (Hepatitis A/B) package insert, vaccine information sheets for Hepatitis A and B vaccines, and two articles of medical literature.[3] Pet. Ex. 10-14, ECF No. 32. At a status conference on September 22, 2016, petitioner's counsel confirmed that petitioner "requested a ruling on the record as opposed to a dismissal decision." Scheduling Order, ECF No. 33, at 1. The undersigned issued a Ruling on the Record on November 15, 2016, denying entitlement to compensation and dismissing the petition. Decision, ECF No. 34.

B. Court of Federal Claims

Petitioner filed a Motion for Review on December 14, 2016. ECF No. 40. Petitioner

[3] Though the records indicate that petitioner received a Twinrix (hepatitis A and B) vaccine, according to the petition, petitioner alleges injuries only as a result of the hepatitis A vaccine and the petition was not amended to allege otherwise. *See* Petition at ¶¶ 2, 15.

submitted that, while he did not proffer an expert opinion providing a biological mechanism, the combination of Dr. Bourque's opinion and the medical literature filed was sufficient to establish a prima facie case under *Althen*. *Id*. at 5. Respondent filed a response on January 11, 2017, maintaining that petitioner failed to proffer a medical theory of causation which complied with the *Althen* criteria. ECF No. 42.

On May 1, 2017, the Court granted petitioner's motion for review, finding that petitioner had proffered "at least some evidence suggesting a theory of causation," that the undersigned erred in assigning to petitioner the burden of disproving alternate causes and that it appeared the submitted literature was not considered. This matter was remanded to the undersigned for further proceedings. *Mondello v. Sec'y of Health & Human Servs*., 132 Fed. Cl. 316 (2017).

C. Office of Special Masters on Remand

A status conference was held on May 9, 2017; the undersigned suggested hearing testimony from petitioner as well as his treating physician, Dr. Bourque. Scheduling Order, ECF No. 45. Petitioner's counsel advised that Dr. Bourque was no longer petitioner's treating physician and may be difficult to contact. The undersigned informed the parties that, in order to allow time to further develop the record, petitioner should file a Motion to Stay the Proceedings.

Petitioner filed a Motion to Stay Proceedings on June 12, 2017, and a 30 day stay was granted. Motion, ECF No. 47; Order, ECF No. 48. On June 22, 2017, petitioner filed a status report advising the Court that Dr. Bourque had moved her practice from Maine to San Rafael, California; petitioner had reached out to Dr. Bourque but had not yet received a response. Pet. S.R., ECF No. 49. Petitioner was ordered to file a status report by July 6, 2017, indicating petitioner's availability to testify at a fact hearing.

Petitioner filed two status reports on July 5, 2017, stating that petitioner was available to give testimony via video conference on July 12 and 13, 2017, and advising that petitioner would be submitting an affidavit from Dr. Bourque "regarding her conclusions and opinions on the cause and mechanism of Petitioner's medical condition." ECF Nos. 50, 51.

Petitioner was ordered to file a status report by July 17, 2017, suggesting dates in August of 2017 on which both petitioner and Dr. Bourque would be available to testify. Non-PDF Order, issued July 5, 2017. On July 17, 2017, petitioner requested an extension of time until July 31, 2017 to file his status report. ECF No. 52. Petitioner filed a status report on July 31, 2017, stating that petitioner would be available to give testimony in late August, and advising that, while petitioner expected to file an affidavit from Dr. Bourque, it may be necessary to issue a subpoena in order obtain Dr. Bourque's testimony. ECF No. 53.

Petitioner was ordered to file an affidavit from Dr. Bourque by August 14, 2017, as well as a status report indicating both petitioner's and respondent's availability for a hearing on either August 29 or August 30, 2017. Scheduling Order ECF No. 54. Petitioner was also ordered to file a motion to further stay proceedings. *Id*. On August 14, petitioner filed an affidavit from Dr. Bourque and a status report advising that petitioner's counsel was available for a fact hearing on August 22, 28, 30, and 31. ECF Nos. 55, 56. Petitioner also filed a Motion to Stay Proceedings,

requesting a 150 day stay. ECF No. 57. The undersigned granted petitioner's motion in part for a stay of 60 days. ECF No. 58.

Hearings were held via video conference on August 28, 2017 and September 7, 2017 for the testimony of petitioner and Dr. Bourque, respectively. *See* Prehearing Order, ECF Nos. 59-60.

On October 3, 2017, respondent filed an expert report from a neurologist, Dr. Leist. Pet. Ex. E-J, ECF No. 68. That same day, I issued an order stating that on September 7, 2017, Dr. Bourque testified that petitioner suffered from aseptic meningitis as a result of his hepatitis vaccine, which lowered his seizure threshold and was one of several contributing factors to his development of seizures following his ingestion of cyproheptadine eight days after the vaccination. Scheduling Order at 1, ECF No. 69. The order further stated that respondent's expert, Dr. Leist, opined that there was no evidence in the medical records that petitioner suffered from aseptic meningitis following the hepatitis vaccine. Petitioner was ordered to file medical literature in support of Dr. Bourque's opinions showing (1) a connection between the hepatitis vaccine and aseptic meningitis; (2) a connection between aseptic meningitis and seizures; and (3) a connection between the hepatitis vaccine and seizures. *Id.*

On November 14, 2017, petitioner filed a status report stating that he had no further evidence to offer and requesting the opportunity to cross-examine respondent's expert. Pet. S.R., ECF No. 70. During a status conference held on November 15, 2017, respondent objected to petitioner's request to cross-examine Dr. Leist and referred to a discussion on the record following Dr. Bourque's testimony in September, in which petitioner mentioned only reserving his right to have Dr. Bourque respond to Dr. Leist in a written submission. Scheduling Order at 1, ECF No. 71. I agreed that petitioner had reserved his right to have Dr. Bourque respond to Dr. Leist's report, but noted that petitioner's counsel would be allowed to cross-examine Dr. Leist if he felt that it was necessary to ensure that the record was complete. *Id.* Petitioner's counsel stated that he considered the record to be well-developed, and asked for time to reconsider his request to cross-examine Dr. Leist. *Id.* On November 16, 2017, petitioner filed a status report withdrawing his request to cross-examine Dr. Leist, indicating that he no longer felt it was necessary. Pet. S.R. at 1, ECF No. 73. Dr. Bourque did not respond to Dr. Leist's report or opinions.

This matter is now ripe for decision.

II. Relevant Medical History and Petitioner's Testimony

Petitioner provided testimony via videoconference on August 28, 2017. At the time of his testimony, he was very confused. Since his vaccination, petitioner has been diagnosed with stage IV metastatic prostate cancer. Tr. 6. At the time of his testimony, he had just concluded radiation treatment. Tr. 6-8. He often conflated what he claimed to be complaints following the vaccination with those associated with his cancer. For example, when his counsel asked him if he was sick part of the week, or the whole week after receipt of his vaccination, petitioner responded, "It was horrible. It was horrible. I was awake, I hurt, I can't describe how I felt. There's no way to describe how it feels. It hurts – I didn't know I had the bone cancer for years, and that's why it got advanced, and that's why it hurts so bad. Everything hurts. And I just had the thing last – shot yesterday – yesterday or the day before yesterday and I'm still trying to recover from the shots." Tr. 15.

Petitioner was referring to his last cancer treatment received the day before his testimony. Petitioner's counsel did an admirable job trying to keep petitioner focused and on point.

A. Petitioner's Health Prior to the Hepatitis Vaccination

Petitioner was born on October 2, 1943. Pet. Ex. 3 at 218. Petitioner served in the Vietnam War; he was honorably discharged after receiving a severe blow to the head and crush injuries to his knees and back. Pet. Ex. 2 at 80, 83. Petitioner received his primary care at Togus Veterans Administration Hospital ("Togus"). He was treated for hypertension, Post-Traumatic Stress Disorder ("PTSD"), osteoarthritis, hearing loss, gastroesophageal reflux disorder ("GERD"), migraines, abnormal glucose, chronic back pain, and chronic hepatitis C. *Id*. at 99-100. His past medical history also included Agent Orange exposure, alcohol dependence, Stevens-Johnson syndrome after taking hydrochlorothiazide,[4] hyponatremia,[5] and an allergy to sulfa drugs. *Id*. at 83, 155; Pet. Ex. 3 at 304, 308; Tr. 30-32, 45.

On November 22, 2012, one year prior to his alleged vaccine related injuries, petitioner presented to the emergency room with nausea, vomiting, fever and headache as a result of hyponatremia. *See generally* Pet. Ex. 5. Petitioner returned two or three days later due to continued headache. He had apparently fallen and hit his head. A head CT was performed and was normal. *Id*.

Just prior to the receipt of the vaccine alleged herein, petitioner was admitted to Togus' inpatient rehabilitation program for alcohol and cannabis dependence following 15 years of a fifth of whiskey a day. Pet. Ex. 2 at 79. Petitioner had a certificate for medical marijuana and ate a brownie at night to help him sleep. *Id*. at 118. Petitioner regularly used benzodiazepine to treat panic attacks and anxiety but claimed to have discontinued its use prior to his vaccination. *Id*. at 111, 117.

On November 15, 2013, petitioner presented for follow-up at Togus. Pet. Ex. 2 at 99. He was noted to be without alcohol for 36 days. *Id*. During that visit, he received a Twinrix hepatitis A and B vaccine. *Id*. at 102. Petitioner alleges that only the hepatitis A vaccine caused him to develop seizures. Pet. at ¶¶3, 15. At hearing, petitioner stated that he did not recall the nurse who administered the vaccine informing him that he could develop fever, chills, or muscle aches after the vaccine. Tr. 33-34.

---

[4] Petitioner had Stevens – Johnson Syndrome from hydrochlorothiazide, which treats water retention. Stevens-Johnson Syndrome is a reaction to medications or injection, with a red-purplish rash that spreads and blisters. It requires emergency medical attention, usually hospitalization, and permanent avoidance of the medication. *Stevens-Johnson syndrome*, MAYO CLINIC (Apr. 22, 2014), http://www.mayoclinic.org/diseases-conditions/stevens-johnson-syndrome/basics/definition/con-20029623 (LAST VISITED OCT. 31, 2016).

[5] Hyponatremia is a condition that occurs when the level of sodium in the blood becomes abnormally low. Hyponatremia can cause nausea, vomiting, headache, confusion, fatigue, muscle weakness, and seizures. *Hyponatremia*, MAYO CLINIC (May 28, 2014), http://www mayoclinic.org/diseases-conditions/hyponatremia/basics/symptoms/con-20031445 (LAST VISITED NOV. 2, 2016). Petitioner had been diagnosed with hyponatremia a year prior to the administration of his hepatitis vaccine, during his hospital visit on November 22, 2012. *See generally* Pet. Ex. 5.

B. Petitioner's Health after the Hepatitis Vaccination and Testimony

Petitioner testified that as soon as he received the vaccine, he immediately felt sick; his headache was "screaming." He had no idea how he drove home. He admitted to having headaches since Vietnam, but this one was worse, but he didn't say anything to anyone at Togus. Tr. 11; 39. According to the petitioner, Togus is over a two-hour drive, or 250 miles, from his home, and though he put his home address into the GPS, he got lost several times and drove past his own house. Tr. 11. By the time he got home, he had a fever, headache, nausea, and vomiting. Tr. 39-40. He has not "eaten right" since receiving the hepatitis vaccine. Tr. 13.

Petitioner stated that in the week following the vaccination, he suffered from vomiting, fatigue, headaches, and could not stay awake. He also had a high fever. Tr. 13, 16-17. Petitioner testified that other than his usual medications, he did not take anything for the vomiting, headache, or fever that week. Tr. 49-50. Petitioner did recall his wife making him a protein drink during the week after the vaccination. Tr. 52.

According to petitioner the headache, fever, nausea, and vomiting persisted until his wife called an ambulance to take him to the hospital. Tr. 14. Petitioner testified that his wife called the doctor at Togus twice to report petitioner's symptoms and left messages, but the doctor did not call back. Tr. 40. He later stated that his wife called the doctor in Newport, not Togus, but he couldn't remember her name.[6] Tr. 49.

Petitioner was reminded by counsel that his wife had to call an ambulance after he took cyproheptadine.[7] Tr. 18. According to the petitioner, he was given cyproheptadine for pain and he took it for the first time four or five days after the vaccination because he was in severe pain, his headache was "so bad," and he was "sick as a dog." Tr. 19, 52. He later conceded that the pain he was referring to after the vaccination was probably from the cancer, not the vaccination, admitting that he has had pain from the cancer way before he received the vaccination. Tr. 27, 44. Petitioner stated that after he took the cyproheptadine, he began seeing flashing lights as well as "little tiny red bugs." Tr. 18. His wife became scared and called an ambulance when she found him in a La-Z-Boy recliner, seizing. Tr. 18, 20. According to the petitioner, he was shaking so much that the EMTs could not administer the propofol. Tr. 20. Petitioner stated that his wife was told he stopped breathing at least three times. Tr. 20.

---

[6] Petitioner has not produced any medical records or telephone records to confirm that any phone calls were made to any doctor the week following the vaccination. Petitioner's wife did not testify at hearing, though she was present outside of the hearing room during petitioner's testimony. The undersigned asked both counsel if either wanted testimony from Mrs. Mondello after petitioner had finished testifying, but both counsel stated that they did not.

[7] Cyproheptadine is an antihistamine used to relieve allergy symptoms such as sneezing, itching, watery eyes, runny nose, and other symptoms of allergies. *Cyproheptadine*, University of Michigan Health System (Dec. 3, 2013), http://www.uofmhealth.org/health-library/d00790a1 (last visited Nov. 1, 2016). Side effects of cyproheptadine include sedation, dizziness, urticaria, blurred vision, palpitations, and fatigue; overdosage may produce hallucinations, CNS depression, and convulsions. Cyproheptadine may have "additive effects" with alcohol and other CNS depressants, like sedatives or antianxiety agents. Cyproheptadine is contraindicated for "elderly, debilitated" patients. *Cyproheptadine Hydrochloride Tablets – Drug Summary*, PDR net, http://www.pdr net/drug-summary/Cyproheptadine-Hydrochloride-Tablets-cyproheptadine-hydrochloride-1549 (last visited Nov. 1, 2016).

When asked what medications he was taking at the time of the seizure, petitioner could not recall, but stated that his wife gives him his medications. Tr. 40-41. When asked about gabapentin,[8] petitioner responded he believed he took it to help with his memory, and to help him eat. Tr. 42. Petitioner indicated that he used medical marijuana, but denied that he used it at the time he received the vaccine. Tr. 47-48.

Upon his arrival to St. Joseph's Hospital on November 22, 2013, it was noted, "Patient was last known well (about 1 hour PTA). (pt's wife at bedside and reports that pt. recently had a hepatitis A vaccination given to him on Friday and has not been feeling well since. Nausea/vomiting and poor apetite. (sic) Per pt's wife at approx. 5 pm today he began to hallucinate (visual))." Pet. Ex. 1 at 7. Petitioner's wife also reported that petitioner had taken cyproheptadine for the first time at around 4 p.m.; he became confused shortly thereafter and began hallucinating and talking about flashes of light. Pet. Ex. 3 at 296. Petitioner then had a seizure and his wife called an ambulance. *Id*.

Petitioner's Glasgow Score (GCS)[9] upon arrival was 7; he was intubated and administered Valium. Pet. Ex. 1 at 8, 21. A head CT was normal. *Id*. at 25. A urine test was positive for benzodiazepines and marijuana, with elevated glucose, trace blood, and protein. *Id*. at 26-27. Petitioner was then transferred to the emergency department at Eastern Maine Medical Center ("EMMC") with an assessment of "generalized status epilepticus of unknown cause." *Id*. at 31. It was noted that petitioner was a longstanding alcoholic but had been sober for 46 days, and had no prior history of seizures. *Id*. at 7, 22.

While at EMMC, petitioner underwent testing, including a chest x-ray, EEG, and head MRI without contrast. Pet. Ex. 5 at 1393-99. The chest x-ray revealed that petitioner's heart was "mildly enlarged." *Id*. at 1396. Petitioner's EEG reflected "diffuse right-sided slowing," "transient periodic right lateralized discharges involving frontal area," and "intermittent spikes throughout the record involving right frontal area." *Id.* at 1394. Petitioner's MRI of the head showed "no acute or malignant intracranial process," with "moderate burden of white matter signal changes" and "mild diffuse cerebral volume loss." *Id*. at 1400. The general impression of the MRI was a finding of uncertain clinical significance. *Id*.

Petitioner came under the care of Dr. Bourque, a neurologist. Dr. Bourque ordered a lumbar puncture to rule out herpes simplex virus encephalitis "or other bacterial meningitis." Pet. Ex. 7 at 1435. Dr. Bourque noted a concern that petitioner "may have an aseptic meningitis related to the vaccination." *Id*. Petitioner's labs were negative for *cryptococcus* and herpes simplex virus. Pet. Ex. 3 at 290. His lumbar puncture showed a "modest elevation in cerebrospinal fluid protein." *Id*. at 289. Dr. Bourque prescribed 500 mg of Keppra twice a day for seizures. Pet. Ex. 7 at 1435.

---

[8] Gabapentin is an anticonvulsant used to treat refractory focal seizures, neuropathic pain, and migraines. Common side effects include dizziness, ataxia, sedation, fatigue, and nystagmus. *See Dorland's Illustrated Medical Dictionary* 753 (Saunders eds., 32nd ed. 2012); *see also Pediatric Neurology: Principles & Practice* 962-63, 1197, 2378 (Swaiman, Ashwal, & Ferriero eds., 4th ed. 2006).

[9] "GCS" is the abbreviation for "Glasgow Coma Scale." The Glasgow Coma Scale is the most common scoring system used to gauge the severity of an acute brain injury, with a score of "3" as the most severe and a score of "15" as the least severe, or normal. *What Is the Glasgow Coma Scale?*, BRAINLINE.ORG, http://www.brainline.org/content/2010/10/what-is-the-glasgow-coma-scale html (LAST VISITED NOV. 1, 2016).

Petitioner was discharged from EMMC on November 27, 2013, with a diagnosis of "new-onset seizure," delirium and hyponatremia. Pet. Ex. 3 at 285. Petitioner's discharge summary stated:

> "[at] the time of this dictation, there is no specific etiology assigned to this patient's symptoms. Certainly his general condition was consistent with alcohol withdrawal although the patient and multiple family members state that there has been on (sic) use of alcohol in the past six weeks. One must also consider the possibility of withdrawal from benzodiazepines, the effects of the hepatitis A vaccine that he received a few days prior, withdrawal from other medications, side effects of other medications, and a multitude of other metabolic derangements. In addition, the patient's history of a traumatic brain injury in Vietnam may put him at increased risk for development of a seizure disorder. Despite the lack of a specific diagnosis, the patient's general condition has improved remarkably. He is now essentially at his baseline."

Id. at 290.

Petitioner received physical therapy at home through December 2013. *See generally* Pet. Ex. 4. Petitioner next presented to Mayo Practice Associates ("Mayo") on January 9, 2014, complaining of left trapezius strain and knee pain. Pet. Ex. 8 at 1475. Petitioner's records list "cyproheptadine HCl" as one of his allergies, with a reaction of "seizures, confusion." *Id*. at 1476. Petitioner returned to Mayo on January 23, 2014, for a follow-up of palpitations. *Id*. at 1477. The assessment was that he had an elevated prostate-specific antigen, palpitations, and benign localized prostatic hyperplasia. *Id*. at 1479.

On January 30, 2014, petitioner presented to Dr. Bourque for a follow-up. Pet. Ex. 7 at 1421. Dr. Bourque noted that she had initially met petitioner at the hospital on November 23, 2013 when he presented with a new onset of seizures. *Id*. Her notes for that date state:

> "At the time of the hospitalization, he had had a hepatitis A vaccination 1 week prior, and for that week had had nausea, vomiting, headache, and chills. He had been tremulous and just generally not feeling well. On the day of presentation, he took for the first time ever cyproheptadine 4 mg, and he had never taken this medication before. His wife states that within 20-30 minutes he started having visual hallucinations, and she went to call 911 and when she came back, she found him seizing."

Id. "He has not had any further severe headaches that occurred the week of presentation. He also has not had any fevers or lateralized weakness. There have been no seizures." *Id.* Following her examination, Dr. Bourque documented

> "Impression and Plan: [Petitioner] presented to hospital in November 2013 one week following hepatitis A vaccination and was found to have altered mental status following intake of cyproheptadine and subsequent recurrent seizures. He has done well post discharge on Keppra in terms of no further seizures. Overall, his mental status has returned close to baseline according to the family, although his wife states

he has occasional episodes where his ability to give directions seems impaired."

Id. at 1422. Dr. Bourque suggested he be seen by neuropsychology to get a baseline and assess cognitive strengths and weaknesses. *Id*.

On February 24, 2014, a repeat EEG was performed which was normal. Prior findings seen during his hospitalization had resolved. Pet. Ex. 7 at 1430.

On April 7, 2014, petitioner returned to Dr. Bourque for follow up of seizures. Dr. Bourque noted: "He has been on Keppra ever since the episode, which occurred during a week when he had had the hepatitis A vaccine and was not feeling well and was subsequently given 4 mg of cyproheptadine and shortly after developed visual hallucinations and seizures. He has continued on the (sic) Keppra and has not had any further seizures." Pet. Ex. 7 at 1429. He had gone back to drinking alcohol but stopped again a week and a half ago. *Id.* He started driving with no issues and there has been no further "confusion spells." *Id.* A repeat EEG performed on February 24, 2014 was normal and the prior findings seen during the hospitalization had resolved. *Id*. at 1430. Following examination, Dr. Bourque reported:

> "Impression and Plan: [Petitioner] had presented to hospital on November 2013 one week after a hepatitis A vaccination and developed hallucinations and seizures shortly after taking cyproheptadine. He has had no further seizures. His EEG is now normal. I did discuss with [petitioner] and his wife today that in light of the provoked nature of his seizures and the normal EEG, we could consider tapering off the Keppra, although there is potential for recurrent seizures. He is not interested in pursuing this option as it would mean stopping driving for 6 months. We also discussed the possibility of switching Keppra to Trileptal, however, he finds he is tolerating it better and is not interested in not driving for 3 months during the switch." *Id*.

Petitioner next presented to Dr. Bourque nearly a year later on March 20, 2015 for possible "breakthrough seizure." Pet. Ex. 7 at 1426. Petitioner testified that he had tried to wean himself off Keppra without consulting a doctor; he became sick immediately. Tr. 22-23. He stated that after he started slurring his words and his speech was garbled, he started retaking Keppra. Tr. 23. Dr. Bourque noted that petitioner "had hepatitis A vaccine and was given 4 mg of cyproheptadine. He had an abnormal EEG at that time and was started on Keppra. We continued the Keppra as we did not know if he would have any further predisposition to seizures, and he did not want to go with driving cessation and his wife was worried about another seizure." *Id.* Dr. Bourque advised that he should remain on the full dose and she would see him in the fall to discuss tapering. *Id.* at 1427.

Petitioner returned to Dr. Bourque on October 2, 2015 for follow up. Pet. Ex. 7 at 1450. He had no further seizures. Under "Impression and Plan," Dr. Bourque noted that petitioner "continues to have a history of hospitalization with what was suspected to be possible be (sic) a provoked seizure in 2013, with an abnormal EEG at that time. When he tried taking himself off Keppra earlier this year, he had what was an atypical spell that may have represented a seizure so we will continue the Keppra." *Id*. at 1451.

On March 18, 2016, petitioner returned to Dr. Bourque for a follow up. Pet. Ex. 9 at 1485. He was again noted to have had a seizure in November of 2013 after he had "a hepatitis vaccine and had been feeling unwell and was given cyproheptadine." *Id*. Since an "unusual episode" when he tried to wean off Keppra, he has had no further seizures. *Id.* "He does find that overall he is not very good in familiar places and finding his way. He also finds it difficult to do things that he previously did for years. He does continue to have intermittent lapses in his alcoholism." *Id.* After her examination, Dr. Bourque noted

> "Impression and Plan: [petitioner] continues to have a history of hospitalization in November 2013 for suspected provoked seizure, which was likely a combination of being unwell from a hepatitis A vaccine and the compilation of cyproheptadine….He has some various cognitive complaints, which are likely multifactorial in light of his prior head injuries, alcoholism, chronic pain and untreated psychiatric illness.…He does continue on thiamine."

Id. at 1486. He was discharged from neurological care on that date. *Id*.

Petitioner testified that, in the summer of either 2016 or 2017, his Keppra was increased after his wife accidentally slammed the trunk lid on his head, causing him to have a seizure the next day. Tr. 24. Petitioner is being treated for Stage IV metastatic prostate cancer. Tr. 6.

III. Expert Opinions and Literature

The petitioner relied upon his treating neurologist, Dr. Suzanne Bourque, to support his claim that the seizures he suffered were caused by the hepatitis A vaccine he received. Dr. Bourque is a neurologist with a specialty in neuromuscular disease. Tr. 60; Pet. Ex. 15. She earned her medical degree from the University of British Columbia, Vancouver, in 2006 and completed a residency in neurology in 2011, followed by a one-year fellowship in neuromuscular disease. Tr. 60-61; Pet. Ex. 15. Dr. Bourque practiced at EMMC until April of 2016. Tr. 61. She now works for Kaiser Permanente in San Rafael, California. Tr. 60.

In response to Dr. Bourque's testimony and the literature submitted by petitioner, respondent submitted an expert report from Dr. Thomas Leist. Dr. Leist has a Ph.D. in biochemistry from the University of Zurich and a medical degree from the University of Miami. Resp. Ex. F at 1. He completed his residency in neurology at Cornell Medical Center. *Id*. Since 2000, Dr. Leist has been a professor of neurology at Thomas Jefferson University, where he is also the director of Hospital-based Neurology Infusion Services. *Id*. Dr. Leist did not testify.

Dr. Bourque based her theory upon her experience as a neurologist, petitioner's clinical presentation, and elevated proteins present in the petitioner's cerebrospinal fluid ("CSF"). Her theory was that petitioner developed aseptic meningitis[10] following receipt of the hepatitis A

[10] Aseptic meningitis describes any clinical syndrome characterized by meningeal inflammation not caused by an identifiable pathogen in the CSF. Allan R. Tunkel et al., *Acute Meningitis*, 1 MANDELL, DOUGLAS, AND BENNETT'S PRINCIPLES AND PRACTICES OF INFECTIOUS DISEASES 1189 (7th ed. 2010), hereinafter "Infectious Diseases." Common symptoms in adults with aseptic meningitis include headache, photophobia, stiff neck, rash, diarrhea, cough, upper respiratory symptoms, anorexia, and vomiting. *Id*. at 1204-05.

vaccine, which lowered his seizure threshold to the extent that introducing cyproheptadine to his already-primed system caused him to have a seizure. Tr. 77.

Dr. Bourque explained that viral illness or vaccination can cause the tissues covering the brain and spinal cord to become inflamed, leading to aseptic meningitis.[11] Tr. 74, 82; Pet. Ex. 16 at 2. According to Dr. Bourque, "meningitis" is the general term for inflammation of the meninges and brain. When no bacteria is present, it is called "aseptic." Tr. 83. According to Dr. Bourque, there is no test for aseptic meningitis, but symptoms of fever and elevated protein are an indication of the disease. Tr. 83. Petitioner's history of nausea, vomiting, and worsened headaches after the hepatitis vaccine made her suspect aseptic meningitis. Tr. 67-68; Pet. Ex. 16 at 2; Pet. Ex. 3 at 307. She therefore ordered a lumbar puncture to rule out herpes simplex virus encephalitis and aseptic meningitis. Pet. Ex. 16 at 2. The test results were negative for a viral infection. Dr. Bourque admitted that sometimes CSF proteins are elevated for no reason.[12] Pet. Ex. 16 at 2; Tr. 101-02, 119-20.

Dr. Leist dismissed Dr. Bourque's theory of aseptic meningitis, stating that petitioner's medical records did not support the diagnosis. Resp. Ex. E at 6. According to Dr. Leist, petitioner's diagnostic work up showed a white cell count of less than 1, red cell count of 3, glucose of 82 and protein of 88. Pet. Ex. 3 at 1279; Tr. 141. When aseptic meningitis is present, the white cell count is elevated; petitioner's white cell count was not elevated. Resp. Ex. E at 6; *see also* Resp. Ex. G[13] at 1. Dr. Leist further stated that petitioner's elevated CSF protein was a normal increase typically seen after seizures. Resp. Ex. E at 7; Resp. Ex. I[14] at 1, 3. Dr. Leist also stated that petitioner's medical history of lower back injury or his later diagnosis of stage IV prostate cancer could have been responsible for the elevated CSF protein level.[15] Resp. Ex. E at 7.

---

[11] Noninfectious etiologies of aseptic meningitis include, but are not limited to, certain drugs, vaccines, systemic illness, and medical procedures. Infectious Diseases at 1190.

[12] "CSF pleocytosis is almost always presents" in aseptic meningitis. The total CSF cell count is usually 100 to 1000 cell/mm^3. However, "elevated CSF protein and decreased CSF glucose concentrations, if present, are usually mild…." Infectious Diseases at 1207.

[13] Barbara Negrini et al., *Cerebrospinal Fluid Findings in Aseptic Versus Bacterial Meningitis*, PEDIATRICS, 105(2): 316-19 (2000), filed as Resp. Ex. G. In this study, cases of aseptic meningitis were defined as having at least 20 white blood cells/mm^3. This study was done on children and the authors noted that the data was difficult to interpret because many of the patients received antibiotics prior to the lumbar puncture. Petitioner was given acyclovir on November 24, 2013, due to Dr. Bourque's concern for viral infection, but discontinued after the lumbar puncture results were available. Pet. Ex. 3 at 959.

[14] Vaso Zisimopoulou et al., *Cerebrospinal fluid analysis after unprovoked first seizure*, FUNCT NEUROL, 31(2): 101-07 (2016), filed as Resp. Ex. I. This study was on males with an average age of 36. The results showed that CSF protein was higher than normal after an unprovoked seizure, and implied a disruption of the blood-brain barrier in patients with unprovoked seizures. Abnormal protein levels showed significant positive correlation with male gender and older age. It was noted that "Lumbar degenerative changes and/or stenosis found in older patients can potentially confound the correlation of age with CSF protein elevation." *Id.* at 3. Petitioner had chronic back pain. Pet. Ex. 2 at 99-100.

[15] Petitioner refused a referral for a prostate biopsy for elevated prostate-specific antigen (PSA) during a visit to Mayo Practice Associates on January 23, 2014. Pet. Ex. 8 at 1479; Resp. Ex. E at 4.

Dr. Leist submitted that the Institute of Medicine reviewed the adverse events following hepatitis A and B vaccination, and aseptic meningitis is not listed as an adverse event for either vaccine. Resp. Ex. E at 6. The IOM Report states that three publications reported encephalitis or encephalopathy after hepatitis B vaccine, but did not provide any support for a connection other than temporal relationship. *Id*. at 6-7; Resp. Ex. H.[16]

Dr. Bourque further opined that seizure activity can manifest itself after anything that lowers the seizure threshold, such as a prior head injury. Tr. 68, 70, 74. She explained that petitioner had a "provoked" seizure because he seized after a triggering event, like the use of a medication, noting that unlike unprovoked seizures, someone suffering from a provoked seizure is less likely to have another seizure. Tr. 77-78. When petitioner came under her care, she researched the role of the hepatitis vaccine to determine a cause for his seizures. She could not recall if she found anything about hepatitis vaccine specifically, versus vaccinations in general. Tr. 105, 120. She did not research the medically appropriate time period for a vaccine to cause seizures, nor did she know whether hepatitis A vaccine can cause seizures. Tr. 105-06, 120.

She also looked up cyproheptadine to determine whether it was a potential cause for petitioner's seizures and found that seizures were a potential side effect of the medication. Tr. 65-66; 117-18; *see* Resp. Ex. C,[17] Resp. Ex. D.[18] Dr. Bourque agreed that the cyproheptadine could have been responsible for petitioner's abnormal EEG while hospitalized, but did not believe that it would have caused petitioner's elevated CSF protein. Tr. 118-20.

According to Dr. Bourque "…anything in theory could have triggered this." Tr. 95, 98-102. "That's the hard thing with seizures, it's always kind of estimating the potential contributors and what their susceptibility is and it's hard to be definitive." Tr. 118. Dr. Bourque opined that a combination of petitioner's prior traumatic brain injury, his recent sobriety after a long history of alcoholism, and the hepatitis vaccine contributed to his lowered seizure threshold. Tr. 131-32. The cyproheptadine was the "trigger" for petitioner's seizures, based on timing, and had a major role. Tr. 85, 132.

Dr. Leist agreed that the cyproheptadine taken by the petitioner was the "provoking agent" of petitioner's seizures. Resp. Ex. E at 6. Dr. Leist submitted that animal models show that administering cyproheptadine made it easier to induce seizures, increase the severity of seizures, and reduce the efficacy of anti-epileptic medications. Resp. Ex. E at 6; Resp. Ex. C.[19]

---

[16] K. Stratton, et al., ADVERSE EVENTS OF VACCINES: EVIDENCE AND CAUSALITY (2012) at 421-38, filed as Resp. Ex. H.

[17] Damanpreet Singh and Rajesh Kumar Goel, *Proconvulsant potential of cyproheptadine in experimental animal models*, FUNDAM CLIN PHARMACOL, 24: 451-55(2010) (Noting that cyproheptadine is frequently prescribed as an appetite stimulant, and found that cyproheptadine reduces seizure threshold and decreases the efficacy of clinically used anti-epileptic drugs), filed as Resp. Ex. C.

[18] Luke Shankar et al., *Cyproheptadine induced seizures*, MED RES CHRON, 2(1) 41-43 (2015) (concluding that cyproheptadine reduces seizure threshold, increases the severity of seizures, and decreases the efficacy of clinically used anti-epileptic drugs), filed as Resp. Ex. D.

[19] *Supra*, n.17.

Dr. Leist added that petitioner's other health issues were more likely to blame for his feeling ill in the week prior to the seizure. Dr. Leist stated that though petitioner's wife had reported that he had experienced nausea, vomiting and poor appetite following the hepatitis vaccine, he had similar gastrointestinal complaints a year earlier associated with hyponatremia and had been hyponatremic on October 10 and 15 of 2013 during his alcohol rehabilitation. Resp. Ex. E at 7; Pet. Ex. 2 at 65. Dr. Leist added that petitioner was discharged from alcohol rehabilitation with a new prescription for Venlafaxine, which may have been responsible for his not feeling well and has been associated with hyponatremia in the elderly with symptoms of headache, difficulty concentrating, memory impairment, confusion, weakness and unsteadiness which may lead to falls. Seizures are also associated with the medication. Resp. Ex. E at 7-8; Resp. Ex. J.[20]

Dr. Leist concluded that there was no evidence in the record that petitioner suffered from aseptic meningitis on November 22, 2013, or that petitioner had any adverse reaction to the hepatitis vaccine he received. Dr. Leist concluded that the cyproheptadine was the cause of Mr. Mondello's seizures and that the hepatitis vaccine had no role. Resp. Ex. E at 8.

In support of his petition, petitioner submitted a vaccine information sheet for hepatitis A; a vaccine information sheet for hepatitis B; the package insert for Twinrix vaccine, an article titled "A case-control study of serious autoimmune adverse events following hepatitis B immunization" by David and Mark Geier;[21] and an article titled "Population-Level Evidence for an Autoimmune Etiology of Epilepsy" by Mei-Sing Ong et al.[22] Pet. Ex. 10-14. None of the literature submitted addressed hepatitis A vaccine and/or aseptic meningitis.[23]

The vaccine information sheets submitted by petitioner list the benefits of receiving the hepatitis vaccine, the complications that receiving hepatitis A or B vaccine can cause, and the risks of reaction from the vaccinations which include soreness or redness where the shot was given, low-grade fever, headache and tiredness which could last one to two days, feeling faint, shoulder pain, or an allergic reaction which could happen within minutes to a few hours after vaccination. *See generally* Pet. Ex. 10-11.

Petitioner submitted the package insert for Twinrix which lists "convulsions" among the events that have suspected causal connection to the components of Twinrix. Pet. Ex. 12 at 7. The package insert contains the following: "These events are reported voluntarily from a population of uncertain size, [so] it is not possible to reliably estimate their frequency or establish a causal relationship to product exposure." *Id*. at 6. Special masters have found that vaccine package inserts are not probative of causation. *See H.L. v Sec'y of Health & Human Servs*, No. 10-197V, 2016 WL 3751848, at *13 (Fed. Cir. 2017); *Sullivan v. Sec'y of Health & Human Servs*., No 10-398,

[20] Effexor (venlafaxine hydrochloride) prescribing information, Wyeth Pharmaceuticals, Inc., filed as Resp. Ex. J.

[21] David A. Geier and Mark R. Geier, *A case-control study of serious autoimmune adverse events following hepatitis B immunization*, AUTOIMMUNITY, 38(4): 295-301 (2005), filed as Pet. Ex. 13.

[22] Mei-Sing Ong et al., *Population-Level Evidence for an Autoimmune Etiology of Epilepsy*, JAMA NEUROL, 71(5): 569-74 (2014), filed as Pet. Ex. 14.

[23] Dr. Bourque did not provide any literature in support of her opinions in this matter, despite an opportunity to do so. *See* Scheduling Order, ECF No. 69.

2015 WL 1404957, at *20 (Fed. Cl. Spec. Mstr. Feb 13, 2015)("[s]tatements contained in vaccine inserts do not constitute reliable proof of causation, and cannot be deemed admissions that vaccines in question have the capacity to harm a particular petitioner in a specific manner"); *see also Werderitsh v. Sec'y of Health & Human Servs.*, No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005)(quoting CFR § 600.80 as saying "A report or information submitted by licensed manufacturer…does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect.").

Petitioner submitted a 2005 case study by Dr. Mark Geier and Mr. David Geier[24] titled "A case-control study of serious autoimmune adverse events following hepatitis B immunization." The study relied upon data from the Vaccine Adverse Events Reporting (VAERS) database and discussed the increase of autoimmune diseases following hepatitis B vaccine.[25] Dr. Leist pointed out that VAERS is a passive reporting system which collects data on adverse events associated with vaccinations for signal finding purposes. Pet. Ex. 13; Resp. Ex. E at 5. He explained that VAERS provides neither conclusions regarding causation nor data on incidence. *See Manville v. Sec'y of Health & Human Servs*., 63 Fed. Cl. 482, 494 (2004) (finding that the special master did not err in dismissing "any significant value" of VAERS reports proffered by petitioner where the special master "noted that a VAERS report can be filed by anyone, thereby bringing into question the quantity and quality of the information gathered…"). The article provided no evidence for any association between Hepatitis A/B vaccination and seizure disorder. *Id*. It is notable that studies by David and Mark Geier have been routinely discredited in this program due to Dr. Mark Geier not being qualified to opine on issues of neurology, immunology, or rheumatology.[26]

The Ong article, "Population-Level Evidence for an Autoimmune Etiology of Epilepsy," submitted by petitioner, examined "the relationship between epilepsy and 12 autoimmune

[24] David A. Geier is not a doctor. He has not earned any advanced medical or scientific degrees. *Riggins v. Sec'y of Health & Human Servs*., No. 99-382V, 2009 WL 3319818, at *6-7 (Fed. Cl. Spec. Mstr. June 15, 2009). The State of Maryland revoked Mark Geier's license to practice medicine in 2012. *Hooker v. Sec'y of Health & Human Servs*., No. 02-472V2016 WL 3456435, at *30-31 (Fed. Cl. Spec. Mstr. May 19, 2016).

[25] Pet. Ex. 13, *supra* n.21.

[26] *See Doe/78 v. Sec'y of Health & Human Servs*., 2010 WL 3154546 (Fed. Cl. Spec. Mstr. Jul. 26, 2010) (finding the published medical research of Dr. Mark Geier and his son to be unreliable. (Fn. 16)); *Pafford*, 451 F.3d 1352 (concluding that the special master was justified in rejecting the testimony of Dr. Mark Geier based on the insufficiency of Dr. Geier's credentials); *Raj v. Sec'y of Health & Human Servs*., No. 96-294V, 2001WL 963984 (Fed. Cl. Spec. Mstr. Jun. 14, 2001)(criticizing Dr. Mark Geier as poorly qualified to opine on neurologic issues and finding his testimony to be "quite unpersuasive."); *Haim v. Sec'y of Health & Human Servs*., No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993) (holding that the testimony of Dr. Mark Geier did not meet the level of evidentiary reliability required by *Daubert*, because it was not based upon scientific validity, valid methodology, peer review or testing, and more than minimal support within the scientific community.); *Marascalco v. Sec'y of Health & Human Servs*., No. 90-1571V, 1993 WL 277095 (Fed. Cl. Spec. Mstr. Jul. 9, 1993)(according no weight to Dr. Geier's testimony and finding his affidavit to be "seriously intellectually dishonest" and "an egregious example of blatant, result-oriented testimony" which "undermines wholly his credibility as a witness."); *Ormechea v. Sec'y of Health & Human Servs*., No. 90-1683V, 1992 WL 151816 (Fed. Cl. Spec. Mstr. Jun. 10, 1992)(finding that, "[b]ecause Dr. [Mark] Geier has made a profession of testifying in matters to which his professional background (obstetrics, genetics) is unrelated, his testimony is of little value to the court.").

diseases: type I diabetes mellitus, psoriasis, rheumatoid arthritis, Grave's disease, Hashimoto thyroiditis, Crohn's disease, ulcerative colitis, systemic lupus erythematosus, antiphospholipid syndrome, Sjogren syndrome, myasthenia gravis and celiac disease." Pet. Ex. 14 at 1.[27] Dr. Leist pointed out that the study was of children under the age of 18 and nonelderly adults under the age of 65. Resp. Ex. E at 5. Petitioner was 70 years of age at the time of his seizure, with well documented risk factors for seizures. *Id*. Dr. Bourque confirmed that petitioner did not have an autoimmune disease. Tr. 128.

In order for an article to be relevant to petitioner's claim, petitioner must offer some connection between the disease discussed in the article, the vaccine and petitioner's claimed injury. *See H.L.*, 2016 WL 3751848, at *14, n. 20 (Fed. Cir. 2017)("Establishing a theory that a vaccine can cause injury "X" is not the same as proving that it can cause injury "Y," absent some evidence showing that injuries X and Y share sufficient commonality.").

IV. Legal Framework

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an "off-Table" injury, which requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).[28] Once a petitioner has proven causation by preponderant evidence, "the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing § 13(a)(1)(B)).

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." *Id*. Indeed, "where later testimony

[27] *Supra*, n.22.

[28] The Vaccine Act also requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted for more than six months. § 11(c)(1)(D)(i). It is undisputed that this six-month requirement is satisfied in this case.

conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948). But petitioners can support their claim with oral testimony if it is credible and consistent with the medical records. *See, e.g.*, *Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs.*, No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). In short, "the record as a whole" must be considered. § 13(a).

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010). The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("…uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted…"). Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). And nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Because petitioner did not allege an injury listed on the Vaccine Injury Table, his claim is classified as "off-Table." As noted above, for petitioner to prevail on an "off-Table" claim, he must show by preponderant evidence that his injury resulted from the vaccination at issue. *Capizzano*, 440 F.3d at 1320. Doing so shifts the burden to respondent to show that the injury was caused by factors unrelated to the vaccinations. *Deribeaux*, 717 F.3d at 1367.

To prove causation, petitioner must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner show by preponderant evidence that the vaccination received caused the injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Causation is determined on a case-by-case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y of Health*

& Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). The petitioner is not required to identify "specific biological mechanisms" to establish causation, nor is he required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (*Althen*, 418 F.3d at 1278; *Grant*, 956 F.2d at 1148), and medical probability rather than certainty (*Knudsen*, 35 F.3d at 543, 548-49). Medical probability has been explained as biologic credibility rather than specification of an exact biologic mechanism. As the Federal Circuit stated in *Knudsen*:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, supra, at 3, 1986 U.S.C.C.A.N. at 6344.
>
> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

As for epidemiological support for causation, the Federal Circuit in *Knudsen*, 35 F.3d at 551, ruled for petitioners even when epidemiological evidence directly opposed causation from DPT vaccine. The case concerned the cause of a baby's encephalopathy after a vaccination. Respondent provided evidence that more encephalopathies are caused by viruses than by vaccines, convincing the special master to rule against petitioners. However, the Federal Circuit thought the epidemiologic evidence should not bar petitioners from prevailing. Even though epidemiological evidence supported respondent's defense in *Knudsen* that viruses were more likely to cause encephalopathy than vaccinations, the Federal Circuit held that that fact alone was not an impediment to recovery of damages. In *Knudsen*, the Federal Circuit stated:

> The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

35 F.3d at 550.

The special masters "are entitled–indeed, expected–to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1325.

The Federal Circuit also stated that petitioner does not need epidemiological support in order to prevail and does not have the burden of proving a specific biological mechanism. *Id.* In *Althen* and *Capizzano*, the Federal Circuit stated that petitioner does not need to file supportive medical literature to prevail.

V. Discussion

Respondent defends this case by submitting that there is a lack of support in the medical records for Dr. Bourque's theory of aseptic meningitis. Respondent did not address Dr. Bourque's opinions regarding petitioner's lowered seizure threshold resulting from the hepatitis vaccine and other co morbidities, causing the cyproheptadine to trigger his seizures. Respondent states that the cyproheptadine petitioner took was the sole cause of petitioner's seizures, and petitioner's co-morbidities were the cause of him not feeling well in the week after the hepatitis vaccine. The Federal Circuit rejected respondent's sole cause defense in *Knudsen*, where respondent's expert stated that "the only single thing that could explain all of [the baby's] symptoms, encephalitic and non-encephalitic, was a systemic viral infection." 35 F.3d. at 550. The Federal Circuit in *Knudsen* decided that the baby's rhinorrhea was due to a virus, but her encephalopathy was due to her DPT vaccination. *Id*.

Dr. Bourque stated that when she first saw petitioner, he was already intubated and sedated, and unable to give a history. Tr. 63-64. It was her understanding at that time that petitioner had received a vaccination about a week before and had been feeling unwell for several days, with trembling, headaches, nausea, vomiting, and chills. According to the medical records she had, petitioner's headache was worse that week; she knew little more than that. Tr. 68; Pet. Ex. 3 at 307. She was unclear about the details, but believed he went to his health care provider during that week, who prescribed cyproheptadine; within 20 to 30 minutes of taking the cyproheptadine, petitioner started hallucinating, then seizing. Tr. 64-65, 92.

Dr. Bourque explained that infection can cause seizures; petitioner's EEG results resembled those of patients with herpes simplex virus, which was why she ordered the lumbar puncture. Tr. 74. When petitioner tested negative for viral infection, Dr. Bourque became concerned that "he had some kind of aseptic meningitis from the vaccination, and that superimposed with the cyproheptadine had predisposed him to have seizures at presentation." Tr. 67, 77. According to Dr. Bourque, vaccinations are one of many etiologies listed for aseptic meningitis; symptoms of fever and elevated protein are an indication of the disease. Tr. 83. She explained that viral illness or vaccination can cause the tissues covering the brain and spinal cord to become inflamed, leading to aseptic meningitis. Tr. 74, 82; Pet. Ex. 16 at 2. Petitioner's history of nausea, vomiting, and worsened headaches after the hepatitis vaccine raised a concern for aseptic meningitis. Tr. 67-68; Pet. Ex. 16 at 2; Pet. Ex. 3 at 307. Once the tests ruled out viral infection, but showed elevated CSF protein, it was suggestive of aseptic meningitis. Pet. Ex. 16 at 2; Tr. 101-02, 119-20.

Petitioner's discharge summary did not mention aseptic meningitis.[29] In Dr. Bourque's opinion, that was "because it's – I guess we can't say for certain what – you know, there's no test for aseptic meningitis, rarely protein can be elevated for an unclear reason, but in the context of that picture in the acute setting that's what I suspected…aseptic meningitis is something that is a one-time event and resolves,[30] so it wasn't felt to be an ongoing relevant issue…." Tr. 102.

Dr. Leist disagreed that petitioner had aseptic meninigitis, pointing out that despite petitioner's testimony that he suffered from headaches, nausea, vomiting, and fever immediately after receiving the vaccination on November 15, 2013, there was no medical record of anaphylaxis. He further noted that petitioner was able to drive two hours home, and though petitioner states that he got lost, that could be attributed to his other preexisting cognitive issues. Resp. Ex. E at 7; Tr. 11. Dr. Bourque agreed that petitioner's claim of developing severe headache, nausea, chills, lack of appetite, and shakiness immediately after receiving the hepatitis vaccine was unusual. Tr. 129.

Dr. Leist added that petitioner had prior episodes of nausea, vomiting, and poor appetite, which were associated with hyponatremia, and that petitioner's alcohol rehabilitation records a month prior to his vaccination in October of 2013 noted that he had hyponatremia.[31] *Id.*; Pet. Ex. 2 at 65.

Dr. Bourque agreed that hyponatremia can cause these symptoms and seizures; however, she did not believe that hyponatremia contributed to petitioner's seizure, as his electrolyte panel at EMMC was normal. Tr. 127-28, 131. Dr. Leist countered that petitioner's sodium levels may have been higher due to I.V. fluids.[32] *Id.*

Dr. Leist further proposed that petitioner was prescribed Venlafaxine (Effexor) upon discharge from rehabilitation, which is known to affect appetite and cause weight loss; it has also been associated with seizures. Resp. Ex. E at 7-8; Pet. Ex. 2 at 25; Resp. Ex. J.[33] Patients with liver disease metabolize venlafaxine more slowly, increasing the half-life of the medication. Resp. Ex. E at 8. Petitioner had hepatitis C as well as alcohol dependence. Pet. Ex. 2 at 99-100; Pet. Ex. 3 at 304, 308. However, Dr. Leist admitted that he did not know if petitioner was taking the venlafaxine at the time.

Dr. Bourque explained that petitioner had a provoked seizure, which occurs in the context of an event or a medication that triggers it. Tr. 77-78. She explained the EEG findings stating that petitioner had "tonic-clonic" seizures, meaning that the seizure activity involved the whole brain.

---

[29] Dr. Bourque did not write petitioner's discharge summary. While Dr. Bourque was consulted for her opinion as a neurologist, petitioner's care was coordinated by the hospitalist, Dr. Allen; he wrote the discharge summary. Pet. Ex. 290-91.

[30] Treatment of aseptic meningitis is largely supportive. Recovery is usually complete, without neurologic sequelae. Infectious Diseases at 1215.

[31] *Supra*, n.5.

[32] Petitioner's hospital discharge summary at the time of this event lists hyponatremia as one of his conditions. Pet. Ex. 3 at 285.

[33] *Supra*, n.20.

Tr. 69. She explained that "diffuse right sided slowing," meant slowing of the brain waves on the right side, which is a nonspecific finding. Tr. 71; Pet. Ex. 8 at 1437. According to Dr. Bourque, anything can cause slowing, including infection, structural abnormality, low sugar, and migraines. "Slowing does not tell a lot." Tr. 72-73, 75. EEG findings need to be taken as a whole and not read in parts, explaining that the rest of the findings along with the slowing, "transient periodic right lateralized discharges involving the frontal lobe" and "intermittent spikes," suggested that "there is excess irritability of the brain that is likely predisposing to seizure." Tr. 73. According to Dr. Bourque, the EEG results were "compatible with a focus involving the right frontal area, [and] the diffuse slowing may have been related to postictal phenomenon or lesion state," meaning that there was some irritability, either due to the seizure or an underlying brain lesion. Tr. 75. She agreed that petitioner's abnormal EEG could have been the result of the cyproheptadine. Tr. 118-19. She added that since petitioner's MRI was unremarkable, there were no tumors or structural abnormalities. Tr. 76.

Dr. Leist pointed out that petitioner's EEGs taken before the seizure (November 20, 2008) and four months after the seizure (February 24, 2014) were both normal. Resp. Ex. E at 6; Pet. Ex. 7 at 1430. Dr. Leist agreed that the EEGs during the hospital admission of November 22, 2013, following the seizures, were abnormal, indicating that the EEG abnormalities were transient and directly related to the seizure presentation on November 22, 2013 from taking the cyproheptadine. Resp. Ex. E at 6; Pet. Ex. 5 at 1394.

When questioned about the discharge summary which stated "There is no specific etiology sign (sic) to the patient's symptoms, " Dr. Bourque stated, " I think that was accurate from their perspective that there was no – we couldn't prove exactly what had been the exact cause of his problems." Tr. 93-94; Pet. Ex. 3 at 290. The discharge note further stated that petitioner's alcohol withdrawal, hepatitis A vaccine, withdrawal from other medications, side effects of other medications, and a multitude of other "metabolic derangements" should be considered in determining the cause of petitioner's seizure. Dr. Bourque agreed "it's just a catch-all phrase that anything in theory could have triggered this." Tr. 94-95.

Dr. Bourque stated petitioner's presenting complaints of not feeling well during the week prior and following the hepatitis vaccine, along with the elevated CSF protein level suggested to her that petitioner was experiencing irritation in his brain. Then the cyproheptadine was introduced, triggering the seizure. According to Dr. Bourque, how each factor contributed to the seizures, she did not know, only that it was a combination of petitioner's prior head injury, long term alcoholism, and hepatitis A vaccination that could lower his seizure threshold, and the contribution of the cyproheptadine was needed at that time for the seizure to occur. Based on the timing, the cyproheptadine played a major role, and with seizures, it is all about threshold. If petitioner had been at a different threshold when he took it, he may not have seized. "That's the issue with seizures and that's why it's hard to say with any certainty the contributors." Tr. 85-86, 131-32.

While Dr. Bourque agreed that petitioner's abnormal brain activity seen on the EEG could have been a side effect of the cyproheptadine alone, she would not agree that cyproheptadine was the only cause of petitioner's seizures, referring to the elevated CSF protein which led her to suspect aseptic meningitis. Tr. 100-02, 118-19, 121.

Dr. Leist submitted that, although petitioner reportedly did not feel well in the week following his vaccination, there is no record that he suffered from changes in awareness, alertness, perception, or cognition from his usual baseline until around 4:30 pm on November 22, 2013, shortly after he took cyproheptadine for the first time. Resp. Ex. E at 7; Pet. Ex. 7 at 1435; Tr. 77. In Dr. Leist's opinion, the cyproheptadine was the "provoking agent" of petitioner's seizures. Resp. Ex. E at 6. Dr. Leist disregarded petitioner's testimony that he had vomiting, fatigue, headaches, high fever, and could not stay awake in the week following the hepatitis vaccine. Tr. 13, 15-17.

Dr. Bourque and Dr. Leist agreed that the cyproheptadine provoked petitioner's seizures. Dr. Bourque opined that she suspected aseptic meningitis caused by petitioner's receipt of the hepatitis vaccine and reported fever, severe headaches, and vomiting thereafter, but she considered that all of petitioner's co-morbidities in combination with the hepatitis vaccine lowered petitioner's seizure threshold so that introducing the cyproheptadine to an already primed system resulted in the development of seizures. While Dr. Leist disagreed and explained why he believed that petitioner did not have aseptic meningitis, he never addressed Dr. Bourque's theory of lowered seizure threshold. He opined that the cyproheptadine alone was the cause of petitioner's seizures. Dr. Leist attributed all of petitioner's complaints in the days following the hepatitis vaccine to his various co-morbidities, concluding that the hepatitis vaccine had nothing to do it. Dr. Leist even described the effects of venlafaxine as responsible for petitioner's not feeling well, a medication prescribed to petitioner when he was discharged from alcohol rehabilitation, without any proof that petitioner had ever taken the medication. Dr. Bourque's opinion is more compelling and persuasive in this case.

In further support of her opinions in this case, Dr. Bourque explained her office records and its wording in detail.

In her first follow up visit with petitioner on January 30, 2014, Dr. Bourque noted under "Impression and plan" that "[petitioner] presented to the hospital in November 2013 one week following hepatitis A vaccination and was found to have altered mental status following intake of cyproheptadine and subsequent recurrent seizures…." Pet. Ex. 7 at 1422-23. Dr. Bourque explained that the cyproheptadine was closer in time to his seizures and was a contributor, but she did not know whether petitioner would have had a seizure if he had been feeling well prior to taking the cyproheptadine. Tr. 99-100. Dr. Bourque explained, though she did not explicitly write that she believed that the combination of the hepatitis vaccine and cyproheptadine led to petitioner's seizures, "that was my implication." Tr. 103.

Dr. Bourque was then asked about the visit on April 7, 2014, Pet. Ex. 7 at 1429-31, in which she wrote "had presented to the hospital on November 2013 one week after hepatitis A vaccination and developed hallucinations and seizures shortly after taking cyproheptadine." Tr. 104. She stated that she did not explicitly state that the combination of the two things led to the seizures but "to me I did there…it's sort of the facts that occurred around his seizures, as I would view it." Tr. 104.

The next visit discussed was on March 20, 2015, in which Dr. Bourque wrote, "[Petitioner] had a history of hospitalization with what was suspected to possibly have been a provoked seizure

in 2013." Pet. Ex. 7 at 1427. Dr. Bourque explained that she used the word "possibly" because provoked seizures have a much lower risk of recurrence and a lower need for continued use of anti-seizure medicine. Tr. 80, 108. However, petitioner described an incident following his attempt to wean himself off Keppra in which he may or may not have had a breakthrough seizure. Tr. 78-79. According to Dr. Bourque, this incident was unclear and she was not convinced that it was a breakthrough seizure, but petitioner and his wife became nervous and so she continued Keppra. Tr. 80-81; 108. Dr. Bourque further explained that another reason for keeping petitioner on Keppra was in part because, in the State of Maine, you cannot drive for six months after tapering off anti-seizure medication. Tr. 80.

In her October 2, 2015 office note, Dr. Bourque again referred to petitioner's seizure as "possibly" provoked. Pet. Ex. 7 at 1451. Dr. Bourque stated that it was seven months later and since she was still unclear of what to make of the "breakthrough" seizure, "[I]t became unclear to me definitively at that point what we were dealing with." Tr. 109-10.

In his final visit on March 18, 2016, Dr. Bourque noted, "[Petitioner] continues to have a history of hospitalization in November 2013 for suspected provoked seizures which was likely a combination of being unwell from hepatitis A vaccine and the compilation of cyproheptadine." Pet Ex. 9 at 1486; Tr. 111. Dr. Bourque agreed that this was the first time that she noted in the record that petitioner was unwell following the hepatitis A vaccine. Tr. 111-12. She stated that she meant "combination," not "compilation." Tr. 111. It was also pointed out to Dr. Bourque that this record was the first time she stated that petitioner's suspected provoked seizures were likely a combination of being unwell from hepatitis A vaccine and receipt of cyproheptadine. In response, Dr. Bourque testified: "Yeah, I guess my – my other—impressions were explaining – I outlined what had occurred without being able to say for sure, but just outlining the facts of what had happened. And here I put that I suspected it was provoked by those two causes. I feel like that's what I alluded to the whole time." Tr. 111-13.

Finally, according to Dr. Bourque, the medically appropriate time period for the onset of seizures from aseptic meningitis varies based on the individual and other factors. Tr. 128. Dr. Leist did not address the timing issue.

Neither expert disputes that petitioner suffered from a host of co-existing conditions at the time he received the hepatitis vaccine. Neither disputes that petitioner suffered seizures following his taking the cyproheptadine. They disagree, however, as to what may have caused petitioner's nausea, severe headache, fever and vomiting in the week following the hepatitis vaccine and whether petitioner suffered from aseptic meningitis during that week. They also disagree as to whether the cyproheptadine was the sole cause of petitioner's seizures. Upon learning of all of petitioner's co-morbidities during the hearing in which she gave testimony, Dr. Bourque was adamant that all of petitioner's co-morbidities in combination with the hepatitis vaccine served to lower petitioner's seizure threshold so that his taking cyproheptadine triggered the onset of seizures. Dr. Leist did not discuss the lowering of the seizure threshold, but concluded that the cyproheptadine was the sole cause of the seizures.

I must analyze this case in terms of *Shyface v. Sec'y of Health & Human Services*, in which Cheyenne Shyface was vaccinated with whole-cell DPT at the time he was beginning an *E. coli*

infection. Both the DPT and the *E. coli* infection could and did cause fever, which rose to 110 degrees, resulting in his death four days later. 165 F.3d. at 1345. Respondent defended the case and argued that the *E. coli* infection was the cause of the baby's fever and death. Testimony from Cheyenne's treating physician was that both the vaccine and the infection were equally responsible for his fever and death. The Federal Circuit held that each of the two factors, the vaccine and the infection, was a substantial factor in causing the baby's very high fever and death and but for the vaccination, the baby would not have had the high fever and would not have died. The Federal Circuit ruled in favor of petitioners even though petitioners did not prove that DPT vaccine was the only or predominant cause of death. *Id*. at 1353.

Here, petitioner's treating physicians in the hospital included the hepatitis vaccine as a contributing factor to the cause of his seizures, and petitioner's treating neurologist testified to it. The Federal Circuit's direction in *Capizzano*, 440 F.3d at 1326, is for special masters to consider seriously the opinions of the vaccinee's treating doctors consistent with 42 U.S.C. § 300aa-13(b)(1)(A) and (B), directing the special masters to consider the entire record, including the diagnoses and medical judgments of doctors. Thus, the undersigned must conclude that the opinion of petitioner's treating physicians that the combination of the hepatitis vaccine, co-morbidities and cyproheptadine were all factors in petitioner's development of seizures is determinative of the outcome of this case.

The undersigned finds that petitioner has satisfied the three prongs of *Althen*: (1) vaccines, which include hepatitis vaccines, can cause aseptic meningitis indicated by elevated proteins in the CSF, and causing headache, nausea, vomiting, and fever, and either alone or in combination with other co-morbidities can also reduce seizure threshold resulting in seizure activity if faced with a trigger, in this case, cyproheptadine; (2) the hepatitis vaccine did cause aseptic meningitis or irritation to petitioner's brain resulting in fever, vomiting, more severe headache and sleepiness and in combination with his co-morbidities lowered his seizure threshold resulting in his seizures after taking cyproheptadine; and (3) petitioner's onset of headache, nausea, vomiting, fever in the days immediately following his hepatitis vaccine was appropriate in timing and indicative of aseptic meningitis or irritation to his brain, which acting in combination with his co morbidities lowered his seizure threshold so that he seized within an hour of taking cyproheptadine within the week following the hepatitis vaccine.

VI. Conclusion

The undersigned finds in favor of entitlement. This case shall proceed in damages.

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master