IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 99-649V
Filed: November 29, 2006
To Be Published

RYAN JAMES SZEKERES,	*	
	*	Entitlement Decision;
Petitioner,	*	Hepatitis B; POTS;
	*	Judgment on the Record;
v.	*	Circumstantial Evidence of
	*	Vaccination
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Clifford Shoemaker, Esq., Shoemaker & Associates, Vienna, VA, for petitioner.
Vincent Matanoski, Esq., U.S. Department of Justice, Washington, DC, for respondent.

Vowell, Special Master:

DECISION[1]

On August 5, 1999, Mr. Ryan Szekeres ["Ryan"] timely filed a petition for compensation under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–10[2] *et seq.* ["the Vaccine Act"], alleging that an April 16, 1997 hepatitis B vaccination caused him unspecified injuries. On July 11, 2006, he filed a Motion for Judgment on the Record, stating therein that "the record supports a prima facie case of POTS[3] from a Hepatitis B vaccination." Petitioner's Motion for

[1] Because I have designated this decision to be published, petitioner has 14 days within which to request redaction of any material "that includes medical files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be publicly available. 42 U.S.C. § 300aa12(d)(4)(B).

[2] Hereinafter, for ease of citation, all "§" references to the Vaccine Injury Compensation Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000 ed.).

[3] "POTS" is an abbreviation for "postural orthostatic tachycardia syndrome." It is a disorder of the autonomic nervous system characterized by orthostatic intolerance (the

Judgment on the Record, p. 1.

Having considered the entire record, I find that petitioner has failed to establish a *prima facie* case that a vaccine caused or significantly aggravated his medical condition and he is therefore not entitled to compensation.

I. Procedural History

When the petition was filed on August 5, 1999, none of the statutorily-mandated supporting documents were filed with it.[4] On September 1, 1999, petitioner was ordered to file those supporting documents. No records were filed in response to this order and on April 27, 2000 (at petitioner's request), the case was stayed pending completion of discovery in the Autism Omnibus Proceedings. Nevertheless, petitioner continued to file periodic status reports but did not file any medical records.[5] Petitioner was therefore ordered to file a medical expert report by September 12, 2002. Order, dated July 10, 2002.

On July 19, 2002, petitioner again requested that the case be stayed. While no formal stay was issued, there was no further action on the petition until the case was reassigned to me on February 8, 2006. In a recorded status conference held on March 27, 2006, petitioner's counsel

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development of symptoms upon standing). It is currently defined as an increase in heart rate of at least 30 beats per minute within 10 minutes of standing. *See,* Blair P. Grubb, *et al.*, "The Postural Tachycardia Syndrome," 17 *J. Cardiovasc. Electrophysiol*. No. 1 at 108 (2006). Court Exhibit ["Ct. Ex."] 1. "Tachycardia" is a rapid heart beat, usually referring to a heart rate of over 100 beats per minute. *Dorland's Illustrated Medical Encyclopedia* ["*Dorland's*"] at 185 (30th ed. 2003). I note that some of the documents filed in this case refer to "paroxysmal" orthostatic tachycardia syndrome. It is unclear whether this is confusion with paroxysmal supraventricular tachycardia ["PSVT"] or simply a transcription error. PSVT and POTS are different conditions. PSVT is a periodically occurring rapid heartbeat. *Id.* Other symptoms include heart palpitations, chest tightness, anxiety, and dizziness. Medline Plus Medical Encyclopedia, http://www.nlm.nih.gov/medlineplus/ency/article/000183.htm (visited November 20, 2006). Ryan, his parents, or one of the many physicians who treated Ryan noted all of these symptoms at various times between July and November 1997 and Ryan was diagnosed with POTS and PSVT by different physicians during this time frame. Ryan's symptoms, test results and diagnoses are discussed in more detail, *infra*.

[4] Section 300aa–11(c) of the Vaccine Act requires the petition to be accompanied by certain documentary evidence, including records pertaining to the vaccination and subsequent treatment. *See also,* Vaccine Rule 2(e), RCFC, Appendix B.

[5] *See, e.g.*, Motion to Designate Master File, dated Dec 9, 1999; Motion to Issue Subpoenas, dated August 14, 2001; and Status Reports dated February 15, 2000, May 16, 2000, August 21, 2000, December 12, 2000, March 13, 2001, and July 19, 2002.

indicated his intent to transfer this case to another attorney after the completion of some pending medical testing for mercury.[6]

I lifted the stay and ordered petitioner to file medical records, a status report, and an amended petition[7] by April 26, 2006, unless a notice of appearance by new counsel was filed by that date. *See,* Order dated April 13, 2006. On April 25, 2006, petitioner filed a status report indicating that the possible transfer of the case to another attorney would "not be done until after the testing referred to in the last status conference is completed." The report indicated that counsel was arranging for petitioner to be tested for mercury in order to find an expert "willing to address the issues of causation in this case." Status Report, dated April 25, 2006. Petitioner did not file either medical records or an amended petition with this status report.

On May 17, 2006, petitioner filed another status report. This report indicated that petitioner had decided not to pursue the claim and requested 30 days to file a voluntary dismissal or motion for judgment on the record. I granted this request on May 22, 2006. On June 19, 2006, petitioner requested a 14 day enlargement of time to file medical records and the motion for judgment. In view of the lack of response to the previous orders to file the medical records and an amended petition, I conducted a status conference to determine why the enlargement was necessary. After determining that the medical records were already in the possession of petitioner's counsel and that petitioner desired to file an affidavit, I set a deadline of July 11, 2006 for petitioner to file anything he wished me to consider in a ruling on the record. *See* Order dated June 21, 2006. Petitioner's Exhibits ["Pet. Ex."] 1-15, consisting of medical records, were filed on June 30, 2006, and on July 11, 2006, petitioner filed his affidavit and a Motion for Judgment on the Record. Respondent filed a response on July 28, 2006, arguing that petitioner had failed to establish a *prima facie* case of vaccine causation.

II. Medical History

The medical records filed in this case are far from complete. The earliest medical record filed is from October 1996, when Ryan was seventeen. Pet. Ex. 2, p. 1. The most recent medical records filed are dated in March 2005. Pet. Ex. 15, p. 3. The records reflect a significant number of office visits, emergency room visits, medical tests, and hospitalizations from October 1996 through October 1997; medical testing in December 1997 and January 1998; treatment and hospitalization in April and May 1998; an emergency room visit in January 1999; and a flurry of treatment from May through September 1999. The next record is dated September 2002. There is another gap in the records between September 2002 and February 2005. Between February

[6] The theory in this case, as indicated during the recorded status conference, concerned the effects of the thimerosal preservative (a mercury-based compound) used in the hepatitis B vaccine.

[7] The original petition failed to specify the medical condition for which compensation was sought. No amended petition was ever filed in this case.

2005 and March 2005 (the last record filed), Ryan had several emergency room visits and tests.

The medical histories taken after the onset of Ryan's medical problems in 1997 variously describe him as having completed the 8th grade, having attended two years of high school, or having graduated from high school.[8] The majority of the histories indicate that he left high school sometime after two years of matriculation as the result of allergies and asthma that were exacerbated by attendance at school. Although Ryan was taking medication for asthma, there are no records of medical visits for asthma or allergies during his school years. *See, e.g.*, Pet. Ex. 2, pp. 1, 4-5, 7. He was apparently still attending high school in November 1996, as the records contain a request by his mother to document Ryan's medical appointment on November 8th to a school official. After leaving school, Ryan was an independent writer involved in reviewing software for websites. Pet. Exs. 4, pp. 39-40; 6, p. 7. One record states that he was placed on social security disability insurance in 1999. Pet. Ex. 6, p. 5.

Although no childhood medical records were filed, medical histories in the records reflected that Ryan's birth was normal, he met developmental milestones, and his other childhood illnesses included a bout with gastroenteritis at the age of 13 months. Pet. Ex. 14, p. 23. They also indicate that Ryan developed allergies and asthma in childhood and had several emergency room visits for asthma. *See, e.g.*, Pet. Ex. 2, p. 1.

The first record filed concerns a visit to Milcom Health Care ["Milcom"] on October 24, 1996 for an infected toenail. It is unclear whether this record represents a visit to a new primary care provider[9] or whether these were the only records available from the provider at the time of the request. The chart also contains an entry reflecting that Ryan suffered from asthma triggered by exercise and stress and had been taking Proventil[10] and Beclovent[11] for his asthma. Pet. Ex. 2, p. 1. Ryan continued to have difficulties with his toe, returning to Milcom on November 8,

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[8] *See, e.g.*, Pet. Ex. 4, p. 30 (completed the 8th grade); Pet. Ex. 14, p. 17 (attended high school until age 16); Pet. Ex. 6, p. 7 (finished two years of high school); and Pet. Ex. 4, pp. 39-40 (just graduated from high school). Ryan's affidavit, Pet. Ex. 16, p. 2, indicates that complications stemming from his hepatitis B vaccination caused him drop out of school and that he has not yet attained his GED. Ryan was 17 ½ when he received this vaccination.

[9] The medical records found in Pet. Ex. 2, pp. 1-13 (records from Milcom) are independently hand-numbered in the upper right corner as pages 1-14. Either a page is missing (page 6 or page 7) or the remaining hand-numbered pages through page 13 of Pet. Ex. 2 are misnumbered. The exhibit numbers in the lower right corner of the pages are machine-generated. As both numbering systems for these records begin on page 1, this may suggest that the October 24, 1996 visit was Ryan's first to Milcom.

[10] Proventil is the trade name for albuterol. *Dorland's* at 1530. Albuterol is a bronchodilater used to treat asthma. *Id*. at 45.

[11] Beclovent is the trade name for beclomethasone dipropionate. *Id.* at 209.

1996; March 17, 1997; and April 10, 1997. *Id*., pp. 2, 4-5, 7. He also received a refill for his asthma medications at the March visit. *Id*., p. 5. He received a prescription to treat a possible fungal infection during the April visit, but ceased taking it a few days later because of gastric upset. *Id*. at 7.

The medical records do not document the administration of the hepatitis B vaccination, either at the April 10, 1997 visit to Milcom, or at any other time. The petition alleges the vaccine was administered on April 16, 1997. Petition at ¶ 3. Ryan's affidavit places the vaccination on April 17, 1997. Pet. Ex. 16, p. 1. The Motion for Judgment on the Record indicates Ryan received the vaccination on April 17, 1997. *Id*. at 1. There are no records that Ryan visited Milcom on any of those dates. If the affidavit, petition, and motion were the only information available, I could not conclude that Ryan actually received the hepatitis B vaccination[12]. However, two entries in Ryan's Milcom medical records, dated June 9 and June 16, 1997, concern reminders that Ryan was due for a "Hep B #2" or "Hep," presumably referring to a hepatitis B vaccination. *Id*., p. 8. A July 15, 1997 entry also reflects that Ryan needed "Hep B #2." *Id*., p.10. Based on these entries and coupled with Ryan's affidavit, I find that Ryan did have a hepatitis B vaccination sometime in mid-April of 1997.[13]

The first indication of any cardiac problem is contained in an April 28, 1997 telephone call from Ryan's mother, Mrs. Szekeres, to Milcom. The note reflects that Mrs. Szekeres called to inform Ryan's physician that Ryan's heartbeat had "gone from fast to slow." Pet. Ex. 2, p. 8. There is no record that Ryan was seen for this problem, although the note indicates that an EKG[14] would be ordered. *Id*.

The records from Milcom next indicate a call on July 2, 1997, regarding refills of Ryan's asthma prescriptions. Ryan was prescribed 90 four milligram tablets of Proventil, with one refill,

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[12] Section 11(c)(1)(A) of the Vaccine Act requires supporting documentation demonstrating that a vaccine on the Vaccine Injury Table was actually administered. A vaccine record or a chart entry reflecting administration of a vaccination is not required. *See Centmahaiey v. Sec'y, HHS*, 32 Fed. Cl. 612, 621 (1995).

[13] Ryan's affidavit states that he received his hepatitis B vaccination at the same time his sister received hers. His sister also filed a petition for compensation under the Vaccine Act. A decision in that case, No. 01-197V, was issued simultaneously with this decision. It specifies the date on which his sister received her first hepatitis B vaccination and the medical record containing evidence thereof.

[14] "EKG" is an abbreviation for an electrocardiogram. *Dorland's* at 593. The exhibits contain a number of EKGs performed on Ryan but none during the April 1997 time frame.

with instructions to take one every eight hours or twice daily.[15]

From July 14, 1997 through October 29, 1997, Ryan was seen at St. Joseph's Hospital (Pet. Exs. 2, pp. 32-57 and 12, pp. 28-29); Swedish Covenant Hospital ["Swedish Hospital"][16] (Pet. Ex. 2, pp. 14-31, 58-67); Michael Reese Hospital (Pet. Ex. 2, p. 77 contains a reference to this visit, although no records from this facility were filed); Rush Presbyterian-St. Luke's Medical Center ["Rush"] (Pet. Ex. 4); Children's Memorial Hospital ["CMH"] (Pet. Ex. 1 and Pet. Ex. 2, pp. 68-94); Northwestern Memorial Hospital (Pet. Ex. 10); the University of Illinois-Chicago Medical Center ["UIC"] (Pet. Ex. 14); Loyola University Medical Center ["Loyola"] (Pet. Exs. 9 and 3, pp. 65-70); and by his primary care provider at Milcom.[17] He may also have been seen at Ravenswood ["Ravenswood"] Hospital. *See* telephone message at Pet. Ex. 2, p. 12. The office visits, emergency room visits, and hospitalizations were occasioned by a variety of symptoms that began with complaints of an unusually fast heartbeat and dizziness on July 14; chest tightness on or about July 22, headache with difficulty concentrating and short-term memory problems on August 25; increased bowel movements first mentioned on September 2; urinary retention on October 2; an episode of unresponsiveness on Oct 4; sore jaw upon awakening beginning on October 5; and the loss of some vision in his left eye on October 19, 1997. He was hospitalized at Rush twice during this period for evaluation and testing, from September 2-5, 1997 and from October 17-20, 1997.

Based on the absence of medical records documenting any medical problems between April 28, 1997 and July 12, 1997, I adopt the conclusions of his treating physicians that Ryan was generally well during this period, notwithstanding his affidavit and a non-contemporaneous medical history provided by his mother.[18]

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[15] The prescription in the records states "PO Q 8° or BID" which translates as "by mouth every 8 hours or twice daily." Neil M. Davis, Medical Abbreviations ["Med. Abbreviations"] at 287, 301, 389, and 65 (12th ed. 2005).

[16] Although records from Swedish Hospital were filed as Pet. Ex. 13, those records only refer to treatment in 2005. Some 1997 records from Swedish Hospital are found in the Milcom records at Pet. Ex. 2, pp. 14-31. It is impossible to determine whether these records are complete.

[17] Many of the exhibits contain pages from other treating institutions and health care providers. Where only the exhibit number is referenced, most of the records within that exhibit are from the facility identified.

[18] Ryan's affidavit (Pet. Ex. 16) is dated July 6, 2006. He asserts that his first symptoms of illness post-hepatitis B vaccination began at an internet exposition on April 20, 1997, when he became light-headed and slid down the wall of an exhibit booth. He did not indicate that he sought any medical treatment for this event. In July 1999, Dr. Daniel Homer recounted a history of Ryan's illness by Mrs. Bette Szekeres, Ryan's mother. She stated that Ryan developed

On July 14, 1997 at 0939, Mrs. Szekeres telephoned Milcom to say that Ryan had "finished all of his asthma medication." Pet. Ex. 2, pp. 8-9. At the prescribed dose of one tablet of Proventil every eight hours (or three per day) made on July 2, 1997, this would indicate that Ryan had taken a month's supply of the medication in less than two weeks. One common side effect of Proventil is an elevated heart rate or tachycardia.[19] She also reported during this telephone call that Ryan felt like his chest was being squeezed. There is no indication in the Milcom records about what advice was given, but at 1348 on July 14, 1997, Ryan was seen in the emergency room at Swedish Hospital for complaints of shortness of breath, vomiting, and a decreased appetite for a couple of days. He had a slight fever (100.1 degrees). Pet. Ex. 2, p. 14. The chart records a past medical history of heart problems ("ST to BRADY"),[20] which likely refers to the April 1997 incidents of variability in Ryan's heart rate. *Id.*

The copy of the record in this exhibit is poor and most of the nurses' notes are illegible, but it appears that Ryan was placed on a cardiac monitor and sinus tachycardia was noted.[21] He had some abnormal blood gas findings, suggestive of hyperventilation. *Id.*, p. 15, 17. An EKG was also performed and read as normal. *Id.*, p 9. Ryan was diagnosed with hyperventilation, prescribed Xanax,[22] and discharged. Pet. Ex. 12, p. 28.

At 2105 that same evening, Ryan was seen at St. Joseph's hospital with similar complaints of a fast heartbeat and dizziness, but with the additional symptom of headache. He

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symptoms of weakness, leg pain, dizziness, and nausea on April 20, 1997, and that about eleven days later, he developed diarrhea and postural changes in his heart rate. Pet. Ex. 3, p. 59. In March 2005, either Ryan or his mother (the record suggests that Mrs. Szekeres was the historian, although at this point Ryan was 25 years old) reported that he received the hepatitis B vaccine on April 19, 1997 and thought that he contracted viral encephalitis from the vaccine. Pet. Ex. 6, p. 7. For reasons stated later in this opinion, I do not credit these reports. Only the variability in Ryan's heart rate, which occurred on or about Saturday, April 26, 1997, is contemporaneously documented in the medical records.

[19] *See Physician's Desk Reference* ["*PDR"*] at 1194 (58th ed. 2004). Albuterol is the generic version of Proventil. *Dorland's* at 1530.

[20] "ST" is a common medical abbreviation for "sinus tachycardia." *Med. Abbreviations* at 340. Sinus tachycardia is a rapid heart beat. *Dorland's* at 1850. "BRADY" is a common medical abbreviation for bradycardia, or slow heart beat. *Med. Abbreviations* at 69; *Dorland's* at 246.

[21] Sinus tachycardia is a normal finding during exercise or anxiety. It is abnormal when it reflects hypoxia, hypotension, shock, or fever. *Dorland's* at 1850.

[22] Xanax is a drug often prescribed for anxiety disorders and panic attacks. *PDR* at 2798.

and his mother left without being seen by a physician after a drug screen urinalysis[23] and an EKG were both normal. Pet. Ex. 12, pp. 28-30, 32. They returned to Swedish Hospital at 2323 that evening. Pet. Ex. 2, p. 20. The presenting complaints were headache and dizziness. Ryan was not running a fever and no medical history of heart problems was recorded at this visit. His physical examination was normal, and after being seen by a physician, he was discharged with an appointment to see his primary physician the following day. *Id.,* pp. 20-21.

Ryan returned to Milcom on July 15, 1997, reporting a global, throbbing headache unrelieved by Tylenol and that the on-call physician at Swedish Hospital refused to admit him in spite of a heart rate of 155. The Milcom doctor (whose signature is illegible) who saw Ryan contacted this on-call physician, who denied refusing to admit Ryan. *Id.*, p. 9.

The treating physician at Milcom obtained the records of treatment from Swedish Hospital and recorded the diagnosis from the emergency room visit as "hyperventilation syndrome." Ryan's EKG was essentially normal, with one brief episode of very mild sinus tachycardia. Either during the office visit at Milcom or during the emergency room visit at Swedish Hospital, Ryan's heart rate was recorded as 83 beats per minute[24] at a time when he made a subjective complaint of a racing heartbeat. *Id.* Nevertheless, plans were made to place Ryan on a Holter monitor[25] for twenty-four hours. Pet. Ex. 2, pp. 9-10.

Mrs. Szekeres called Milcom on July 16, 1997 to indicate that Ryan was having problems breathing. During the follow-up to this telephone call, the physician recorded that Ryan had a headache unrelieved by ibuprofen. Ryan claimed to be experiencing occasional shortness of breath, but was able to speak easily. He was wearing the Holter monitor. Ryan was instructed to make a follow up appointment at CMH. *Id.*, p. 11. Noting that there was no correlation between Ryan's diary of symptoms and any abnormalities in his cardiac rhythm, Dr. David Berkson read the Holter monitor as essentially normal. Pet. Ex. 12, p. 5.

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[23] PSVT, a condition later diagnosed in Ryan, is sometimes associated with illicit drug use. Medline Plus, http://www.nlm.nih.gov/medlineplus/ency/article/000183.htm (Last visited November 28, 2006). There are no indications anywhere in the medical records or otherwise that Ryan used illegal drugs, but his rapid heart rate may have raised that suspicion in the emergency room at St. Joseph hospital. The urinalysis performed there was a limited drug screen urinalysis, testing for such drugs as barbiturates, cocaine, opiates, and marijuana.

[24] A cardiologist who later saw Ryan indicated that this heart rate was within normal limits. *See* Pet. Ex. 1, p. 32.

[25] A Holter monitor records heart rate and rhythm for a period of time up to seventy-two hours. It is used to identify cardiac rhythm disturbances and to correlate them with the patient's subjective symptoms through a diary completed by the patient. Kathleen D. Pagona & Timothy J. Pagona, *Mosby's Manual of Diagnostic and Laboratory Tests* ["*Mosby's Labs*"] at 587-88 (3d. ed. 2006).

On July 21, 1997, Ryan saw Dr. Christopher Johnsrude, a cardiologist at CMH. He evaluated the Holter monitor report, an earlier EKG from Swedish Hospital, and an EKG taken during his examination of Ryan. Other than mild sinus tachycardia, he noted no cardiac problems and indicated that Ryan's chest tightness was most likely pulmonary or asthmatic in nature. Pet. Ex. 1, pp. 31-32. Ryan's parents disagreed with his conclusion, feeling that Dr. Johnsrude was missing a cardiac problem of significance. *Id.*, p. 32.

At some point between the July 21 visit to Dr. Johnsrude and July 31, Ryan saw a pulmonologist at Michael Reese Hospital. Exactly what this pulmonologist concluded is unknown. There were no medical records filed pertaining to this visit, and the Milcom records (Pet. Ex. 2, p. 12) and a letter written by Dr. Cherie Zachary (*Id.*, pp. 77-78), an allergist at CMH, contain divergent references to his findings. The entry in the Milcom chart indicates that the pulmonologist found nothing wrong with his lungs. Doctor Zachary's letter indicates that the pulmonologist treated Ryan with additional asthma medications. These new medications apparently caused increased tachycardia, resulting in a referral to another cardiologist, Dr. David Abrams, at Northwestern University Hospital.

There are no records from Dr. Abrams in the exhibits. From the references in the Milcom records at Pet. Ex. 2, pp. 12-13, and 77, it appears that Dr. Abrams disagreed with Drs. Johnsrude and Becker about the Holter monitor results. Doctor Abrams apparently diagnosed PSVT sometime around July 28, 1997. *Id*., p. 13. He placed Ryan on 180 mg per day of Verapamil, a calcium channel blocker used to treat PSVT. *Id*., p. 77.

Ryan was seen at Swedish Hospital emergency room on August 11, 1997 for complaints of chest pain, elevated heart rate, and shortness of breath. His heart rate ranged from 84-98 during the approximately six hours he spent at the hospital. He was diagnosed with "unexplained tachycardia" and encouraged to followup with his primary care physician. Pet. Ex. 2, pp. 59-60.

An echocardiogram performed on August 18, 1997 was read as normal by Dr. C. Elise Duffy. Pet. Ex. 2, p. 76. Ryan also had a normal chest x-ray and normal pulmonary function test on August 18, 1997. *Id.,* pp. 80, 79. An exercise study performed that same day was not normal; Ryan experienced a very rapid rise in his heart rate and blood pressure when exercising. Doctor Duffy noted that he was not physically conditioned, and in view of a family history of cardiac disease, strongly recommended an exercise program. *Id.,* pp. 81-82.

In an August 25, 1997 letter to Dr. Abrams, Dr. Duffy indicated that she saw Ryan for a follow-up on August 22. She referred to urinary testing and to "event monitoring"[26] that showed either sinus rhythm or sinus tachycardia. On August 25, she received a call from Mr. Szekeres, Ryan's father, saying that Ryan had experienced another episode of severe chest pain and had been seen in the emergency room at Swedish Hospital, where another EKG had been performed.

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[26] Event recording or monitoring and ambulatory monitoring are other terms used to describe Holter monitoring. *Mosby's Labs* at 587.

She indicated that she would restart Ryan on Verapamil that day and recommended referral of Ryan to Swedish Hospital. Pet. Ex. 11, p. 193.

Ryan was next seen in the emergency room at Rush on September 2, 1997 at 1120 with a complaint of chest pain since the evening before. *Id.,* p.189. Whether he was actually restarted on Verapamil on August 25 is not clear, because the emergency room record indicated that Ryan was not taking any medications.[27] His primary care doctor was listed as Dr. Trohman. *Id.*

Ryan was admitted to Rush's cardiac care unit late on the afternoon of September 2, 1997. The admission note history reflects that Ryan was well until July 14, when he started to notice chest pain accompanied by dizziness. Pet. Ex. 11, pp. 109-10. It described frequent chest discomfort, rapid heart rate, increased bowel movements (two to three times a day), and sweating easily. He denied having palpitations, fever, chills, psychiatric, thyroid, or other cardiac problems and stated that there was nothing dramatic going on in his life. He indicated that he had not used his asthma inhaler in two months, since he began having the chest pain. *Id*.

The admission record also noted the extensive cardiac testing previously conducted on Ryan at other facilities, with sinus tachycardia being the only abnormal finding. The plan on admission suggests that the admitting physician did not consider a cardiac etiology for Ryan's symptoms to be likely, as it indicated that psychiatric and endocrinology consultations might be necessary. *Id.*, p. 110. A note on Ryan's social history comments that he had recently graduated from high school, his minor sister had been hospitalized for reasons his mother declined to explain, and that he "hates sports."[28] *Id*., p. 113.

Ryan was seen by Dr. David Baldwin, an endocrinologist, on September 3, 1997. His evaluation of Ryan appears at Pet. Ex. 1, p. 34-35. A Holter monitor recorded Ryan's heart rate at 100-120 beats per minute while awake and 50-70 beats per minute while asleep. Ryan had also complained of a headache all day. After Dr. Baldwin observed that Ryan's heart rate increased from 92 beats per minute while lying down, to 120 after standing for one minute, and to 148 after standing for fifteen minutes, he diagnosed Ryan with POTS. He explained that POTS, a disease characterized by an increased heart rate upon standing, was caused by an autoimmune neuropathy of the veins of the legs, and that the standard treatment was Florinef.

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[27] A later record from this hospitalization indicated that the Verapamil resulted in some initial improvement, but was stopped when his symptoms did not resolve. *Id*., p. 113. Whether a physician was involved in this decision is likewise unclear.

[28] I note that the records from this hospitalization are not in any particular order. This note clearly continues, but I could not determine which, if any, of the pages of the records was the continuation page. The next page of this exhibit is a nursing note.

Pet. Ex. 1, pp. 34-37. He prescribed Florinef[29] and potassium chloride. Pet. Ex. 11, p. 50.

Apparently the diagnosis of POTS did not explain Ryan's chest pain or headache, because Ryan's treating physicians at Rush recommended a psychiatric consultation on September 4, 1997. Mrs. Szekeres was described as "very protective" and reluctant to consider a possible psychiatric cause for Ryan's symptoms. Pet. Ex. 4, p. 16.

Ryan was discharged on September 5, 1997 with a diagnosis of POTS, prescriptions for Florinef (0.2 mg per day) and for calcium chloride, and recommendations that he increase his activity level and follow a low cholesterol diet. Pet. Exs. 4, p. 17; 11, p. 174. He was to have a follow-up with Dr. Baldwin the following Wednesday. Pet. Ex. 11, p. 174.

Ryan saw Dr. Baldwin in mid-September. Doctor Baldwin recorded that all of the test results from Ryan's hospitalization at Rush were normal. His morning cortisol was low normal and his stimulated cortisol was slightly low, but hydrocortisone replacement therapy did not change his symptoms. However, the Florinef did appear to have a positive impact on Ryan's standing heart rate. *Id*., pp. 49-50. This information was reflected in a September 27, 1997 letter from Dr. Baldwin to the Rush Neurology clinic, requesting an evaluation of Ryan's headaches. *Id.* Dr. Baldwin recounted that Ryan had been seen in the UIC emergency room that day for a severe headache. By report from the emergency room physician to Dr. Baldwin, Ryan's CT[30] scan and neurological examination were both normal. Results from a lumbar puncture[31] were pending. The headache was relieved by 10 mg of intravenous Compazine.[32] *Id.,* p. 50.

The UIC emergency room visit also resulted in a referral to the UIC neurology clinic. On September 29, 1997, Ryan was seen by Dr. Carol Macmillan in the Pediatric Neurology Clinic at UIC. His presenting complaint was "severe headache for 2 months." Pet. Ex. 14, p. 23. Ryan was taking Florinef and albuterol. The medical history provided was that he was asymptomatic

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[29] Florinef is an adrenocortical steroid marketed for treatment of Addison's disease. *PDR* at 2159. Its use in treating POTS is unlabeled, meaning that the manufacturer does not market the drug for that condition.

[30] A CT scan refers to a computed tomography scan of the brain, used to diagnose central nervous system disease. It consists of a computerized analysis of x-rays of the brain. *Mosby's Labs* at 1095-96.

[31] A lumbar puncture involves placing a needle in the subarachnoid space of the spinal column to measure pressure and to obtain cerebrospinal fluid for laboratory examination. The presence of blood or bacteria and the amount of glucose or protein present in the spinal fluid may assist in diagnosis of autoimmune and demyelinating disorders and many other diseases. *Mosby's Labs* at 677-83.

[32] Compazine is a tranquilizer used in the short term treatment of anxiety. *PDR* at 1470.

until July, when he developed dizziness and palpitations, followed by a headache on July 14. The headache had changed in intensity during the intervening period, but had not disappeared and was not relieved by analgesics. Ryan also indicated that he had some short-term memory problems, beginning about 2-3 weeks after the headaches began. Hydrocortisone made the headaches worse and it was discontinued. *Id.,* pp. 23-24.

Ryan's neurological exam was normal, including his memory. Doctor Macmillan reviewed the CT scan, the results of the lumbar puncture, and Dr. Baldwin's diagnosis of POTS. Her impression was that Ryan suffered from "development and post-viral syndrome consisting of P.O.T.S. and chronic daily headache." She prescribed Amitriptyline.[33] Ryan's mother was to call in three weeks to discuss his progress and Ryan was to return to the clinic in two months. *Id.,* p. 24-25.

Doctor Macmillan wrote to Dr. Baldwin on September 29, 1997 about her examination and treatment of Ryan. This letter (Pet. Ex. 14, pp. 17-18) contains most of the same information as the notes of her examination found at Pet. Ex. 14, pp. 23-24. The letter noted that Ryan's symptoms, including vomiting, began on July 12, and on July 14, he developed a headache, providing support for her impression that Ryan suffered from POTS and headache as a result of a post-viral syndrome. In the letter, as in her neurological examination notes, she refers to Ryan's condition as paroxysmal orthostatic tachycardia. She informed Dr. Baldwin of the prescription for Amitriptyline. *Id.*, p. 18.

In what appears to be a telephone consultation on October 1, 1997 between Mrs. Szekeres and a nurse in the Pediatric Neurology Clinic, Ryan was reported to have a headache worse than ever before, accompanied by nausea. The nurse discussed this with Dr. Macmillan, who prescribed Toradol.[34] *Id.*, p. 15.

Ryan's mother called the Pediatric Neurology clinic again at 0830 on October 1, 1997. Pet. Ex. 14, p. 8. While this telephone call has a time reference (and the one appearing on page 15 discussed above does not), this conversation clearly occurred later in time. By report, Mrs. Szekeres had talked to the neurology resident on call in the emergency room the night before to say that Ryan had not urinated all day since receiving Compazine. At the direction of the resident, she gave Ryan one liter of a sports drink, but Ryan had still only voided a very small amount in 24 hours. Ryan's headache remained "9 on a scale of 1-10" and his diarrhea (which she claimed had continued for the past 2 ½ months) had increased after one dose of Toradol. *Id*., p. 8.

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[33] Amitriptyline is a tricyclic antidepressant used to treat depression. *PDR* at 2194. *See also* http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a682388.html (Last visited November 27, 2006).

[34] Toradol is a nonsteroidal anti-inflammatory drug used for moderately severe acute pain. It may be prescribed in lieu of opiates for pain management. *PDR* at 2966-68.

The nurse discussed this telephone call with Dr. Macmillan, who advised that Ryan should see his primary care doctor or return to the emergency room. When the nurse conveyed this information to Mrs. Szekeres, she commented that she did not have a primary care doctor anymore as the one they had been seeing did not believe Ryan was ill. Mrs. Szekeres was advised to take him to the emergency room if he still had problems voiding. *Id*.

Mrs. Szekeres called the Pediatric Neurology clinic again on October 1, 1997 to report that Ryan had voided, but his headache remained severe and his diarrhea had increased. She was again advised to take him to the emergency room. *Id.,* p. 9.

Some notes are missing from Pet. Ex. 14, as the next entry is dated at 0830 on October 3, 1997, and refers to nursing notes from Oct 2, 1997 that are not present in the records. Ryan did not go to the emergency room on October 1, as advised by Dr. Macmillan. His mother contacted the neurology resident on call on the evening of October 2, and was again advised to bring Ryan into the emergency room. *Id*, p. 13. Mrs. Szekeres called the Pediatric Neurology Clinic again on the morning of October 3, 1997, saying that the Toradol must have done something to Ryan's urinary tract system. She reported that he was eating and drinking, and "peeing like a racehorse" but that the headache persisted at the same level of intensity. *Id*.

Once again, the nurse discussed the call with Dr. Macmillan, who indicated that it was highly unlikely that Ryan's urinary problems were caused by Toradol, and suggested that Ryan be given another dose of Toradol, while continuing the Amitriptyline. Mrs. Szekeres refused to consider giving Ryan any more Toradol, commenting that Ryan did not react to medication like other patients, and that Dr. Macmillan would have to figure out what to do for him. *Id*. Mrs. Szekeres indicated that she was holding Dr. Macmillan medically responsible and that she expected the doctor to return her call. *Id.*, p. 14.

After several more calls from Mrs. Szekeres in a similar vein, Dr. Macmillan finished seeing her clinic patients and consulted with Ryan's cardiologist and endocrinologist before having the clinic nurse return Mrs. Szekeres' call. Doctor Macmillan discovered that Ryan had a neurology appointment at Rush's adult neurology clinic the next week, and suggested that he keep that appointment. When the nurse conveyed this information to Mrs. Szekeres, she denied that they had an appointment, became angry, and hung up. The nurse called her back to reiterate that if Ryan became worse, they should go to the emergency room. *Id*. The note then continues on Pet. Ex. 14, p. 16, with Mrs. Szekeres again stating that she was holding Dr. Macmillan responsible for damaging Ryan, and ending the conversation by hanging up. *Id.*

At 1730, October 3, 1997, Doctor Macmillan wrote a long note in Ryan's chart. She noted that Ryan had multiple intolerances to medications prescribed that week, including Amitriptyline, Ibuprofen, and Toradol. She spoke with Dr. Trohman at Rush, who indicated that he was no longer involved in Ryan's care, but had diagnosed Ryan with inappropriate sinus tachycardia. Doctor Trohman explained that this disease had a heart rate component, a neurologic component (including lightheadedness) and a psychiatric component, and that it was a

difficult disease to treat. Doctor Macmillan also spoke with Dr. Baldwin (the endocrinologist at Rush who had diagnosed POTS), who stated that Ryan's diarrhea had never been mentioned to him and that the first history of headache he had taken dated back only two weeks. He had arranged for a neurology consultation at Rush on October 7, but Ryan's parents were unwilling to wait and took Ryan to UIC. Pet. Ex. 14, p. 11.

Doctor Macmillan then described her telephone conversation with Mrs. Szekeres, who reiterated Ryan's intolerance of amitriptyline and Toradol, and the ineffectiveness of Ibuprofen in treating the pain, and her frustration in finding treatment for Ryan. Doctor Macmillan encouraged her to keep the neurology appointment at Rush and to return to the emergency room if she became more concerned. Doctor Macmillan indicated that Dr. Baldwin would contact Mrs. Szekeres that evening. *Id*., p. 12.

On October 4, 1997, Dr. Macmillan contacted the neurology resident on call to discuss a possible admission of Ryan to UIC that weekend. In one of the more bizarre reports in this case, Dr. Macmillian described her attempts to get Ryan admitted: She called the Szekeres residence at 1130 to talk to Ryan's parents. When advised that they were not at home, she asked to speak with Ryan. When he came to the phone, she identified herself and he hung up the phone. She called back and the call was not answered. She waited five minutes and called back again, speaking to the person who had answered the telephone on her first call. That person hung up when she asked to speak to Ryan. She waited ten minutes and called back; the person who answered the phone again hung up when she asked to speak to Ryan. At 1218, Mrs. Szekeres called Dr. Macmillan to report that Ryan had experienced a five minute episode of staring and unresponsiveness, but had not fallen or experienced any incontinence. He had no memory of the incident. Doctor Macmillan advised Mrs. Szekeres to bring Ryan to the UIC emergency room to be admitted. She agreed to do so. *Id.*, p. 20.

At 1230, the on-call neurology resident received a call from Mrs. Szekeres stating that Ryan would seek care at Loyola Hospital instead. She called back at 1745 to say that Loyola Hospital had refused to admit Ryan and that they were now open to treatment at UIC. *Id.,* p. 19.

Ryan's visit to Loyola's emergency room occurred at approximately 1520 on October 4, 1997. The presenting complaint was a 3-4 second period of staring and unresponsiveness, and the history included three months of headache and POTS. The emergency room report stated that Ryan had been under the care of a doctor at UIC and other university hospitals, but that he had been released from that doctor's care in the last 24 hours and directed to Loyola. It described the extensive work-up of Ryan's complaints at other hospitals and the negative test results. The emergency room arranged for a neurology consult. During the consultation, Mrs. Szekeres became "agitated" and she and Ryan left the emergency room, refusing to stay for discharge instructions. Pet. Ex. 3, pp. 65-67. The neurologist's assessment was that Ryan had multiple medical problems with normal physical and neurological examinations. He assessed the headache as functional in the course of continuous stress and as inconsistent with migraine. He did not believe the staring episode was consistent with an absence seizure and recommended that

Ryan follow up with his primary care provider and with the psychiatric service. *Id.*, p. 70.

Ryan saw Dr. Baldwin again on October 8, 1997. He noted that Ryan had not had any symptoms of increased heart rate and that he was to see a neurologist at Rush that day for his headache problems. He recounted that Ryan had seen a neurologist at UIC, but that she and Ryan's mother could not work together. He increased Ryan's prescription for Florinef by 0.1 mg per day and doubled his prescription for potassium chloride. Ryan was to return in four weeks. Pet. Ex. 4, p. 5.

Ryan next saw Dr. Steven Lewis and Dr. John LaVaccare, neurologists at Rush on October 8, 1997. They recorded Ryan's history as headache pain, short term memory loss, and a staring episode on October 4, and awakening with a sore jaw on October 5 and 8, 1997. They indicated that Ryan had been hospitalized at UIC for this staring episode and treated with Depakote,[35] but that the drug caused nausea and vomiting. Mrs. Szekeres had differences with the UIC medical staff and she and Ryan were escorted out of the hospital. All testing at UIC, with the exception of low cortisol, were read as normal.[36] Upon examination at Rush, Ryan was noted to have some mild short-term memory deficits. The two neurologists noted that his history of a blank stare, headache, and memory loss could all be symptoms of complex partial seizures and recommended an electroencephalogram ["EEG"] and neuropsychological testing. *Id.,* p. 25-26.

The EEG was mildly abnormal, with intermittent temporal slowing. *Id.*, p. 28. The two days of neuropsychological testing found that Ryan had average intelligence and severely impaired measures of immediate and delayed memory. The clinical neuropsychologist who performed the testing described Ryan as socially immature, quite dependent, and with a strong need for attention. He suggested that Ryan might resent his dependency. He concluded that it was difficult to tell if Ryan was experiencing emotional stress because of his neurological problems or if the stress was the cause of his symptoms. He noted that Ryan's performance on memory tests was variable and more impaired than might be expected and strongly recommended a psychiatric referral. *Id.*, pp. 30-32.

Ryan was admitted to Rush on October 17, 1997 for 72 hours of continuous video and EEG monitoring to evaluate him for possible complex partial seizures. *Id*., p. 50. No seizure activity or staring episodes were observed during the hospitalization. Although his mother had reported a two week history of nocturnal shaking episodes prior to his hospitalization, none were observed during his hospital stay. *Id.,* p. 36. However, the day before his scheduled discharge, Ryan complained of a partial vision loss in his left eye. Vision testing was consistent with hysterical visual fields deficits; Ryan complained of vision loss in certain areas, but reacted to threats and movement in the areas of claimed vision loss. *Id*., p. 51, 46. The vision findings

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[35] Depakote is a drug used to treat seizure disorders. *PDR* at 430-31.

[36] No medical records pertaining to this admission to UIC were filed.

were discussed with Mrs. Szekeres, who reportedly became "belligerent." *Id.*, p. 51. Ryan was discharged on October 20, 1997, with ambulatory 48 hour EEG monitoring, with no recorded episodes of shaking or staring. Doctor Antonio Gil-Nagel assessed Ryan's symptoms as psychogenic in origin and recommended counseling. *Id.*, p. 37.

Ryan was next evaluated by Dr. Daniel Heir, a neurologist at UIC. He suggested a trial of Prozac for five days. Pet. Ex. 14, pp. 5-7. There are no records that reflect whether Ryan actually tried the drug. During the period from December 21-29, 1997, Ryan had a number of tests, none of which were abnormal. Pet. Ex. 4, pp. 53-64. A brain MRI on Jan 12, 1998 was likewise normal. *Id.*, pp. 65-67.

The next medical record is from Ravenswood's emergency room, where Ryan was seen on April 6, 1998 for bowel problems and referred to his primary care provider. *Id.*, p. 69. Ryan was apparently seen again by Ravenswood physicians, but the only record of this consultation reflects an April 21, 1998 referral from Ravenswood to the National Institutes of Health ["NIH"] in Bethesda, MD for evaluation of POTS. *Id.*, p. 80.

Ryan's hospital course at NIH was curtailed. The day after Ryan was admitted, his mother had a disagreement with the nursing staff. Mrs. Szekeres believed that Ryan had lost his way to another part of the hospital and blamed the staff for failing to escort him. Ryan was later found in the bathroom of his room. At his request, Ryan was discharged that day without further testing. The diagnosis upon discharge was POTS, by history. *Id.*, pp. 81-84.

Aside from one emergency room visit to Swedish Hospital in January 1999 for dizziness and excessive urination (*id.*, p. 94), Ryan's next record of treatment is by Dr. Brian Olshansky at Loyola in May 1999. Pet. Ex. 3, pp. 61-62. The medical history taken included continuously fast heart rates, dizziness, and light-headedness upon walking. It noted that he had been seen by many physicians and tried on a variety of medications, including Depakote and Florinef. Doctor Olshansky indicated that POTS was a possible diagnosis, but that there appeared to be a complex multiplicity of neurological symptoms that were unexplained and which might be related to a dysautonomic condition.[37] Ryan related the onset of his symptoms to the toe infection he experienced in 1996-97. Pet. Ex. 3, p. 61; Pet. Ex. 2, pp. 1-2, 4-5, 7.

Ryan was evaluated on June 8, 1999 by Dr. Daniel Homer, a neurologist at Evanston Hospital. He noted that POTS could cause headaches, but if so, they would be relieved by lying down. Ryan's headaches were unaffected by his position. *Id*., p. 55. An MRI and magnetic resonance angiogram ordered after this visit were both normal. In July, 1999, a neurologist at Northwestern noted that the testing Dr. Homer ordered failed to disclose any reason for Ryan's headaches. *Id*., p. 56.

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[37] A dysautonomic condition is a malfunction of the central nervous system. *Dorlands* at 572.

In a letter to another neurologist, Dr. Homer commented on Mrs. Szekeres' research into Ryan's symptoms and her "intriguing and plausible postulate. She realized that Ryan had received Hepatitis B vaccine on April 17, 1997. She reports that his first symptoms of weakness, leg pain, dizziness and nausea began on April 20, 1997. About 11 days later, he developed diarrhea as well as postural changes in his heart rate." *Id.*, pp. 59-60. Doctor Homer wrote that "Hepatitis B vaccine can cause delayed, presumably autoimmune, adverse reactions in a small number of susceptible individuals." *Id*., p. 59. After noting that Mrs. Szekeres had downloaded or obtained information regarding adverse reactions to hepatitis B vaccine, including post-infectious encephalomyelitis, he commented: "Several anecdotal reports have indicated an apparent relationship between hepatitis B vaccine and chronic headaches, chronic fatigue, or POTS." He opined: "My own view about Ryan's case is that this theory of the etiology of his neurologic and constitutional symptoms is entirely plausible and credible but currently unprovable." *Id.*, pp. 59-60.

Other than negative event monitor testing over a period of 30 days in 1999 (Pet Ex. 9, p. 23) and a cardiac evaluation that showed possible right ventricle dysplasia in 2002 (Pet. Ex. 10, p. 3), there were no further medical records of treatment until February 2005. In an emergency room visit to Northwestern on February 21, 2005, Ryan complained of seizures and confusion. By history, Ryan's seizures began when he was 17 and lasted for a few months. He claimed he had an allergic reaction to Depakote. Ryan was referred to the neurology clinic, (Pet. Ex. 10, pp. 15, 19), where all tests, including a CT scan and EEG, were normal. *Id.*, pp. 5, 7. The only medication Ryan indicated he was taking at the time of this emergency room visit was Proventil. *Id.*, p. 15.

Ryan returned to the Northwestern emergency room on March 1, 2005, complaining that he had experienced four seizures that day. *Id.,* p. 14. The records submitted do not indicate the outcome of this visit, but an MRI performed on March 25, was unremarkable. *Id*., p. 9.

On March 7, 2005, Ryan was seen at a pain and rehabilitation clinic. According to the handwritten notes, it appears that Ryan's mother provided the following history: Ryan had a hepatitis B vaccination on April 19, 1997 followed by viral encephalitis. His mother observed intermittent nocturnal shaking. He was seen at Rush and UIC, and was discharged from UIC with no follow up, being told his symptoms would improve over time. He was no longer taking Florinef because it caused him to overload fluids. His current medications were Klonopin[38] and Proventil. Pet. Ex. 6, pp. 5-7.

Ryan was next seen at Swedish Hospital's emergency room, having started a new seizure medication and subsequently developing a rash. He was treated with an antihistamine and released. Pet. Ex. 13, pp. 16-17. In a March 23, 2005 visit to Lake Shore Medical Associates, Ryan was described as having a six year history of seizures. Pet. Ex. 15, pp. 3-4. He had a normal MRI following this visit. *Id.*, pp. 5-6. This was the last medical record filed.

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[38] Klonpin is a medication prescribed for seizures and panic disorders. *PDR* at 2920-21.

III. Causation Determination

To be eligible for compensation under the Vaccine Program, a petitioner must either demonstrate a "Table" injury, to which a statutory presumption of causation attaches, or prove by a preponderance of the evidence that a vaccine listed on the Vaccine Table caused or significantly aggravated an injury. *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Because the injury alleged, POTS, is not one listed on the Vaccine Injury Table (42 C.F.R. § 100.3), Ryan has the burden of demonstrating by preponderant evidence that his injury was caused by the hepatitis B vaccine. Based on my review of the entire record,[39] I conclude that Ryan has failed to establish that the vaccine caused him any injury.

In the case of an "off-Table" injury, a petitioner must demonstrate by preponderant evidence that the vaccination caused his 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." *Althen,* 418 F.3d at 1278. *See also*, *Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006).

Petitioner need not show identification and proof of specific biological mechanisms, as "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition; showing that the vaccination was a "substantial factor" in causing the condition and was a "but for" cause is sufficient for recovery. *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). *See also, Pafford v. Sec'y, HHS,* 451 F.3d 1352, 1355 (Fed. Cir. 2006). Petitioners may not be 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. Causation is determined on a case by case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y*, *HHS* 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see, Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof failed to meet that burden).

When a petitioner alleges an "off-Table" injury, eligibility for compensation–the *prima facie* case–is established when the petitioner demonstrates, by a preponderance of the evidence,

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[39] *See* § 300aa–13(a): "Compensation shall be awarded...if the special master or court finds on the record as a whole..." *See also*, § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

that: (1) petitioner received a vaccine set forth on the Vaccine Injury Table; (2) he received the vaccine in the United States; (3) he sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months.[40]

I have factually concluded that Ryan had a hepatitis B vaccination and that the vaccine was administered in the United States. The hepatitis B vaccine is one listed on the Vaccine Injury Table. *See* 42 C.F.R. § 100.3. Whether Ryan actually suffered any illness or disease caused by the hepatitis B vaccine is not, however, established by the facts of this case.

Ryan's Diagnoses.

Three threads connect all the medical visits and hospitalizations from the onset of Ryan's cardiac symptoms through the last record filed. The first is the inability to link Ryan's symptoms with any objective medical test, with the exception of his increased heart rate upon standing.[41] The second thread is the strong suggestion by several of the treating physicians that Ryan's symptoms, including headache, visual disturbances, and adverse reactions to virtually any prescribed medication except Proventil, might be psychosomatic in origin. The third thread is the family's hostile interactions with health care providers, resulting in Ryan and his mother either leaving or being escorted from several hospitals and severing treating relationships with many doctors. There may be a fine line between an understandable frustration with the inability of medical professionals to diagnose and treat an illness and that of an irrational and hostile reaction to suggestions that psychological rather than physical causal factors are in play. However, in view of the gamut of health care providers with similar opinions and issues with the Szekeres family, I incline to the latter assessment in this case.

Although the Motion for Judgment on the Record indicates that Ryan suffered from POTS, that diagnosis is not the only one in the records. Doctor Baldwin's diagnosis of POTS is countered by Dr. Abrams' diagnosis of PSVT, Dr. Trohman's diagnosis of inappropriate sinus tachycardia, and Dr. Olshansky's suggestion of a dysautonomic syndrome. While the label for the illness is not crucial in an "off-Table" case (s*ee, e.g., Kelley v. Sec'y, HHS*, 68 Fed. Cl. 84, 100 (2005)), the differing diagnoses cast some doubt on Dr. Homer's opinion that Ryan had POTS caused by the hepatitis B vaccine.

Assuming, *arguendo*, that the POTS diagnosis is correct, it appears that this condition

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[40] Section 300aa–13(a)(1)(A). This section provides that petitioner must demonstrate by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1)..." Section 300aa–11(c)(1) contains the four factors listed above, along with others not relevant in this case.

[41] While one EEG showed some intermittent temporal slowing, none of the subsequent EEGs recorded any abnormalities.

persisted for at least six months: medical professionals documented sinus tachycardia in mid-July 1997; the condition was diagnosed in early September 1997, and Ryan was referred to NIH for evaluation of POTS in May 1999. While NIH diagnosed the condition only by history, the referring physician apparently considered Ryan's symptoms sufficiently established to warrant the referral.

Evidence of Causation.

Applying *Althen* to this case, I conclude that Ryan has failed to establish any of the three factors by preponderant evidence. The July 28, 1999 letter from Dr. Homer found at Pet. Ex. 3, pp. 59-60, is the only evidence of causation submitted. For a variety of reasons, I find it inadequate to prove causation.[42]

Doctor Homer's letter is based on an incorrect appreciation of the facts of this case. He relied upon Mrs. Szekeres' recounting of the onset of Ryan's symptoms and what those symptoms entailed. I do not consider Mrs. Szekeres' account to be reliable, as it is not supported by contemporaneous medical records. As the Court of Federal Claims has noted, a doctor's "conclusions...are only as good as the reasons and evidence that support them." *Davis v. Sec'y, HHS*, 20 Cl. Ct. 168, 173 (1990). Special masters frequently accord more weight to contemporaneously recorded medical symptoms than those recounted in later medical histories, in affidavits, or in trial testimony. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." *Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 506 U.S. 974 (1992). *See also*, *Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Memories are generally better the closer in time to the occurrence and the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). When an expert's opinion is based upon facts not established by the record, a fact-finder may reject the expert's opinion. *See Bradley v. Sec'y, HHS,* 991 F.2d 1570, 1574 (Fed. Cir. 1993)(where the special master discounted a medical expert opinion on causation because the opinion was largely based upon petitioner's uncorroborated testimony regarding onset that the special master found not to be credible).

The time between vaccination and the onset of Ryan's symptoms noted by Dr. Homer is based on Mrs. Szekeres' report. The only symptom he relied upon as closely related to the vaccination that is mentioned in contemporaneous medical records is the telephone message that Ryan's heart rate was "going from fast to slow" in late April, 1997. This symptom was not recorded by any medical professional. In another case, the lack of professional corroboration of a racing heart might not be significant or necessary. However, in view of the documented

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[42] Obviously, Dr.Homer's letter predates the Federal Circuit's decision in *Althen* by many years. The *Althen* decision, however, was not an entirely new approach to causation. *Althen* restated, clearly and concisely, the causation standards that were applied in many earlier Vaccine Act decisions. *See, e.g., Grant*, 956 F.2d at 1148 and *Hines*, 940 F.2d at 1525.

difficulty of connecting Ryan's subjective notations of a racing heart with the Holter monitor's or medical staff's simultaneously recorded heart rates, I place little reliance on Mrs. Szekeres' telephonic account of Ryan's symptoms, let alone her recitations of those symptoms made two years later.

The symptoms Mrs. Szekeres described as occurring in April or May of 1997 (dizziness, nausea, diarrhea, and postural heart rate changes) are not documented in the records as having occurred until July 1997 or later. There is no documentation at all that Ryan suffered from leg pain. Thus, Dr. Homer's opinion is seriously undercut by his misapprehension of Ryan's symptoms and their juxtaposition to the vaccination. Doctor Homer's letter fails to indicate any window of time in which a reaction to the hepatitis B vaccine might reasonably be expected. Ryan's documented symptoms began approximately three months after the vaccine was administered. Other than a *post hoc, ergo propter hoc* analysis, there is nothing to suggest that Ryan's symptoms arose within a temporal window consistent with a vaccine reaction.

Doctor Homer's letter also fails to address a medical theory of causation or the logical sequence of cause and effect that led him to conclude that the vaccine was causal. He does not explain how the hepatitis B vaccine might cause or contribute to an autoimmune reaction. He does not explain how vaccine components might cause vascular neuropathy (as described by Dr. Baldwin as the medical basis for POTS) or any other cause for POTS.

Doctor Homer does not make it clear whether he is independently aware of "delayed, presumably autoimmune adverse reactions in a small number of susceptible individuals" or whether he is relying on Mrs. Szekeres' conversations with researchers and her internet research for this proposition[43]. While it is certainly not necessary that an expert offering an opinion on causation in vaccine litigation be involved in medical research himself, medical opinions relying solely upon searches of internet websites and interviews conducted by a lay person will be inherently less reliable than those based on medical research reported in scientific journals, personally conducted scientific experiments or studies, or reports from more trusted sources.

Additionally, I have no information about Dr. Homer's qualifications to render an opinion on vaccine causation himself. I have not been provided a copy of his *curriculum vitae* and I know nothing about his background, training, or experience, other than that he was a medical doctor, presumably a neurologist, on the staff of Evanston Hospital in Evanston, IL in 1999. While a treating doctor's opinion may be sufficient evidence of causation (*see Capizzano*, 440 F.3d at 1326), the court must be satisfied that any offered medical or scientific opinion is reliable. *Terran v. Sec'y, HHS*, 195 F.3d 1302, 1316 Fed. Cir. (1999) (applying *Daubert v. Merrell Dow Pharm. Inc*., 509 U.S. 579, 591-92 (1993) to a special master's consideration of medical or scientific evidence). Even accepting Dr. Homer as qualified to render an opinion on causation,

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[43] I note that the paragraph following this quoted language begins with the phrase, "my own view about Ryan's case," suggesting that the previous paragraph was based on Mrs. Szekeres' beliefs and research.

this record fails to demonstrate that his opinion has a reliable factual or scientific basis.

In 1999, Dr. Homer stated that his theory about vaccine causation of Ryan's symptoms was "currently unprovable." In view of petitioner's failure to produce any additional scientific evidence in the seven years since that opinion was rendered, it is reasonable to conclude that such evidence is still unavailable.

Conclusion

Petitioner has not demonstrated by a preponderance of the evidence that his condition was either caused or significantly aggravated by the hepatitis B vaccination he received in mid-April 1997. He has thus failed to establish a *prima facie* case for compensation and the petition for compensation is therefore DENIED. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

November 29, 2006
Date

s/Denise K. Vowell
Denise K. Vowell
Special Master