

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 01-197V

Filed: November 29, 2006

To be Published

GRACE SZEKERES

Petitioner,

v.

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

Respondent.

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Entitlement Decision;
Hepatitis B; POTS; CFS;
Judgment on the Record

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

DECISION¹

Vowell, Special Master:

On April 4, 2001, Ms. Grace Szekeres² timely filed a petition for compensation under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10³ *et seq.* [“the Vaccine Act”], alleging that hepatitis B vaccinations she received on April 15, 1998, May 22, 1998, and November 11, 1998 caused her chronic fatigue syndrome, fibromyalgia, memory loss,

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 To avoid confusion between Ms. Grace Szekeres and her mother, Mrs. Bette Szekeres, I will refer to the petitioner as “Grace” throughout this opinion.

³ 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.).

gastrointestinal problems, and POT's (sic) syndrome.⁴ Petition at ¶ 3. On July 11, 2006, she filed a Motion for Judgment on the Record, stating therein that "the record supports a prima facie case of POTS and Chronic Fatigue Syndrome from three Hepatitis B vaccinations." *Id.* at 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 any of her medical conditions and she is therefore not entitled to compensation.

I. Procedural History

When the petition was filed on April 4, 2001, none of the statutorily-mandated supporting documents were filed with it.⁵ No other filings were made in this case over the next eleven months. On July 10, 2002, petitioner was ordered to request that her case be stayed or to file an expert report by September 12, 2002. Petitioner requested that her case be stayed.

It remained stayed until April 2, 2004, when it was reassigned to another special master, who subsequently directed petitioner to file a status report by June 18, 2004. In a status report filed on that date, petitioner's counsel indicated, *inter alia*, that he was working with petitioner to compile a list of health care providers and expected the list to be completed within two weeks; he was unable to estimate when the medical records would be received; he would file by June 25, 2004 all the medical records that petitioner had provided to him; he would file an amended petition within 30 days of receiving all medical records; he would file petitioner's affidavit within the next 30 days; and he would file witness statements within the next 60-90 days. *See* Petitioner's Status Report, dated June 18, 2004.

Petitioner was ordered to file a status report by July 23, 2004 to update this information. Order, dated June 24, 2004. That status report was not filed until July 30, 2004, although petitioner did file vaccine records and miscellaneous medical records already in her possession on July 2, 2004. Petitioner's affidavit was not filed. Petitioner also filed three additional exhibits on July 30, 2004. More medical records were filed on August 6 and 13, 2004, and on September 3 and 17, 2004. Additional medical records were received on December 10, 2004. Those were the last filings in the case for nearly fourteen months.

⁴ "POTS" is an abbreviation for "postural orthostatic tachycardia syndrome." It is a disorder of the autonomic nervous system characterized by orthostatic intolerance (the 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). "Tachycardia" is a rapid heart beat, usually referring to a heart rate of over 100 beats per minute. *Dorland's Illustrated Medical Dictionary* ["*Dorland's*"] at 1850 (30th ed. 2003). Grace's symptoms, test results and diagnoses are discussed in more detail, *infra*.

⁵ 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.

On January 19, 2006, petitioner was ordered to file a status report by February 3, 2006. That report was not filed until February 22, 2006, one day after the case was reassigned to me. In that status report, petitioner's counsel stated:

At the present time tests are being performed to see if these cases involve a form of mercury poisoning. Without such evidence, Grace's case is one that would be clinically difficult to prove. Until the results of the tests are received and evaluated, it is not known how we will proceed with this case. It is requested that time be allowed to perform this further evaluation.

Petitioner's Status Report, dated February 22, 2006.

At a recorded status conference on March 27, 2006, followed by a written order dated April 4, 2006, I ordered petitioner to file a status report stating whether the medical tests referred to in the February 2006 status report had been performed. I also ordered her to set forth a cogent theory of her case. *See*, Order, dated April 4, 2006, as amended April 13, 2006.

In response, petitioner filed a status report that indicated that the mercury testing that was allegedly "being performed" in February 2006 was now being scheduled. I directed petitioner to file a report that provided more specific information about when the tests were requested, who was performing the tests, when the tests were scheduled to be performed, and when the results would be filed with the court. As petitioner had never filed an amended petition as previously ordered, I also directed petitioner to set forth her theory of causation and the relationship of mercury to her medical condition. Order, dated May 4, 2006.

In response, petitioner filed a status report on May 13, 2006 indicating that she no longer wished to pursue her claim and requesting 30 days to file a motion for voluntary dismissal or a motion for judgment on the record. I granted that request. Order, dated May 15, 2006. On June 20, 2006, I held a telephonic status conference in which petitioner's counsel requested additional time to file petitioner's affidavit before filing a motion for judgment on the record. I gave petitioner until July 11, 2006 to file that affidavit, but cautioned her counsel that I would not grant any further extensions of time. On July 11, 2006, petitioner filed her long-overdue affidavit, a statement from her mother, and a Motion for Judgment on the Record. Respondent filed a response to that motion on July 28, 2006, arguing that the record failed to establish a *prima facie* case that a vaccine had caused petitioner's condition.

II. Medical History

The medical records filed in this case are incomplete and relatively unorganized. Scattered records from a variety of health care providers are contained in a single exhibit, Petitioner's Exhibit ["Pet. Ex."] 2, and many pages of that exhibit are difficult to read. Some records in Pet. Ex. 2 contain the medical stamp plate record of "Kathleen" or "Bette" Szekeres,

not Grace Szekeres.⁶ See, e.g., Pet. Ex. 2, pp. 39-42. The medical exhibits cover the period from February 1994 to November 2004.

By medical history, Grace was obese by the age of one year. Pet. Ex. 2, p. 192. While in high school, she was diagnosed as “morbidly obese.” Pet. Ex. 2, p. 181. There is no indication that she suffered from any other chronic medical conditions until 1998, although the incomplete nature of the records makes this difficult to determine with certainty.

Grace received her first hepatitis B vaccination on April 17, 1997. Pet. Ex. 1, p. 2. There is nothing in the record to indicate that she had any medical problems after this vaccination. The first medical records subsequent to this vaccination reflect that she was seen by Dr. David Fisher for earache, chest pain, and a urinary tract infection in March 1998. Pet. Ex. 2, pp. 20-21.

In April 1998, Grace was first seen for long-standing menstrual difficulties, including abdominal pain and irregular periods. *Id.*, p. 23. She received a second hepatitis B vaccination on April 15, 1998.⁷ Pet. Ex. 1, pp. 1, 4. The medical visits for the months subsequent to this vaccination primarily concern the work-up and treatment of her menstrual difficulties, although reappearance of some earlier diarrhea, abdominal pain, and knee pain from a fall at school were noted. Pet. Ex. 2, pp. 24-25. She received a third hepatitis B vaccination on May 22, 1998. Pet. Ex. 1, pp. 1, 4.

A trial of two different oral contraceptives to treat her menstrual problems was terminated after two months with Mrs. Szekeres reporting that Grace’s symptoms had worsened while taking them. Pet. Ex. 2, pp. 24-26. An obstetrician was consulted and recommended that Grace see a gastroenterologist, as he did not think the abdominal cramps that she experienced while on oral contraceptives were related to her menstrual problems.

In July 1998, Grace changed primary care physicians, seeing Dr. Phyllis Schmitz for the first time. Pet. Ex. 2, p. 27. There is no indication in the record why she left the care of Dr. Fisher. The medical history Dr. Schmitz obtained reflected that Grace had no history of constipation or painful urination, but did complain of occasional dizziness. *Id.*, p. 1. She also noted that Grace had a brother who had been diagnosed with postural tachycardia. Doctor Schmitz diagnosed excessive uterine bleeding (menomenorrhagia) and ordered an ovarian ultrasound examination. She included a long list of potential causes for Grace’s symptoms,

⁶ Bette Szekeres, petitioner’s mother, apparently also uses the name “Kathleen Szekeres.” See Pet. Ex. 17, p. 2 (statement of Bette Szekeres). I note that the table of contents filed with Pet. Exs. 1 and 2 indicates that Pet. Ex. 2 is comprised of miscellaneous records obtained from petitioner, rather than directly from a health care provider. There are a number of gaps in the records contained in Pet. Ex. 2.

⁷ Although this was Grace’s second vaccination, her primary care provider either did not have the record of her earlier vaccination or elected, in view of the interruption of the series after the first vaccination, to restart the entire series. As a result, Grace ultimately received four, rather than the usual three, hepatitis B vaccinations.

including polycystic ovarian syndrome⁸ [“PCOD”], fibroid,⁹ Cushing’s syndrome,¹⁰ and a pituitary adenoma. *Id.*, pp. 1-2. A pelvic ultrasound performed on July 31, 1998 ruled out PCOD, as Grace’s uterus and ovaries were normal, except for a single small follicular cyst. *Id.*, pp. 43, 27, 28.

Grace was referred to Dr. Elley, who agreed with Dr. Schmitz that Grace did not have PCOD. He ordered an adrenocorticotrophic hormone [“ACTH”] stimulation test. *Id.*, pp. 27-28. This is a test used to evaluate the functioning of the adrenal glands and to evaluate patients with Cushing’s syndrome. *Mosby’s Manual of Diagnostic and Laboratory Tests* [“*Mosby’s Labs*”] at 32 (3d ed. 2006).

Grace was admitted to Swedish Covenant Hospital on October 2, 1998 with abdominal pain and a temperature of 101 degrees. Pet. Ex. 2, pp. 7, 11. An abdominal ultrasound found gallstones and her gall bladder was removed via laparoscopic surgery that evening. *Id.*, p. 18. Although the records of this hospitalization and surgery are by no means complete (the nursing notes and some laboratory tests were not filed in any exhibit), there is no indication that this surgery included visualization of her ovaries.¹¹ Less than two weeks after this surgery, Grace underwent abdominal and brain magnetic resonance imaging [“MRI”]. Both MRI tests were performed to evaluate Grace for PCOD. The results of both tests were unremarkable, with no evidence of PCOD noted. *Id.*, pp. 47-48. Mrs. Szekeres and Grace discussed the MRI results with a health care provider at Swedish Covenant Hospital on October 15, 1998. *Id.*, p. 34.

Grace received her last hepatitis B vaccination at her next visit to Dr. Schmitz on November 10, 1998. Pet. Exs. 1, pp. 1, 4; 2, p. 34.

Thereafter, Grace saw Dr. David Ehrmann for an endocrinology work-up. The records contain a letter from him to Mrs. Szekeres, dated March 4, 1999, referring to an examination of Grace on January 16, 1999. He noted that Grace had irregular menses, increased body hair, acne, and obesity. Doctor Ehrmann wrote:

⁸ Polycystic ovarian syndrome is a symptom complex associated with ovaries with many cysts (“polycystic”), lack of ovulation, and a pattern of male hair distribution. *Dorland’s* at 1828.

⁹ Fibroids (leiomyomas) are benign uterine tumors. *Dorland’s* at 1011. They may cause excessive uterine bleeding.

¹⁰ Cushing’s syndrome is often caused by adrenal tumors. Symptoms include fat deposits on the face, neck, and trunk, diabetes, and muscular wasting and weakness. *Dorland’s* at 1815.

¹¹ Laparoscopic surgery involves small incisions that allow the insertion of a laparoscope to view the internal organs. A laparoscopic cholecystectomy (removal of the gall bladder) involves the removal of the gall bladder through these small incisions, rather than through a single larger incision. The discharge summary describes the abdominal ultrasound findings, mentioning that Grace’s appendix was normal, but does not mention her uterus or ovaries. Grace or her mother later reported that she was diagnosed with PCOD at the time of her gallbladder surgery, although no record documents such a finding during the surgery. *See* discussion, *infra*.

The good news is that with the exception of the mild increase in the free testosterone level, all of the results are completely normal. The free testosterone is the hormone that is responsible for some of the issues in Grace, specifically the hair growth and, perhaps, the irregular periods.

He noted that the testosterone increase was mild and was likely related to her weight. Pet. Ex. 2, pp. 49-50.

In June 1999, Dr. Schmitz sought to refer Grace to the endocrinology department at Children's Memorial Hospital for evaluation of a recent insulin level of 27. In this referral letter, Dr. Schmitz mentioned Grace's "past medical history complaints of painful menstruation and polycystic ovary disease." *Id.*, p. 17. Because the ultrasound and MRI performed in October 1998 showed no evidence of polycystic ovaries, it is unclear whether this comment represents a new diagnosis, a reference to a diagnosis made earlier but not reflected in the medical records filed, or simply a reference to Grace's symptoms.

Grace's next medical record is dated July 8, 1999, and was likely written by Dr. Dean Kravis. He noted a history of painful menses and that ovarian cysts were found during gall bladder surgery. He indicated that her insulin resistance was probably secondary to her weight and prescribed both Glucophage (a drug used to treat insulin resistance) and weight reduction. Pet. Ex. 4, p. 5.

Although there are no records reflecting who ordered a Holter monitor test¹² and an MRI of Grace's heart, those tests were performed in July 1999. The results appear in the records at Pet. Exs. 2, p. 44; 4, p. 7; and 8, p. 3. The Holter monitor showed some abnormalities; the MRI was normal. *Id.* Apparently Dr. Kravis referred Grace to Dr. Janet Strasburger, a pediatric cardiologist at Children's Memorial Hospital, as the next record is a letter from Dr. Strasburger to Dr. Kravis, dated September 8, 1999. Doctor Strasburger indicated that she had seen Grace for a recent bout of severe chest pain and extreme fatigue. This is the first mention of extreme or chronic fatigue in Grace's exhibits.¹³ Doctor Strasburger noted that Grace's brother had

¹² 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. *Mosby's Labs* at 587-88.

¹³ I was unable to find a medical record in which a diagnosis of chronic fatigue syndrome is made, as distinguished from medical histories that report such a diagnosis. "Chronic fatigue" is mentioned in several medical histories taken about Grace after August 1999, but chronic fatigue syndrome is not listed in any record until August, 2000. Chronic fatigue syndrome is a "persistent debilitating fatigue of recent onset, with reduction of physical activity to less than half of usual, accompanied by some combination of muscle weakness, sore throat, mild fever, tender lymph nodes, headaches, and depression, with the symptoms not attributable to any other known causes." *Dorland's* at 1813. Doctor Strasburger later connected Grace's fatigue to deconditioning associated with her obesity and POTS-like syndrome. Pet. Ex. 2, p. 79.

orthostatic tachycardia and that Grace was now displaying similar symptoms.¹⁴ She had prescribed fludrocortisone to treat this condition, but Grace was not taking the medication. Doctor Strasburger reinforced the need to take the fludrocortisone and also prescribed potassium chloride. Pet. Ex. 2, p. 81. This also appears to be the first record in which a diagnosis of POTS is made.

Grace switched doctors again, to Dr. Gerald Berkowitz, although the date of the switch and the reason for it are unclear from the records. Grace was evaluated for renal cysts on October 2, 1999, and the negative report from that test was sent to Dr. Berkowitz. *Id.*, p. 184. He also saw Grace for tonsillitis in December 1999. *Id.*, p. 189.

He referred Grace to Dr. Abraham Shashoua in January 2000, to evaluate her for PCOD. In the history, Dr. Shashoua noted that polycystic ovaries were seen on laparoscopy and commented that this diagnosis would explain her laboratory tests and clinical findings. *Id.*, pp. 183-84.

The next record (Pet. Ex. 2, p. 195) shows a gynecological visit on January 25, 2000, although the record does not identify the doctor. The history taken recorded that Grace had POTS since a hepatitis B vaccination three years earlier and that her brother had the same vaccination and same disease. An undated record at page 197 of Pet. Ex. 2 indicated that Grace suffered from chronic fatigue, fibromyalgia,¹⁵ and irritable bowel, in addition to POTS. If the records are in chronological order, this is the first mention of fibromyalgia as a diagnosis. In a handwritten note on an authorization for Grace to consult with Dr. Dewhite, made at approximately the same time as the gynecological visit, Dr. Berkowitz indicated that, after reviewing Grace's records, she might have congenital adrenal hyperplasia, but not PCOD, as her laboratory work was not consistent with PCOD. *Id.*, p. 198.

The next medical record filed dates from May 2000, and indicated that Grace was having

¹⁴ I note that POTS is often first diagnosed in adolescence. *See, supra*, n. 4 (Grubb article at 2).

¹⁵ Fibromyalgia refers to pain and stiffness in the joints. *Dorland's* at 697. With the exception of knee pain from a fall at school in 1998 and chondrochondritis in 2000, there are no records indicating that Grace suffered from any joint or muscle pain prior to this entry. Although petitioner's Motion for Judgment on the Record at 3 references Pet. Ex. 2, pp. 39-40 for evidence that Grace suffered joint and muscle problems, these records pertain to Mrs. Szekeres, not Grace. The first record reflecting joint pain in Grace is Pet. Ex. 17, p. 7, a medical history taken in November 2000.

heart palpitations. Doctor Berkowitz prescribed Lopressor,¹⁶ albuterol,¹⁷ and Florinef.¹⁸ *Id.*, p. 189. He referred Grace to Dr. Abdul Sattar, who saw her on May 18, 2000. Doctor Sattar recited the diagnosis of PCOD, based on findings during the laparoscopic cholecystectomy, but noted that the ultrasound of her ovaries was normal. He commented that Dr. Erdmann did not believe she had PCOD and recorded that the Glucophage prescribed to treat her insulin resistance gave her diarrhea. Doctor Sattar's conclusion was that Grace needed to get her weight down to 180 pounds (she weighed 312 pounds at this visit) before any meaningful assessment of her endocrine system could be made. Pet. Ex. 2, pp. 192-93.

Doctor Strasburger evaluated Grace again in June 2000. In a letter to Dr. Berkowitz, Dr. Strasburger noted that Grace, then 17 ½ years old, was off all medications; her mother felt that she tolerated Midodrine¹⁹ "very poorly"; and that fludrocortisone (Florinef) was ineffective. Dr. Strasburger recorded that Grace's blood pressure on standing was improved, but that her heart rate on standing continued to be abnormal. She also noted that Grace had significant cardiovascular deconditioning. Pet. Ex. 2, p. 82.

In August 2000, Grace and her mother saw Dr. Sheryl Murray. Doctor Murray recorded that the reason for the visit was to obtain a referral to an ear, nose and throat ["ENT"] specialist. By medical history,²⁰ Dr. Murray noted that Grace:

suffers Pot's [sic] Syndrome (postural orthostatic tachycardia syndrome) resulting from a hepatitis B injection. Unfortunately her older brother received the same injection, and both of them are suffering from this disorder....As a result of her Pot's [sic] Syndrome, she also suffers from chronic fatigue syndrome....Lastly, the patient has problems with recurring strep pharyngitis, and she would like to see an ENT specialist.

Id., p. 181; Pet. Ex. 6, p. 6. Doctor Murray continued her note with the following assessment and

¹⁶ Lopressor is the brand name for metoprolol tartrate. *Dorland's* at 1067. It is a beta blocker used to treat cardiac problems. *Id.* at 1147.

¹⁷ Albuterol is a bronchodilator used to treat asthma. *Dorland's* at 45.

¹⁸ Florinef (fludrocortisone) is an adrenocortical steroid marketed for treatment of Addison's disease. *Physician's Desk Reference* ["PDR"] at 2159 (58th ed. 2004). It was likely prescribed to treat Grace's POTS, although its use in POTS is unlabeled, meaning that the manufacturer does not market the drug for that condition. Although there are references in Grace's records to possible adrenal problems, it is unlikely that she had Addison's disease, a condition caused by the destruction of the adrenal cortex (*Dorland's* at 528), as an MRI in October, 1998 did not find any problems with her adrenal glands. Pet. Ex. 2, p. 47.

¹⁹ Midodrine is a drug used in the treatment of orthostatic hypotension. *PDR* at 3155.

²⁰ This history is preceded by the notation "S:" which is a common medical abbreviation for subjective findings. See Neil M. Davis, *Medical Abbreviations*, at 318 (12th ed. 2005).

plan: “We will use Dr. Strasburger as her PCP [primary care provider] since I have no experience in treating this type of pediatric endocrine illness.” *Id.* Doctor Murray did not examine Grace or conduct any tests. The record is merely a recitation of Grace’s medical history and her mother’s request for referral to other physicians.

This record from Dr. Murray is one of the two records that attribute Grace’s POTS to a hepatitis B vaccination, the other being a history taken by an unidentified doctor eight months earlier. Doctor Murray’s notations apparently form the basis for petitioner’s contention that she has established a *prima facie* case of causation. *See*, Motion for Judgment on the Record at 4.

Although Dr. Murray did not indicate that Grace was suffering any pain or discomfort at this visit, the next day, Dr Strasburger saw Grace for “substernal chest pain over the past 4 days of severe intensity,” noting that palpitation of her chest brought tears. Pet. Ex. 2, p. 78. In the letter she wrote to Dr. Murray after this visit, Dr. Strasburger referred to Grace’s condition as a “POTS-like syndrome,” rather than POTS. She also noted that Grace was quite deconditioned, but made no mention of chronic fatigue syndrome. *Id.*

The ENT consultation approved by Dr. Murray was with Dr. Michael Goldman on September 22, 2000. In a letter to Dr. Murray, Dr. Goldman reported that Mrs. Szekeres had provided a medical history of enlarged tonsils and strep infections on a monthly basis and told him that previous physicians had suggested a tonsillectomy. Mrs. Szekeres also provided a history of POTS, chronic fatigue syndrome and fibromyalgia. On examination, Grace’s tonsils were enlarged. Doctor Goldman agreed that Grace met the criteria for tonsillectomy, but indicated that she would need cardiac clearance before surgery. *Id.*, p. 180. At the bottom of this letter, Dr. Murray’s initials appear below a handwritten note dated October 2, 2000, indicating that Grace and Mrs. Szekeres had left Dr. Murray’s practice and that Grace was to follow up with Dr. Rachel Oosterbaan. *Id.*

Doctor Strasburger also referred Grace to another physician, Dr. Samer Dibs at Northwestern Memorial Hospital, in October 2000. In her letter to Dr. Dibs, Dr. Strasburger noted that Grace was nearly 18, and that Dr. Strasburger had exhausted her clinical expertise in dealing with Grace’s problems. *Id.*, p. 79. After summarizing her treatment of Grace, Dr. Strasburger indicated that the most likely clinical diagnosis for Grace’s condition was POTS, with chronic deconditioning complicated by obesity. She mentioned chronic fatigue, but did not include chronic fatigue syndrome in her diagnosis. *Id.*, pp. 79-80.

Grace and Mrs. Szekeres saw Dr. Dibs on October 20, 2000. The referral did not go well. Doctor Dibs described Mrs. Szekeres as upset that he had not yet received the referral letter from Dr. Strasburger. He took Grace’s medical history and reviewed several cardiac tests from July, 1999, and then indicated that he needed to perform additional tests. Mrs. Szekeres was adamantly opposed to any additional testing and informed Dr. Dibs that they were there only for cardiac clearance for a tonsillectomy. She and Grace then left the room. Pet. Ex. 14, pp. 9-10. Doctor Dibs noted the difficulty of making a full assessment of Grace, indicating that the records

suggested inappropriate sinus tachycardia and/or postural orthostatic tachycardia syndrome. *Id.*, p. 10.

Mrs. Szekeres and Grace saw Dr. Oosterbaan for the first time three days after the visit to Dr. Dibs. Doctor Oosterbaan appeared quite concerned about the tenor of Mrs. Szekeres' comments and skeptical of both Mrs. Szekeres' motivations in seeking treatment and the reliability of the medical history and symptoms she provided. In a lengthy note, Dr. Oosterbaan indicated that Mrs. Szekeres answered all questions for Grace; referred to many of the doctors Grace had seen as "idiots"; and said that it was a good thing she didn't have a gun "because she would blow off all their heads." Doctor Oosterbaan observed that Mrs. Szekeres had fired most of the doctors she had seen. Mrs. Szekeres insisted that Grace was too sick to go to school, although Grace appeared healthy, albeit obese, to Dr. Oosterbaan. Pet. Ex. 2, pp. 200-01; also at Ex. 6, pp. 3-5. Doctor Oosterbaan recounted that Mrs. Szekeres stated that her children were very lucky to have her because they were both unhealthy and needed her and explained that she was suing the government and was threatening to sue all the doctors who were idiots. *Id.*

This conversation and examination lasted over an hour and a half. The principal complaint of illness was that of headaches for a month. While Grace denied having any weakness or tingling, Mrs. Szekeres insisted that Grace had those symptoms and demanded an MRI and a referral to a neurologist. Doctor Oosterbaan urged a psychiatric consultation, explaining to Mrs. Szekeres that the stress of her children's illnesses warranted such a consultation. *Id.* There is no record that Mrs. Szekeres ever saw a psychiatrist and this is the only record from Dr. Oosterbaan that was filed.

The next record of medical treatment of Grace was provided by Dr. Dibs' office, and is dated November 16, 2000, reflecting a return to Dr. Dibs after Grace and Mrs. Szekeres walked out of the October 2000 visit. Pet. Ex. 14, pp. 7-8. Portions of this record are too dark to read. The clear entries indicate that Grace was there because she needed a tonsillectomy, had three to four strep throat episodes per year, was unable to tolerate Midodrine and Florinef, and was dizzy at all times. She also complained of fatigue, diarrhea, occasional shortness of breath, and joint pains. The examining physician's signature is indecipherable, but the doctor concluded that Grace probably had POTS.

The records provided become even more spotty after November, 2000. Grace had some unrelated testing in April 2002 (Pet. Ex. 8, p. 4), and a technically limited echocardiogram in August 2002, which showed mild left ventricular hypertrophy and trivial tricuspid regurgitation, but which was otherwise normal. Pet. Ex. 7, p. 6. She had a colonoscopy in April 2003 which showed no evidence of irritable bowel disease. *Id.*, pp. 12, 14, and 23. A pelvic ultrasound in September 2003, showed a right adnexal cyst for which a complex cystic structure could not be ruled out. *Id.*, p. 5. The most recent record filed in this case is from Dr. Dibs, and is dated November 16, 2004. It indicated that Grace had fainted while walking with her brother. Pet. Ex. 14, pp. 5-6.

III. Causation Determination

Although the petition for compensation in this case initially identified several medical conditions as caused by the hepatitis B vaccination, the Motion for Judgment on the Record identified only POTS and chronic fatigue syndrome as the conditions for which she contends she has established a *prima facie* case of causation.

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 injuries alleged, POTS and chronic fatigue syndrome, are not ones listed on the Vaccine Injury Table (42 C.F.R. § 100.3), Grace has the burden of demonstrating by preponderant evidence that her injury was caused by the hepatitis B vaccine. Based on a review of the entire record,²¹ I conclude that Grace has failed to establish a *prima facie* case. Because I conclude that no *prima facie* case has been established, respondent has no obligation to demonstrate causation by a “factor unrelated” to the vaccine.²²

In the case of an “off-Table” injury, a petitioner must “show by preponderant evidence that the vaccination brought about her 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... .”

²¹ 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).

²² See § 300aa–13(a)(1)(B).

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, that: (1) petitioner received a vaccine set forth on the Vaccine Injury Table; (2) she received the vaccine in the United States; (3) she sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) that the condition has persisted for more than six months.²³

I have factually concluded that Grace had four hepatitis B vaccinations that predated her POTS symptoms and that the vaccines were administered in the United States. The hepatitis B vaccine is one listed on the Vaccine Injury Table. However, both Grace’s diagnoses and the cause of her symptoms remain problematic.

Diagnoses.

POTS Diagnosis. The records filed in this case establish that Grace was first diagnosed with POTS (or a POTS-like syndrome) in September, 1999, nearly a year after her last hepatitis B vaccination. She evidently displayed some cardiac symptoms in the July 1999 timeframe, as she had Holter monitoring in that month, and a cardiac MRI was performed in August 1999. At best, then, the first symptoms of cardiac problems appear seven to eight months after the last hepatitis B vaccination in November 1998. Although it appears that Dr. Strasburger withdrew from a definitive POTS diagnosis as she continued to treat Grace, referring to it instead as a “POTS-like syndrome,” the preponderance of the evidence supports a finding that Grace did have POTS. In any event, the label for the illness is not crucial in an off-Table case. *See, e.g., Kelley v. Sec’y, HHS*, 68 Fed. Cl. 84, 100 (2005).

Chronic Fatigue Syndrome Diagnosis. There is no record of a diagnosis of chronic fatigue syndrome anywhere in the exhibits filed. Chronic fatigue syndrome is listed in the medical history provided by petitioner or her mother to various of Grace’s health care providers, but no doctor records it in his or her diagnosis of Grace. I find inadequate evidence that Grace actually suffered from chronic fatigue syndrome, as opposed to fatigue secondary to deconditioning and obesity.

Several medical histories recite a prior diagnosis of chronic fatigue syndrome. A medical

²³ 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 at issue in this case.

history provided by a patient may form the basis for a factual conclusion that a petitioner actually suffers from the condition described in that medical history. Medical records containing contemporaneous information supplied to health care professionals for the purpose of obtaining medical diagnosis and treatment are, ordinarily, powerful evidence. *Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). A patient who provides inaccurate or misleading medical histories or recitations of symptoms risks receiving inappropriate medical treatment. However, in this case I am exceedingly unwilling to accept as trustworthy the medical histories of alleged diagnoses provided by Grace or Mrs. Szekeres when their statements are unsupported by other evidence. Without records or circumstantial evidence to support the medical histories that Grace and her mother provided, there is inadequate reliable evidence that Grace actually had chronic fatigue syndrome.

Simply put, Grace and Mrs. Szekeres are not accurate historians. They did not accurately report diagnoses and medical histories to health care providers on numerous occasions. Instead, the records reveal a pattern of reports that Grace suffered from medical conditions not substantiated, and sometimes even contradicted, by objective medical tests.

For example, the medical histories in 1998-2000 that record Grace's diagnosis of PCOD were made to physicians upon Grace's first visit to those doctors and were not accompanied by any evidence substantiating that diagnosis. The history of PCOD is repeated thereafter in those physicians' records, letters, and reports. The history of PCOD may have been consistent with Grace's reports of physical symptoms, but, as Dr. Berkowitz noted when he reviewed the laboratory evidence, the history is not substantiated by any of the objective physical tests (ultrasound or MRI examinations) performed. The diagnosis is attributed in histories to findings from the laparoscopic cholecystectomy, but the discharge summary and other records pertaining to that surgery do not mention polycystic ovaries as even an incidental finding, and the abdominal MRI conducted two weeks later was completely unremarkable.

Other histories of diagnoses are unsupported by the records. Several doctors recorded a history of fibromyalgia, but none of the exhibits reflect any doctor making that diagnosis. Mrs. Szekeres reported to a physician in 1999 that Grace suffered from monthly strep throat infections, but the medical records substantiate, at most, four instances of tonsillitis, sore throat, strep throat, or an upper respiratory infections in the period from March 1998-June 1999.

Grace's affidavit, Pet. Ex. 16, likewise reported medical symptoms not substantiated by the medical records. She recorded that she became tired easily, very achy, and experienced heart fluttering after her second hepatitis B vaccination in April, 1998. These symptoms are not contemporaneously recorded anywhere in the records filed, even though she saw a doctor for long-standing menstrual problems two days after the April vaccination, and again on May 22, 1998, when she received her third vaccination. Her affidavit states that she experienced flu-like symptoms after the May vaccination and went to the doctor two to three days later. *Id.*, p. 1. There is no record of this visit. Grace stated that her symptoms became even worse after the final hepatitis B vaccination and that she developed constant dizziness. *Id.*, p. 2. However, the

first record after the vaccination is a month later and concerns a visit for strep throat. The record does not reflect dizziness as a symptom. Pet. Ex. 2, pp 37-38. She reported fever and chills for two days. A strep test was positive. *Id.*

Most of page 2 of Grace's affidavit is concerned with her symptoms of memory loss, heart palpitations, pain, tiredness, and diarrhea.²⁴ None of the medical records filed list memory loss as a problem or complaint²⁵. Diarrhea is mentioned prior to her gall bladder surgery in October 1998, but the next mention of it as a symptom does not occur in the records until 2000.

I thus find there is inadequate evidence to establish a diagnosis of chronic fatigue syndrome. Finding adequate evidence for the POTS diagnosis, the records establish that this condition persisted for at least six months. *See* § 300aa-11(c)(1).

Applying *Althen* to the Facts.

Accepting, *arguendo*, that Grace developed both POTS and chronic fatigue syndrome subsequent to her hepatitis B vaccinations, I must next determine whether there is a preponderance of evidence that the vaccinations were causal. The August 30, 2000 letter from Dr. Murray found at Pet. Ex. 2, p. 181 and again at Pet. Ex. 6, p. 6, is inadequate to establish any of the three *Althen* factors by preponderant evidence. The medical record from an unknown provider from January 2000 (Pet. Ex. 2, p. 195) is likewise inadequate.

Doctor Murray's letter is not a reliable medical opinion or record. It is clear from the context that Dr. Murray was not opining that the vaccinations caused Grace's POTS. Doctor Murray was simply recording what Mrs. Szekeres or Grace reported to her. 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). I have explained, *supra*, my findings regarding the reliability of their reporting of previous diagnoses. To the extent Dr. Murray's recording that the hepatitis B vaccinations caused Grace's POTS can be considered a medical opinion on causation, I find it to be one based on unreliable reporting by petitioner and her mother.

²⁴ While Mrs. Szekere's statement (Pet. Ex. 17) appears to substantiate Grace's affidavit in terms of symptoms, timing, and doctor visits, it, in addition to being unsworn, suffers from the same infirmities as Grace's affidavit. It cites to medical visits and diagnoses unsubstantiated by medical records and provides no explanation for the lack of records to substantiate the symptoms, visits, and diagnoses.

²⁵ One could consider Mrs. Szekeres' answering questions for Grace at the visit with Dr. Oosterbaan as some circumstantial evidence that Grace suffered from a poor memory. It is clear, however, from the nature of Dr. Oosterbaan's comments on this visit that she considered Mrs. Szekeres' answering for Grace as symptomatic of a problem with Mrs. Szekeres, not Grace or her memory.

Another reason that this letter is not a *reliable* medical record or opinion is Dr. Murray's concession that she lacked experience with POTS and her deferral to Dr. Strasburger for treatment of Grace's POTS. I have no information about Dr. Murray's qualifications to render an opinion on vaccine causation. I have not been provided a copy of her *curriculum vitae* and I know nothing about her background, training, or experience, other than that she was a medical doctor. Of note, Dr. Strasburger, the pediatric cardiologist to whom Dr. Murray deferred, never mentioned hepatitis B as causal at any point in her treatment of Grace from September 1999 (when she first diagnosed Grace with POTS) through October 2000, when she referred Grace to another physician.

Also noteworthy in determining the reliability of Dr. Murray's "diagnosis" are: the very abbreviated period during which she saw Grace, from August 30, 2000 to, at the latest, October 2, 2000;²⁶ the lack of any examination or testing performed by Dr. Murray; and the stated reason for the consultation—to obtain a referral to a nutritionist and an ENT specialist, not for treatment or diagnosis of Grace's condition. A visit for a referral does not automatically render any causation opinion unreliable, but the purpose for the visit is a factor to be considered in determining the weight to be given to the opinion.

*Doctor Murray's letter fails to address the Althen factors.*²⁷ Doctor Murray's letter fails to address a medical theory of causation between the hepatitis B vaccinations and POTS. She did not provide any insight into how the hepatitis B vaccine might cause or contribute to the development of POTS. 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). The letter likewise fails to provide a logical sequence of cause and effect. It is silent on the issue of "proximate temporal relationship," other than noting that the symptoms occurred after the vaccination. The letter fails to indicate any window of time in which a reaction to the hepatitis B vaccine might reasonably be expected. Grace's documented symptoms began approximately eight months after the final vaccination was administered. Other than a *post hoc, ergo propter hoc* analysis, there is nothing to suggest that Grace's symptoms arose within a temporal window consistent with a vaccine reaction.

An expert medical opinion or treating doctor's opinion that a vaccine caused a disease need not be in any particular form or format. Petitioner must, however, either through the expert opinion alone, or in conjunction with other evidence, establish all of the *Althen* factors. In the final analysis, the court must be satisfied that any medical or scientific opinion is reliable. *Terran v. Sec'y, HHS*, 195 F.3d 1302, 1316 (Fed. Cir.1999) (applying *Daubert v. Merrell Dow*

²⁶ There is only one page of records from Dr. Murray in the exhibits filed, even though it appears twice (at Pet. Ex. 2, p. 181 and Pet. Ex. 6, p. 6). It thus appears from the records that Grace saw Dr. Murray only once.

²⁷ Obviously, Dr. Murray'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.

Pharm. Inc., 509 U.S. 579, 591-92 (1993) to a special master's consideration of medical or scientific evidence). Petitioner has failed to meet her burden under *Althen*. To the extent Dr. Murray's letter may be considered as evidence of causation, it is not reliable evidence of causation. The January 2000 medical record from the unknown provider suffers from these same infirmities.

Conclusion

Petitioner has not demonstrated by a preponderance of the evidence that her condition was either caused or significantly aggravated by the hepatitis B vaccinations she received between April 1997 and November 1998. She 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