In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(E-Filed: March 14, 2007)

PUBLISHED

SHANNON HAWKINS, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	)	No. 00-646V Motion for Judgment on the Record; Failure to Offer either a Medical Theory or Opinion of Causation; Denial of Compensation

Ronald C. Homer, Boston, MA, for petitioner.

Althea W. Davis, with whom were Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Vincent J. Matanoski, Acting Deputy Director, and Gabrielle M. Fielding, Assistant Director, Department of Justice, Civil Division, Torts Branch, Washington, DC, for respondent.

DECISION DENYING COMPENSATION[1]

[1] Vaccine Rule 18(b) states that all of the decisions of the special masters will be made available to the public unless the decisions contain trade secrets or commercial or financial information that is privileged or confidential, or the decisions contain medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. Within 14 days of the filing of a decision or substantive order with the Clerk of the Court, a party may identify and move for the redaction of privileged or confidential information before the

On November 2, 2000, Melissa Hawkins, as mother and next friend, filed a petition pursuant to the National Vaccine Injury Compensation Program[2] (the Act or the Program) seeking compensation for injuries allegedly sustained by her minor daughter, Shannon Hawkins (Shannon), as a result of the Hepatitis B vaccination she received on November 4, 1997. Petition at 1. On October 16, 2001, Shannon Hawkins moved to amend the case caption. Chief Special Master Golkiewicz granted her motion to amend the case caption on October 18, 2001. Shannon Hawkins is currently the sole petitioner in this case because she is no longer a minor.

On November 27, 2001, Shannon filed an amended petition, to which she attached Petitioner's Exhibits 1-7. See Petitioner's Exhibits (P's Exs.) 1-7. In support of her amended petition, Shannon filed additional medical records, contained in Petitioner's Exhibits 8-10, and an affidavit from her mother, Melissa Hawkins. Shannon alleges that she developed postural orthostatic tachycardia syndrome ("POTS"),[3] as a result of the third Hepatitis B vaccination she received on November 5, 1997.[4] Amended Petition at 1.

On May 10, 2006, respondent filed a Rule 4 Report (R. Report), pursuant to Vaccine Rule 4(c), recommending no compensation because petitioner had not met her burden of establishing entitlement under the Vaccine Program. R. Report at 11. Specifically, respondent stated that petitioner "has yet to offer a reputable medical or scientific theory causally connecting the vaccine to [her] alleged injury," id., and explained that respondent was "unable to find in the record any medical opinion

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document's public disclosure.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (West 1991 & Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

[3] "Postural tachycardia syndrome (POTS) is a disorder characterized by a pulse rate that is too fast when the patient stands. Symptoms include rapid heartbeat, lightheadedness with prolonged standing, headache, chronic fatigue, chest pain, and other nonspecific complaints. Causes of POTS usually are not identified in individual patients." National Institute of Neurologic Disorders and Strokes (http://www.ninds.nih.gov/disorders/postural_tachycardia_syndrome/postural_tachycardia_syndrome.htm).

[4] Shannon's vaccination records reflect that she was vaccinated on November 4, 1997. There is a handwritten note on the records indicating that this date is incorrect and that she was in fact vaccinated on November 5, 1997. P's Ex. 5 at 2.

attributing the claimant's condition to her hepatitis B vaccination," id. at 11.

On September 19, 2006, the undersigned granted petitioner's motion for enlargement of time and ordered petitioner to file a medical expert on or before October 11, 2006. On October 11, 2006, petitioner's counsel filed a Motion for a Ruling on the Record (P's Motion). Petitioner's counsel states that "the Court has had the opportunity to review the petitioner's exhibits in this case," and urges the Court to "now resolve the issue of whether the hepatitis B vaccination administered on November 5, 1997, more likely than not, caused [Shannon] to suffer postural tachycardia syndrome ('POTS')." P's Motion at 2.

Petitioner's motion for judgment on the record is ripe for decision.

I. Facts

Shannon was born on March 1, 1983. P's Ex. 2 at 2. With the exception of two noted medical issues in her pediatric records, specifically, chronic knee problems and head trauma, Shannon's medical records reflect that Shannon was a healthy child. See generally P's Ex. 1.

On December 20, 1993, Shannon visited her primary care provider, Dr. Margaret Vandenbark. Shannon's chart from this visit reflects that her chief complaint was "cracking, popping" and pain in both knees. P's Ex. 1 at 231. Shannon's medical records indicate that she experienced knee pain while playing soccer and during physical education. Id. On May 5, 1995, Dr. R. Montgomery examined Shannon during her first orthopedic consultation. P's Ex. at 220. From this visit, Dr. Montgomery's patient notes reflect that Shannon's "knees hurt mostly with running. . . . She has been involved in jazz dance for several years, and that never causes knee pain." Id. The record reflects that Shannon's pain continued and worsened through 1996. See generally P's Ex. 1 at 198-231. Shannon was referred to Dr. Stephen J. Ebner, an orthopedic surgeon, who first examined Shannon on July 17, 1996, for "bilateral knee pain, left greater than right." P's Ex. 1 at 199. Dr. Ebner diagnosed Shannon with chondromalacia.[5] P's Ex. 1 at 200.

Shannon's medical records also indicate that she experienced head trauma prior to her hepatitis B vaccination in November of 1997. On January 18, 1994, Shannon "fell off a chair at school[, and] hit back of head." P's Ex. 1 at 229. She experienced "pain at site," but no "l[oss] o[f] c[onsciousness]." Id. Nearly one year later, Shannon had an

[5] Chondromalacia is a "softening of the articular cartilage, most frequently in the patella." Dorland's Illustrated Medical Dictionary 356 (30th ed. 2003).

"onset of [weekly] headaches approximately at 12 years of age." P's Ex. 4 at 25.

On February 11, 1997, two years after the onset of her weekly headaches, Dr. F. M. Nomura diagnosed Shannon with an upper respiratory infection after she first complained of a sore throat and then developed a "cough, headache, diffuse abdominal pain, and [a] decreased energy level, and runny nose." P's Ex. 1 at 195. Two months later, on April 11, 1997, Shannon complained of joint pain in her fingers without swelling, but testing revealed no radiographic abnormality. P's Ex. 1 at 268.

Shannon received hepatitis B vaccinations on April 23, 1997, May 28, 1997, and November 5, 1997.[6] P's Ex. 5 at 2, 4. Shannon was fourteen at the time that she received her third hepatitis B vaccination. P's Ex. 5 at 3. According to her mother's affidavit:

> Approximately three weeks after receiving the vaccine, [Shannon] showed the first symptoms of the illness she suffers from today. It was just before Thanksgiving, and we were visiting my mother who lived in California. While on a car trip to in Los Angeles, Shannon became sick. Initially, I thought that she was car sick, and then I thought that she may have the flu. I can recall at Christmas that year, Shannon was complaining of not feeling well. As a mother, I down played it, thinking she wasn't eating properly. As time passed, and she wasn't getting any better, I realized she was genuinely sick. In January of 1998, she went to a dance with her sister. When Shannon came home early from the dance because she was sick, I knew there was something wrong with this child. She went from being a dynamic bundle of energy, to a different child with no energy.

Amended Petition at 2.

On January 28, 1998, twelve weeks after her third hepatitis B vaccination, Dr. Lisa Kroonen, a family practitioner, evaluated Shannon's complaints of a three-day history of "crampy abdominal pain" and nausea. P's Ex. 1 at 181. Shannon described her pain as "intermittent with each episode lasting about 10 minutes." Id. She had no fever, chills, weight loss, or loss of appetite. Id. It was Dr. Kroonen's impression that petitioner had a viral syndrome or irritable bowel syndrome ("IBS"), for which Dr. Kroonen recommended increased fiber intake. Id.

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[6] The hepatitis B vaccine is "a noninfectious viral vaccine derived by recombination from hepatitis B surface antigen and cloned in yeast cells; administered intramuscularly for immunization of children and adolescents and of persons at increased risk for infection." Dorland's Illustrated Medical Dictionary at 1999.

On February 4, 1998, Shannon saw Dr. Marianne Dwyer, a pediatrician, complaining of a "swirling stomach" and nausea and lightheadedness that had persisted since Christmas. P's Ex. 1 at 179. Her appetite had decreased, and the record reflects that Dr. Kroonen advised her to try Mylanta. Id. The next day, she saw her primary care physician, Dr. Vandenbark, with a complaint of continuing abdominal pain. P's Ex. 1 at 177. Shannon's medical records include a detailed history of her symptoms as follows:

> Nausea began Christmas eve; then New Year's eve had nausea for 1/2 hour during a party; all Christmas break just "didn't feel well." Then felt OK until 1/23 when began to have short bouts of nausea again, worse 1/26-7, then 1/28 devel[oped] LUQ [left upper quadrant] abd[ominal] pain . . . . 1/29 and 1/30 felt OK; 1/31 had LUQ sharp pains again, and severe nausea again 2/3 . . . .

Id. The record reflects that in the two weeks preceding Shannon's visit to Dr. Vandenbark, she had missed five days of school, which was "very unusual for her." Id. Dr. Vandenbark's impression after the examination was "likely IBS," for which Dr. Vandenbark prescribed a continued course of antacids. Id.

On November 4, 1998, Dr. Steven A. Long, an otolaryngologist, evaluated Shannon on referral. Dr. Long noted, "The patient recalls that approximately two weeks before her trip to California when this started the patient had trauma to the right [of her] head consisting of hitting her head on the top of a cedar chest. This did not cause loss of consciousness but did cause some feeling of nausea immediately after the trauma. Until recently, the patient and her mother had not correlated the two [events] at all." P's Ex. 1 at 107.

On January 12, 1999, Dr. Geoffrey Lawrence, performed another otolaryngological evaluation of petitioner. He noted that the results of Shannon's electromyography ("EMG")[7], magnetic resonance imaging ("MRI")[8], and computed

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[7] Electromyography is "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." Dorland's Illustrated Medical Dictionary, supra note 1, at 598. The procedure can assist in the identification of primary muscle diseases. Mosby's Manual of Diagnostic and Laboratory Tests 571 (3rd ed. 2006).

[8] An MRI is "a method of visualizing soft tissues of the body by applying an external magnetic field that makes it possible to distinguish between hydrogen atoms in different environments." Dorland's Illustrated Medical Dictionary, supra note 1, at 908. This procedure

axial tomography ("CAT")[9] tests were all normal. P's Ex. 1 at 66. He also noted that earlier blood tests were positive for antinuclear antibodies ("ANA"), but that Shannon's immunological and rheumatological evaluations were negative for autoimmune diseases. P's Ex. 1 at 66-67. Dr. Lawrence believed that petitioner had hearing loss of the right ear. See P's Ex. 1 at 67. On February 9, 1999, petitioner's hearing tested within normal limits, and Dr. Lawrence was unable to confirm a diagnosis of Shannon's condition. P's Ex. 1 at 65, 273.

On February 10, 1999, Shannon's mother and father accompanied Shannon to Dr. Vandenbark's office to review Shannon's symptoms of dizziness and nausea that had persisted for more than a year. P's Ex. 1 at 59. Dr. Vandenbark's progress notes indicate that Mrs. Hawkins "inquire[d] about the possibility that this might be [a reaction] to the HepB series. She has heard that people have developed various neurologic problems, including M[ultiple]S[clerosis], three weeks after the third HepB shot. Shannon's third HepB was 10/28/97 [sic], and [symptoms] began about mid-Nov." P's Ex. 1 at 59. Dr. Vandenbark referred Shannon to Dr. Richard Konkol, a pediatric neurologist, for a second opinion. P's Ex. 1 at 60.

On February 18, 1999**,** Jeffrey Brown, M.D., Ph.D., Assistant Professor of neurology and otolaryngology at the Oregon Health Sciences University, raised the possibility that Shannon had a vascular loop compressing her eighth cranial nerve. See generally P's Ex. 1 at 44-45. A month later, on March 11, 1999, Dr. Vandenbark ordered a magnetic resonance angiography (MRA)[10] that revealed a "prominent vascular loop of [Shannon's] right [] cerebellar artery which extends into [Shannon's] right internal auditory canal adjoining the intercanalicular segments of the right [VII and VIII cranial nerves]." P's Ex. 1 at 37. But on

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assists in the evaluation of headaches or neurological problems. See Mosby's at 1188.

[9] Computed tomography, also known as computerized axial tomography (CAT) is a procedure during which "the emergent x-ray beam is measured by a scintillation counter; the electronic impulses are recorded on a magnetic disk and then are processed by a mini-computer for reconstruction display of the body in cross-section on a cathode ray tube." Dorland's Illustrated Medical Dictionary, at 1919. The procedure permits evaluation of a well-imaged brain, which is useful in the diagnosis of brain tumors as well as other conditions. See Mosby's at 1095.

[10] A magnetic resonance angiography is useful in the identification and evaluation of abnormalities (such as aneurysms or occlusions) in a patient's cerebral circulation. See Mosby's at 1045-47.

subsequent review of Shannon's diagnostic images by the ear, nose, and throat (ENT) physicians at Kaiser and by a pediatric neuroradiologist and neurosurgeon in Boston, the examining physicians concluded that Shannon's vascular compression was "normal" and not related to her symptomatology. P's Ex. 4 at 25. Accordingly, "no neurosurgical or ENT intervention [was] suggested." Id.

Shannon's medical records indicate that during a subsequent visit to Dr. Brown in May of 1999, her symptoms were "worse than ever." P's Ex. 1 at 28. A subsequent series of acupuncture treatments offered Shannon substantial relief. P's Ex. 1 at 27. On June 24, 1999, however, the results of an electronystagmogram[11] were abnormal; the results suggested a "right vestibular weakness or a strong bias set on the vestibular system on a brain stem basis." P's Ex. 1 at 22; P's Ex. 2 at 40-45.

Nearly eight weeks later, on August 6, 1999, Dr. Joseph H. Piatt, Jr., a pediatric neurosurgeon, examined Shannon "to consider the possibility of a neurovascular compression syndrome as an explanation of her chronic nausea." P's Ex. 1 at 15. Dr. Piatt noted that Shannon's last electronystagmography test revealed a 40% decrease in function on her right side. P's Ex. 1 at 16. He declined to recommend neurosurgical intervention, but he did recommend a consultation with an adult neurosurgeon with more experience evaluating neurovascular compression syndromes. Id.

On September 14, 1999, petitioner visited Dr. Hirohisa Ono, a neurosurgeon, for a second opinion on neurosurgical intervention. P's Ex. 1 at 10-12. Dr. Ono noted that petitioner's symptoms began in November of 1997, when she was sitting in a car and "suddenly developed acute motion sickness." P's Ex. 1 at 10. Dr. Ono also noted that petitioner's MRA revealed a "significant vascular loop in the right internal auditory canal and the question of the vascular compression of the 8th nerve was raised." Id. Because Shannon did not manifest a hearing loss, however, Dr. Ono had "serious doubts" about the likelihood of the vascular compression in Shannon's right ear canal being the cause of her symptoms. P's Ex. 1 at 11.

Dr. Ono's notes also refer to Shannon's head injuries, specifically stating

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[11] Electronystagmography is an electrodiagnostic test "used to evaluate patients with vertigo and to differentiate organic from psychogenic vertigo. With this test, central (cerebellum, brainstem, eighth cranial nerve) pathologic conditions can be differentiated from peripheral (vestibular-cochlear) pathologic conditions." Mosby's at 577.

that Shannon had hit part of her head, without losing consciousness, on a cedar chest "about the same time as the beginning of her symptoms." P's Ex. 1 at 10. Dr. Ono's notes further indicate that Shannon also had a "water skiing injury, but she never lost consciousness . . . . " Id.

A month later, on October 8, 1999, Shannon saw Dr. Joji Kappes, a rheumatologist. Regarding Shannon's condition, Dr. Kappes noted that Shannon last felt well

> two-and-a-half years ago when all of this came on with the heralding event being a facial rash, while camping or hiking in northern California. Then later that year, in November, she took a car trip with her entire family to California and, upon arriving near Pasadena, she started getting car sick. She was there for about a week during Thanksgiving and then returned home by car and was in the front seat and feeling ill and prostrate.

P's Ex. 1 at 374.

Shannon's father took her for extensive evaluation and testing at the Mayo Clinic in Rochester, Minnesota between November 29, 1999, through December 3, 1999. See generally P's Ex. 4. An ENT evaluation, which included vestibular testing, ruled out any inner ear etiology for her symptoms. P's Ex. 4 at 10-11. A neuro-ophthalmology evaluation was normal. P's Ex. 4 at 17. Additionally, on December 1, 1999, Shannon saw Dr. Mark Olsen, a psychiatrist. During her visit to the psychiatrist, Shannon reported that "she was fine before a car ride to Los Angeles to visit her grandmother in late October 1997." P's Ex. 4 at 27. The psychiatrist diagnosed Shannon with a "probable undifferentiated somatoform[12] disorder." P's Ex. 4 at 28.

On December 15, 1999, Dr. Jeffrey Buckhalter, a pediatric neurologist, spoke with Shannon's father and provided the following written summary of Shannon's evaluation at the Mayo Clinic:

> Autonomic reflex testing revealed normal heart rate responses to deep breathing and valsalva maneuver as well as normal skin QSART [quantitative sudomotor axon reflex test] responses at all sites. However,

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[12] Somatoform disorders "can not be attributed to organic disease and appear to be of psychic origin." Dorland's Illustrated Medical Dictionary at 1722.

> when Shannon was tilted from the supine position, her heart rate response was excessive at 1, 5, and 10 minutes, increasing from 76 beats per minute to 128, 123, and 128 beats per minute respectively. This is considered consistent with postural orthostatic tachycardia syndrome (POTS).

P's Ex. 4 at 22-23 (emphasis added). Based on findings consistent with POTS, Dr. Buckhalter started Shannon on a fluid and salt regimen. Id. at 23.

On December 9, 1999, Dr. Jennifer Simpson, performed a rheumatologic examination of petitioner. P's Ex. 1 at 84-86. Dr. Simpson noted a prior history of painful knees, and petitioner's positive ANA in a homogeneous pattern. P's Ex. 1 at 85. Dr. Simpson suspected that petitioner might have a subtle form of lupus, but the results of Shannon's MRI were normal. P's Ex. 1 at 85, 265. Moreover, the extensive rheumatologic lab work conducted one month later revealed no evidence of any rheumatologic disorder. P's Ex. 1 at 71-72.

Shannon's medical records reflect that after one month of the prescribed fluid and salt regimen, her symptoms were "80% better." P's Ex. 1 at 362. Her medical records document her continued improvement through January 2000. P's Ex. 2 at 1. Although Shannon's symptoms persisted, the continued salt and fluid regimen and treatment with Sudafed first, and later with midodrine,[13] appears to have effectively managed Shannon's symptoms. See, e.g., P's Ex. 1 at 315; P's Ex. 6 at 3.

The most recent medical records filed in this case reflect that POTS continues to be identified in Shannon's medical records as one of her active problems. See generally P's Exs. 9-10. A record of a telephone call placed by Shannon to a nurse prior to knee surgery in October 2003 indicates that Shannon's POTS condition affected her on a sporadic basis. See P's Ex. 9 at 142. In anticipation of her surgery, Shannon wondered whether her history of POTS presented any reason for concern. See id. To that end, she reported to the nurse that she had a history of "low b[lood]p[pressure] w/orthostatic hypotension for which [she] saw Dr. Karlin several years ago (and) was given midodrine which she has not used for 'a long time.'" Id. Shannon further reported to the nurse that she "[i]ntermittently feels orthostatic, takes Benadry[l] and feels better." Id.

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[13] Midodrine "is used to treat low blood pressure in someone who has symptoms such as dizziness when going from a sitting to a standing position." See http://www.drugdigest.org/DD/DVH/Uses/0,3915,6192|Midodrine,00.html.

II. Discussion

To prevail on a filed claim under the Vaccine Program, petitioner must establish either: (1) that she suffered a "Table"[14] injury after the administration of a vaccination covered by the Program or (2) that her "off-Table"[15] injury resulted from the administration of a listed vaccine.[16] The Vaccine Injury Table lists certain injuries which, if found to have occurred within a prescribed time period, after the receipt of a listed vaccine, create a rebuttable presumption that the administered vaccine caused the alleged injury. 42 U.S.C. §300aa-14(a). Hepatitis B is a listed vaccine on the Table, but POTS is not listed on the vaccine injury Table. Because Shannon's diagnosed condition does not appear on the Vaccine Injury Table, Shannon does not benefit from the Act's presumption of causation for Table injuries. Accordingly, to establish entitlement to compensation, Shannon must prove an "off-Table" case under the Act.

To prove an "off-Table" case under the Act, Shannon must demonstrate by a preponderance of the evidence that her hepatitis B vaccination more likely than not caused her POTS condition. See, e.g., Grant v. Sec'y of Dept. of Health and Human Servs, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992); Hines v. Sec'y of Dept. of Health and Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Bunting v. Sec'y of Dept. of Health and Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991). See §§300aa-11(c)(1)(C)(ii). To meet this preponderance of the evidence standard, "[petitioner must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Sec'y of Dept. of Health and Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999). Petitioner satisfies this requirement by offering "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; see also Knudsen v. Sec'y of Dept. of Health and Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994); Hodges v. Sec'y of Dept. of Health and Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Jay v. Sec'y of Dept. of Health and Human Servs., 998

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[14] A "Table" injury is an injury listed on the Vaccine Injury Table. 42 C.F.R § 100.3.

[15] An "off-Table" injury does not appear on the Vaccine Injury Table. See 42 C.F.R § 100.3.

[16] A listed vaccine is a vaccine that is covered by the Vaccine Program. 42 U.S.C. §300aa-14.

F.2d 979, 984 (Fed. Cir. 1993); Grant, 956 F.2d at 1148. Shannon establishes a logical sequence of cause and effect by offering "[a] reputable medical or scientific explanation" that may include "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Petitioner does not satisfy her burden merely by showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation.")); Hodges, 9 F.3d at 960.

In Althen v. Secretary of Department of Health and Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005), the United States Court of Appeals for the Federal Circuit reiterated that petitioner's burden is to produce "preponderant evidence" demonstrating: "(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 the vaccination and injury." The Federal Circuit noted that "requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court's well established precedent." Id. at 1281.

According to the Federal Circuit, in order to prove actual causation, petitioner must prove, "by preponderant evidence," both that petitioner's vaccinations were "a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." Pafford v. HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006)(citing Shyface v. HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). "Of course, as noted in Shyface, these prongs must cumulatively show that the vaccination was a 'but for' cause of the harm, rather than just an insubstantial contributor in, or among several possible causes of, the harm." Pafford, 451 F.3d at 1355 (citing Shyface, 165 F.3d at 1352-53 (in which the Federal Circuit determined that although petitioner need not show that the vaccine was the sole or even the predominant cause of her injury, petitioner bears the burden of establishing "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury")). "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 1281.

In Capizzano v. Secretary of Department of Health and Human Services, the Federal Circuit observed that

> medical records and medical opinion testimony are favored in vaccine cases, because treating physicians are likely to be in the best position to determine whether "a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury."

440 F.3d 1317, 1327 (Fed. Cir. 2006) (quoting Althen, 418 F.3d at 1280).

Information contained in a petitioner's medical records and the testimony of medical experts are critical considerations when a special master evaluates a claim of a petitioner because the Vaccine Act forbids the special master from concluding that a vaccine-related injury has occurred based solely upon the claims of the petitioner. 42 U.S.C. § 300aa-13(a)(1)("The special master or court may not make ... a finding [of causation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."). The claim of a petitioner which is premised on a mere temporal association between a vaccination and an injury and the absence of other obvious etiologies does not establish legal causation under the Vaccine Program. See Grant, 956 F.2d at 1148.

Here, petitioner did not submit a report from a medical expert to support her cause-in-fact claim. Without the requisite support in the medical records or in an offered medical opinion, petitioner's claim must fail under the three prongs of Althen. That is, petitioner has not offered a medical theory causally connecting, by a logical sequence of cause and effect and by a proximate temporal relationship, her POTS condition to any of the hepatitis B vaccinations that petitioner received in 1997.

Although Shannon has established that she received three hepatitis B vaccinations as alleged in her amended petition, there is no evidence in the filed record that causally links her vaccination to her development of POTS or to any other alleged condition. See §300aa-11(c)(1)(C)(ii)(I). The undersigned has reviewed the filed record closely and has found no indication in Shannon's medical records that any of her treating physicians attributed her illness or her symptoms to

her hepatitis B vaccinations.

A review of the medical records reveals that Shannon's symptoms of persistent nausea, fatigue, and malaise were consistent between November 1997 and November 1999. See generally P's Ex. 1-4. During this time period, Shannon had an extensive medical evaluation that included examinations by specialists in the areas of "pediatric neurology, vestibular neurology, neurosurgery at Kaiser and at O[regon]H[ealth]S[ciences]U[niversity] as well as ENT, opthalmology, rheumatology, infectious disease, gastroenterology and endocrinology." P's Ex. 4 at 25. At the same time, Shannon's primary care physician, Dr. Vandenbark, continued to provide care and referrals for Shannon. See generally P's Ex. 1-4.

The only statement associating Shannon's injury with her hepatitis B vaccination is found in the records produced from Dr. Brown, an OSHU professor of neurology and otolaryngology. In his evaluation of Shannon, Dr. Brown notes that "[h]er symptoms did have their onset after her third hepatitis vaccination." P's Ex. 1 at 43. Dr. Brown's notes do not address causation, but simply note a temporal relationship between the onset of Shannon's symptoms and the receipt of her hepatitis B vaccination. Dr. Brown is the only physician among the many doctors who evaluated Shannon to note in Shannon's patient history that her symptoms occurred after Shannon's receipt of her third hepatitis vaccination. There is no further notation or mention of Shannon's hepatitis B vaccinations in the medical records during the course of Shannon's extensive evaluations. The singular notation in Shannon's medical records by Dr. Brown of a temporal association between Shannon's third hepatitis B shot and the onset of her symptoms that ultimately led to a POTS diagnosis is not sufficient to establish causation as contemplated by the Vaccine Act. See Grant, 956 F.2d at 1148.

Not only are petitioner's medical records bereft of evidence of causation, Shannon has failed to offer an expert medical opinion causally connecting her hepatitis B vaccination to her development of POTS. On review, the record is devoid of any medical evidence supporting Shannon's claim that her injury was caused in fact by the received hepatitis B vaccination. Without proof of causation, petitioner does not satisfy her evidentiary burden in this case, and her petition must be dismissed.

III. CONCLUSION

The record in this case contains no evidence that causally connects Shannon's hepatitis B vaccinations to her subsequent diagnosis of POTS. Because petitioner has failed to provide either a medical theory or a medical opinion supporting her claim of vaccine causation, petitioner has failed to establish entitlement to compensation under the Vaccine Act. Accordingly, the court must dismiss this case for want of proof. The Clerk of the Court shall enter judgment consistent with this decision.[17]

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Special Master

[17] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.