OFFICE OF SPECIAL MASTERS
99-670V

Filed: October 5, 2004

JOHN DOE,[1]	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael Roberts, Cincinnati, Ohio, joined by *Clifford Shoemaker*, Vienna, Virginia, for Petitioner.
Catherine E. Reeves, U.S. Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION

FRENCH, Special Master

I. PROCEDURAL BACKGROUND

On August 5, 1999, petitioner John Doe filed a petition pursuant to the National Vaccine Injury Compensation Program[2] (hereinafter referred to as "the Program" or "the Act") alleging that he suffered adverse reactions after receiving both a hepatitis A and hepatitis B vaccination,[3] on June 16, 1997. He claims the vaccinations resulted in "injuries, illnesses and other symptoms and conditions . . . including, but not limited to allergic reaction(s) and symptoms known as

[1] Petitioner's real name has been redacted.

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 990660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-1 et seq. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section reference will be to 42 U.S.C.A. §300aa of the Vaccine Act.

[3] Only the hepatitis B vaccine is covered under the Act; accordingly, the hepatitis A vaccine will not be considered in these deliberations.

Anaphylaxis and Anaphylactic shock." *See* Petition for Vaccine Compensation at 2. According to petitioner, he developed symptoms he had not experienced prior to administration of the vaccines, and these symptoms continued to worsen, becoming chronic.[4] Petitioner states that the consensus of the many doctors from whom he sought treatment is that his condition is likely to persist for the foreseeable future. Petitioner is now approximately 43 years old and resides in Town, USA.

Mr. Doe initially filed his claim as a pro se petitioner, and continued to represent himself from August 5, 1999, the day he filed, to April 2, 2001, a period of a year and eight months. On April 2, 2001, he substituted attorney Michael Roberts of Cincinnati, Ohio.

On April 17, 2001, respondent filed the required Rule 4 Report, recommending compensation be denied. *See*, Respondent's Report ("R. Report"). Respondent maintains that petitioner is not entitled to compensation because he has failed to establish that the hepatitis B vaccine caused his present condition, arguing that the medical records do not support petitioner's claim of a "Table case." Respondent insists further that the statutory time limit for the onset of symptoms of the alleged injury required to establish an on-Table case (24 hours) was breached. It would follow that petitioner is not due the presumption of causation provided by statute in a Table case. *See id.* Moreover, respondent argues that petitioner has not demonstrated a logical sequence of cause and effect linking the hepatitis vaccine to the onset of his unusual symptoms and therefore cannot prevail in a causation-in-fact claim. *See id.* To summarize, respondent maintains that petitioner is not entitled to compensation, having failed to meet the legal burden required for compensation under the Act.

This case has moved very slowly for many reasons. The issues are extensive and unusually complicated. Following the onset of his symptoms, Mr. Doe consulted multiple medical experts, domestically and abroad, hoping to find not only a diagnosis for his condition, but to restore his former state of health. For the most part, his efforts were unsuccessful. For the purpose of hearing expert testimony and upon completion of the filing of voluminous medical records, a hearing was held in Washington, D.C. on April 14 and 15, 2003.

Following the hearing, the parties agreed to tap the potential benefits of alternative dispute resolution ("ADR"), a method of negotiation that has been successfully employed in the Program. With the guidance of a disinterested, unbiased third person, ADR has a history of facilitating settlement acceptable to both parties, even in those cases that seemingly could not be otherwise resolved. At the parties' request, Chief Special Master Gary Golkiewicz agreed to participate as mediator in ADR. The parties could not, however, come to an agreement and those

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[4] Petitioner alleges that hepatitis B vaccine caused his condition. Not until the post-hearing briefs, did he suggest that the vaccine exacerbated a pre-existing condition. In fact, petitioner's position up until and throughout the hearing, as evidenced by his testimony, is that until he was vaccinated, he was in good health. Whether petitioner was, in fact, in good health prior to administration of the vaccine is at issue in this case.

efforts were abandoned.

The record is now closed and the case is ripe for decision. After reviewing the entire record, and for the reasons set forth below, the court finds petitioner has not carried the burden of proof required under the Act, and is therefore not entitled to compensation.

In providing an analysis of the case, the court will first discuss the statutory provisions and methods of proof as they apply here. Second, the court will lay out the factual background. Next, the court will examine the testimony of the medical experts for the parties, and the documents filed. Finally, the court will explain how petitioner has failed to establish a logical sequence of cause and effect linking Mr. Doe's chronic fatigue syndrome to the hepatitis B vaccination.

II. STATUTORY PROVISIONS and METHODS OF PROOF

To prevail in a vaccine-related case, petitioner must establish entitlement to compensation, and can do so by one of two methods. First, if petitioner can establish that he sustained an injury or condition set forth in the Vaccine Injury Table, and if the injury was observed or manifested within a prescribed time following the immunization alleged to have caused the injury, the statute presumes causation, and petitioner is entitled to compensation. This method of proof is designated a "Table"case. If petitioner is unable to meet the Table case criteria, the statute provides that petitioner may pursue a second method of proof, establishing that the vaccine actually caused the injury, including any sequellae. This method is commonly described as "actual causation" or "causation-in-fact." The actual causation method of proof has been the most common method pursued by petitioners in recent years, although it presents a very heavy burden. As noted in the initial filing in this case, petitioner has pursued his claim as a Table case but also pursues causation-in-fact as alternative proof that his injury is vaccine-related. Upon review of the entire record, the court finds the matter a non-Table case and will analyze it as such.

To demonstrate entitlement to compensation in a non-Table case, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. *See, e.g.*, *Bunting v. Secretary of HHS*, 931 F.2d 867, 872 (Fed. Cir. 1991); *Hines v. Secretary of HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Grant v. Secretary of HHS*, 956 F2d 1144, 1146, 1148 (Fed. Cir. 1992). *See also*, §§11(c)(1)(C)(ii)(I) and (II). While the Act relaxes proof of causation standards for on-Table injuries, it does not relax the standards for non-Table injuries. *See, e.g.*, *Whitecotton v. Secretary of HHS*, 81 F3d 1099, 1102 (Fed. Cir. 1996); *Grant* 956 F2d at 1148. To prevail under an actual causation theory, petitioner must establish entitlement to an award through traditional tort standards to prove legal causation-in-fact. *See, e.g.*, *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

To meet the traditional preponderance of the evidence standard, "[a petitioner must] show a medical theory causally connecting the vaccination and the injury." *Grant*, 956 F.2d at 1148 (citations omitted); *Shyface*, 165 F.3d at 1353. A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury." *Hines* 940 F.2d at 1525; *Grant*, 956 F.2d at 1148; *Jay v. Secretary of HHS,* 998 F.2d 979, 984; *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). The logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." *Grant,* 956 F. 2d at 1148; *Jay*, 998 F.2d at 984; *See also* H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344.

The Federal Circuit has held that for a petitioner to establish a prima facie case of compensation based upon actual causation, petitioner must prove by a preponderance of the evidence that the vaccine was not only a "but-for cause of the injury, but also a substantial factor in bringing about the injury." *Shyface* 165 F.3d at 1352-1353. Petitioner does not meet his affirmative obligation to show actual causation by simply demonstrating an injury that bears similarity to a Table injury or to the Table time periods. *Grant*, 956 F.2d at 1148. *See also* H.R. Rep. No. 99-908, Pt. 1, at 15 (1986, *reprinted in* 1986 U.S.C.C.A.N. 6344. Moreover, a petitioner does not satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. *Grant*, 956 F.2d at 1148 (quoting Hasler v. United States, 718 718 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, a proximate temporal relationship will not support a finding of causation")); *Hodges v. Secretary of HHS,* 9 F. 3d 958, 960 (Fed. Cir. 1993). Nor does a petitioner demonstrate actual causation by solely eliminating other potential causes of the injury. *See, e.g.*, *Grant*, 956 F.2d at 1149-1150; *Hodges*, 9 F.3d at 960.

Petitioner here initially filed his petition as a "Table case," alleging that he has sustained an injury identified on the Vaccine Injury Table, anaphylaxis and anaphylactic shock. In the event the court should find that the claimed injuries do not satisfy the criteria for a Table case, petitioner invoked his right to pursue the causation-in-fact alternative to establish his claim. An initial issue, therefore, is whether petitioner suffered a table injury. A thorough review of the record reveals that petitioner presented no testimonial evidence in an attempt to persuade the court that he did suffer anaphylaxis or anaphylactic shock. None of his experts suggest that petitioner suffered shock. In fact, not even the possibility of petitioner having sustained either injury was raised at hearing.

Moving to the causation-in-fact case, the central remaining issue is whether the vaccine did in fact cause petitioner's many symptoms. Accordingly, the court relies heavily on the experts' interpretation of the medical records as explained through their reports and oral testimony. The discussion begins with a summary, albeit a lengthy one, of the facts of this case.

III. FINDINGS OF FACT

Consistent with all other aspects of this case, the findings of fact are not readily discerned. The parties concede few facts as unchallenged, and it falls to the court to sift through the record to determine that which can be relied upon as fact. Although the court is satisfied that petitioner's claim of persisting malaise is, more likely than not, reliable, the reality of his condition does not suffice for him to prevail in his claim of actual causation. The court is persuaded that Mr. Doe is not malingering, and that although his symptoms are puzzling, they do not appear to have been fabricated. The mountain of medical records filed in this case supports the description of symptoms claimed, although, as will be discussed herein, there are some discrepancies as to when and for how long they appeared. The treating physicians who personally observed petitioner's symptoms have documented those symptoms and provided histories for the purpose of diagnosis and treatment. That factor bears considerable credibility as to Mr. Doe's condition, although it does not explain its cause.

While respondent concedes that Mr. Doe suffers from Chronic Fatigue Syndrome ("CFS"), the parties hotly contest the significance of his pre-vaccine medical history. Petitioner presents that history as one that is, with few exceptions, unremarkable prior to the hepatitis vaccinations, while respondent argues the history is indicative of one who has suffered ongoing serious medical problems prior to the vaccinations. The court begins with a thorough review of petitioner's medical history to reach its own decision. In determining causation, both pre-vaccine and post-vaccine histories are relevant to the court's decision in this case and will be described in detail.

Petitioner was born on May 15, 1961 in Richmond, Missouri. He contracted Rocky Mountain Spotted fever at approximately age four. He played football in college but a severe neck injury ended his football career. Mr. Doe alleges that prior to the hepatitis vaccinations administered on June 16, 1997, his health was generally excellent with the exception of occasional colds, flu, and other common illnesses. He claims that he was very active in a number of endeavors, and "just never had any real health issues at all to speak of." Tr. at 14. Petitioner had gastrointestinal problems, but, he claims, "nothing that was to the point of being debilitating by any stretch." *Id.*

Genetic Factors

Both of Mr. Doe's parents are living. As of 2000, his 56-year-old mother was healthy except for a remote history of uterine and back surgery. Both she and her brother, petitioner's

maternal uncle, have a problem with chronic furunculosis[5] and it is possible that this may be due to a minor immune disorder. Petitioner's father, age 59, is now blind and deaf as the result of Usher's Syndrome, a progressive degenerative genetic disease that affects the central nervous system. Both he and his brother, petitioner's paternal uncle, have this recessive and X-linked genetic disease affecting the central nervous system. Petitioner's great-aunt (paternal) also suffers from Usher's Syndrome. A progressive loss of intellectual abilities occurs in 25% of Usher's patients. Petitioner's immediate family has yet a second genetically inherited disease, retinitid pigmentosa. This is another central nervous system disease, usually autosomal recessive, affecting the photoreceptor layer of the retina. It usually begins slowly in childhood. There are many forms and associations of this genetic disease. One form causes spinocerebellar and cerebellar ataxia. There is no evidence that petitioner has either disease process, although he does have some degree of ataxia. Petitioner's sister is diagnosed with "possible" lupus. The court is puzzled by the fact that few of petitioner's treating physicians reflect full awareness of this unusual genetic history.

Medical History

Petitioner's medical records comprise more than one thousand pages. Although petitioner claims that prior to his vaccinations, he had no illnesses to speak of, his medical history does not support his statement. The records show that problems appear more often than Mr. Doe is willing to acknowledge. Petitioner reports an elevated bilirubin following administration of the vaccination, yet a report from Dr. Howard Deckter of Gastroenterology Consultants of Great Cincinnati shows that lab tests performed on March 16, 23, and 28, 1995, indicates elevated bilirubin (1.5 - 1.9) with normal liver function tests.[6] P. Ex. 4 Med. Rec. Dr. Deckter at 1. Those same results were evidenced after administration of the vaccines and one of petitioner's treating doctors at the time commented that he had no idea how long the condition existed. *See*, P. Ex.4, Med Rec. Dr. Luggen at 123. In addition, Mr. Doe reported right upper quadrant pain with radiation to the left upper quadrant with fullness and had complained of gas with pain for two weeks prior to the March 30, 1995 appointment with Dr. Deckter. Worth noting is the doctor's only notation for family history, "unremarkable." Dr. Deckter's diagnosis at that time was probable irritable bowel syndrome. In March 1995, petitioner visited his primary care physician, Dr. Nunlist-Young complaining of congestion and a cough. At this visit he complained also that he was experiencing hot flashes, disorientation, neck pain, diarrhea, and

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[5] A furuncle is "a painful nodule formed in the skin by circumscribed inflammation of the corium and subcutaneous tissue. . . caused by stapylococci, which enter through the hair follicles, and its formation is favored by constitutional or digestive derangement and local irritation. Called also "boil" and "furunculus." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 27th at 669. Fourunculosis is "the persistent sequential occurrence of furuncles over a period of time." *Id.*

[6] In petitioner's December 3, 2002 affidavit, he acknowledges that in March 1995, lab tests indicated elevated bilirubin, among other symptoms.

pain in the upper-left quadrant of his abdomen. He reported that he was in Florida a few weeks prior to that office visit and visited an emergency room at that time because he had "stool back in [his] colon." Tests again revealed elevated bilirubin, and pain continued to persist in the upper-left quadrant of his abdomen. He also underwent a gallbladder sonogram to detect the possible existence of cholecystitis.[7] Dr. Nunlist-Young suspected that he was suffering from an airborne bacterial illness. Dr. Deckter ultimately diagnosed a slight hiatal hernia, mild duodentis and probable irritable bowel syndrome. Antibiotics cured this brief illness at that time, although liver and bile duct test results continued to be abnormal.

Pre-Vaccination Medical History

Petitioner's medical records are extensive, and require painstaking review. The records reveal the following health problems existing prior to the hepatitis vaccinations.

- March 16, 1993. **Dr.Galen R. Warrent**, urologist. Complaints of orchidalgia[8] but not urinary symptoms or complaints and without urinary problems in the past. Normal examination and urinalysis. Possible epididymitis[9] to be treated with doxycycline.
- July 12, 1993. Petitioner's phone message for **Dr. Nunlist-Young:** Refill Zovirax[10] capsules and cream. [It appears Zovirax is a treatment for herpes.]
- March 28, 1994**. Dr. Donald Nunlist-Young** office visit. Low back pain when bending over yesterday. Pain radiated into right legs.
- Sept. 29, 1994. Petitioner's phone message for **Dr. Nunlist-Young:** needs Zovirax caps and cream.
- March 5, 1995. **Dr. Nunlist-Young** office visit. Had sore throat for past 3 weeks; no other symptoms.
- March 11, 1995. **Dr. Donald Nunlist-Young** observed chest congestion and neck pain. Ten days later, **Dr. Regine Mouton** observed pain in the upper quad. of the abdomen.
- March 21, 1995. **Dr. Nunlist-Young** – "patient reports that he has either bad

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[7] Cholecytitis: inflammation of the gallbladder. DORLAND'S at 322.

[8] Orchitis: inflammation of the testis. *Id*.at 1187.

[9] Epididymitis: inflamation of the epididymis - the chordlike structure along the posterior border of the testis. *Id*. at 567.

[10] Zovirax: is the trademarked name for acyclovir, which is a medication with selective antiviral activity against herpes simplex virus (types 1 and 2), varicella-zoster virus, Epstein-Barr virus, and cytomegalovirus. It is used in the treatment of genital and mucocutaneous herpes virus infections in certain patients, both immunocompromised and nonimmunocomprised. *See id.* at 25, 1867.

gallbladder or liver"; pain right area under rib cage. Said he saw doctor in NY 1½ weeks ago and went to emergency room in Florida with blood in stool. Had raised bilirubin.

- March 22, 1995. Gallbladder ultrasound – normal sonogram with incomplete evaluation of pancreas secondary to overlying bowel gas.
- March 27, 1995. **Dr. Nunlist-Young** office visit. Pain in upper right quadrant abdomen for 3 weeks. Had diarrhea last night. Poor appetite.
- March 29, 1995. **Dr. Nunlist-Young** office visit. Still in pain.
- March 30, 1995 **– Dr. Howard Deckter**, gastroenterologist. Hepatobiliary[11] imaging study indicates normal liver. Impression: "right upper quadrant pain with radiation to left upper quadrant and lower abdomen, not decreased with Zantac or Bentyl; elevated bilirubin with normal LFT's. Probable Gilbert's [disease]." Medical history notes Rocky Mountain Spotted Fever in 1991. Notes "unremarkable" family history.
- April 7, 1995. **Dr. Deckter** – Notes abdominal pain so severe that it wakens him at times, but that pain is decreased with rest. Underwent pandendoscopy with final diagnosis of slight hiatal hernia, mild duodenitis and, probably, irritable bowel syndrome.
- July 26, 1995. Petitioner's phone call to **Dr. Nunlist-Young**. "Sore throat for 2 weeks, no other symptoms. Would like med. prescribed. If you want to see him, he'll be in town next Monday." .
- ?/11/95 – **Dr. Nunlist-Young** office visit. "Here because of chest congestion and coughing for last several weeks. Friend prescribed amoxicillin which helped initially. Has also been feeling 'funny' – described as having hot flashes, disorientated slightly, pain up back of neck (sharp and shooting, sporadic)."
- Dec. 1, 1996. Petitioner's telephone message for **Dr. Nunlist-Young**: "Sick for 2 days, nasal congestion with clear yellow discharge, not much cough, no fever, using herbal medicine."
- ?/25/96 – **Dr. Nunlist-Young** office visit. Sore testicle for two weeks.
- Jan 3, 1997 – **Dr. Nunlist-Young** office visit. Fever, coughing up brown mucus, bad headache. Negative strep. Leaving country on Sunday.
- Feb. 7, 1997. **Dr. Nunlist-Young** office visit. Pain in testicles again.

On Tuesday, June 16, 1997, petitioner visited his primary care physician to alleviate a sore throat and mild fever that had persisted for the three weeks prior to that office visit. P's Affidavit 2, ¶3. The doctor noted at that time that Mr. Doe had been exposed to scarlet fever and that he had been doing more and more business travel overseas. Inasmuch as petitioner was contemplating another trip overseas, he asked that both hepatitis B and A vaccines be

[11] Hepatobiliary: pertaining to the liver and the bile or the biliary ducts. *Id*. at 753.

administered.[12] Tr. at 28. There is a discrepancy in the records as to the date of administration. Respondent contests the June 16, 1997 date and argues that petitioner received his immunization two days later on June 18, 1997. That the doctor administered both vaccines on the same day is uncontested. On the day he was vaccinated, petitioner recalls having been asked to sign a statement that said he had been informed of the possible adverse reactions to the hepatitis vaccines, which the nurse described as "a kind of soreness at the point of injection and that he may not be feeling well for a day or so, nothing more than that." Tr. at 27.

Petitioner claims that within 2 or 3 hours after receiving the vaccinations, he began to experience rapid heartbeat, fever, aches, and pains. P's Affidavit 1 at 1. On that same day, petitioner attempted to travel to Dallas, Texas for a business meeting. He arrived in Dallas but ultimately stayed in his hotel room and didn't attend the meeting because "he was feeling so poor." In the week following the vaccinations, he traveled with his family to the beaches of South Carolina. At that time, he experienced other debilitating symptoms including myalgias, muscle pain, arthralgia, and joint pains. On June 27, 1997, he called his doctor to report that "he had severe joint pain, night sweats" and thought he was suffering "an allergic reaction to hepatitis immunization." He called back on July 2, 1997 stating that he had "weird pains and was not getting better, actually worse." He also reported that his 3-year-old was complaining of joint pain. The symptoms continued during the family holiday, and frequently thereafter he would experience a relapse; the symptoms would wax and wane. Attacks returned with peculiar and tremendous muscle pain, night sweats, aches, and fatigue so severe that he could do no more than lie in bed. Between those episodes, he continued to have difficulties with memory, his gait, and ataxia. Tr. at 4.

When Mr. Doe returned home, his physician had already contacted the manufacturer of the vaccine, Smith Kline Beecham, informing them of Mr. Doe's symptoms. Smith Kline confirmed that "adverse reactions to its hepatitis B vaccinations had been reported and advised Mr. Doe's treating physician to discontinue further vaccinations." The manufacturer stated the symptoms are indicative of serum sickness, and will subside. Mr. Doe received no further vaccinations thereafter, but he was seldom asymptomatic. On July 9, 2004, petitioner again called Dr. Nunlist-Young. The record of that call notes that petitioner wanted the doctor to know he is feeling fine; he is changing insurance companies and wants "these recent episodes explained as an allergic reaction." Tr. at 32.

Over the months, petitioner's doctors were unable to identify a cause of, or relieve his symptoms. He was unable to participate in sports and other activities and alleges that his cognitive abilities were compromised. He claims that he had to give up his profession and has never returned to his former state of health.

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[12] There is a discrepancy in the records as to why petitioner requested the vaccinations. Petitioner states in his affidavit that he wanted them because he was leaving on a family vacation to the South Carolina shore.

At the time of his hepatitis vaccinations, Mr. Doe was serving as a businessman. He was responsible for originating and managing a portfolio of bank investments, lending money to and investing money in various businesses, corporate acquisitions, leveraged buy-outs and equity partnerships. He was required to travel extensively in the United States and abroad.

Post-Vaccination Medical History

Following the vaccinations, petitioner consulted multiple medical experts worldwide seeking a diagnosis for his symptoms and to learn what could be done to restore his former state of health. In most cases, the doctors could merely speculate about his condition; possible etiologies were discussed and numerous lab tests were performed by the many doctors. For almost two years, up until petitioner filed his claim, none of the doctors agreed with petitioner that his condition was vaccine-related.[13] The court finds it significant, however, that many of these doctors name Behcet's syndrome as a probable diagnosis, a fact that will be further explored in this decision. Coincidentally, it wasn't until after petitioner filed his petition that any doctor identified his condition as chronic fatigue syndrome attributable to the hepatitis B vaccine.

Petitioner saw Dr. Michael McClellan on Nov. 16, 1998, almost a year and a half after the vaccination. At that time, Dr. McClellan diagnosed him with Behcet's syndrome, noting that he had also probably suffered aseptic meningitis. Shortly thereafter, petitioner traveled to England where he saw Dr. Spickett who "had no idea what is wrong." On August 8, 1999, having visited more than ten specialists, none of whom diagnosed any condition attributable to the hepatitis B vaccine, petitioner filed a petition under the Act, alleging that he suffered injuries including but not limited to anaphylaxis and anaphylactic shock as a result of the hepatitis B inoculation. Pet. at 1. Less than a month after filing the petition, Mr. Doe saw Dr. Waisbren who "suspected post vaccinal encepahlomylitis and acquired autoimmunity." Then, on January 23, 1999, he again saw Dr. Spicket who at that time suggested a diagnosis of post-vaccine chronic fatigue syndrome. Finally, four doctors, Dr. Spicket, an immunologist; Dr. McClellan, an internist; Dr. Hyde, a general practitioner, and Dr. Waisbren, an immunologist; filed sworn affidavits presenting the same opinion – that petitioner's condition is causally related to his hepatitis B vaccination. The court again notes with question that Mr. Doe filed his petition under the Act prior to any of his doctors diagnosing CFS, or any other condition caused by the hepatitis B vaccine.

Mr. Doe testified that he believed he had sustained an allergic reaction to the hepatitis

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[13] The exception being Dr. Nunlist-Young, petitioner's primary care physician and the doctor who administered the vaccination. It appears Dr. Nunlist-Young expressed his opinion that several of petitioner's symptoms were attributable to the vaccine, based upon the response of Smith-Kline suggesting possible serum sickness. Dr. Nunlist-Young, is on record stating that petitioner suffered an allergic reaction to the hepatitis B vaccine. Yet Dr. Nunlist-Young never provided an affidavit to that effect and was not called upon to testify as the treating physician, on petitioner's behalf. The court questions the absence of testimony from Dr. Nunlist-Young, and why petitioner apparently replaced him with Dr. McClellan as his primary care physician.

vaccines within days of the vaccination. Following is a summary of petitioner's medical chronology from the time of his vaccination:

- **June 16, 1997. Dr. Nunlist-Young** office visit. Doe reports bad throat for 3 weeks and that he was exposed to someone with scarlet fever. Denies rash or joint pain. Strep test negative. Patient wants hep A and B shots.
- **Dr. Nunlist-Young** notes petitioner's phone call in which he complained of severe joint pain, night sweats and says he thinks he's having an allergic reaction.
- **June 27, 1997.** In phone message to **Dr. Nunlist-Young**, Smith Kline Beecham acknowledges reports of serum sickness and reactions that are transient and advises no further hepatitis vaccine.
- **June 30, 1997. Dr. Nunlist-Young** office visit. Complaining of a terrible sore throat that comes and goes. Also has pain that seems to be in different joints in his body.
- **July 5, 1997. Dr. Nunlist-Young** office visit. Concerned he might have Lyme Disease. Presents with fine deep red rash in symmetrical even pattern, non-vesticular, non-itching. Has tingling on left side of his body under scapualar area. Symptoms preceded by sore throat and joint pain for two weeks. Patient is very concerned; thinks he has Lyme Disease and wants to speak to another doctor.
- **July 8, 1997. Dr. Corion Dunn,** infectious disease consultant. Notes sore throat pre-vaccine still present, sometimes feels earache. Severe headaches followed vaccinations, lasting 15-20 minutes. Night sweats that week. Now has sharper pain in abdomen, night sweats gone, sore muscles and joints. Notes father has retinitis pigmentosis, no SLE,[14] RA.[15]
- **July 9, 1997.** Petitioner's phone message to **Dr. Nunlist-Young**. "Wanted you to know he is feeling fine. He is changing insurance company and he wants these recent episodes explained as an allergic reaction."
- **July 10, 1997.** Letter from senior clinical safety specialist for SmithKline Beecham, acknowledging June phone call and asking for pre and post vaccination history.
- **July 17, 1997. Dr. Dunn** notes fluctuating malaise (weakness of legs, night sweats, tingling mild numbness of hands and feet, right foot worse than left.) Notes that patient has had his home renovated. "Pt. placed insulation just before consult."
- **July 30, 1997. Dr. Dunn** notes patient feels somewhat better. Less muscle pain but complains of intermittent sharp abdominal pain in the right upper quadrant area. Performed blood tests: negative for cytomegalovirus, Epstein-Barr, versus

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[14] Systemic lupus erythematosus. *Id*. at 1535.

[15] Rheumatoid arthritis.

- toxoplasmosis,[16] RPR,[17] ANA[18] and sedimentation rates were normal.
- **August 4, 1997.** Handwritten note from **Dr. Nunlist-Young**: "to whom it may concern" indicating that any abdominal pain that was reported in June of 1997 was experienced at the same time as joint pain and could have been related to the reaction to the hepatitis screen and there have been no further complaints of abdominal pain.
- **Oct. 17, 1997. Dr. Nunlist-Young** – Office visit. Mr. Doe complains of joint pain and weak muscles, blisters in mouth began last night, having difficulty walking.
- **Feb.1, 1998.** Petitioner's phone message to **Dr. Nunlist-Young:** "Wants amoxicillin 500 mg and cough med. S.T. [strep throat]. Most of family has had. Going out of town at noon."
- **April 6, 1998. Dr. Nunlist-Young** refers him to rheumatologist, **Dr. Deborah Fritz.**
- **April 24, 1998. Dr. Deborah A. Fritz**, rheumatologist/immunologist. Notes that Mr. Doe reports his motor skills returned to 100% normalcy and joint pain diminished by 80% in severity but continues with mild intermittent arthralgias and myalgias. Notes only a fractured cervical vertebrae with no residual defect for past medical history. Notes only that grandmother has degenerative arthritis and sister may have lupus for family history. Finds no evidence of inflammatory arthropathy, myopathy, or other connective tissue disease and diagnoses him with "chronic benign pain syndrome." Indicates no further rheumatologic evaluation or treatment indicated.
- **June 25, 1998 Dr. Dunn** office visit. Reports malady of summer of 1997 never completely resolved. Intermittent muscle aches and malaise but nothing persistent. Now complains of more pain in leg muscles and triceps, pressure behind his eyes and abdominal pain which could be sharp at times and generally gets worse later in the day and worse with more movement. Pain is sometimes "like a dagger." Dr. notes, "There are certainly some rheumatologic sounds about this and his sister apparently is a Lupus patient. Nevertheless, my assumption is that Dr. Fritz would . . . have found any concrete disease in that area. Other things that can be considered include cholecytitis because of the right upper quadrant

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[16] Toxoplasmosis: an acute or chronic, widespread disease of animals and humans . . .caused by the obligate intracelllular protozoon *Toxoplasma gondii*, transmitted by oocusts [encapsulated zygote in the life cycle of sporozoan protozoa] containing the pathogen in the feces of cats. *Id*. at 1177, 1737.

[17] RPR: rapid plasma reagin (test for syphilis). MEDICAL ABBREVIATIONS 6th Ed. (1993) at 151.

[18] ANA: Antinuclear antibodies. DORLAND'S at 69.

pain, possible gastritis, possible hemochromatosis."[19]

- **July 2, 1998.** Petitioner's phone message to **Dr. Nunlist-Young**. "Weird pains not getting better - actually worse. Now his 3-year-old son is complaining of joint pain.
- **July 10, 1998. Dr. Dunn** office visit. Returns for followup of recent gallbladder ultrasound and lab work. Dr. notes: "He is concerned about sclerosing cholangitis[20] apparently from reading information about this entity on the World Wide Web." Abnormal bilirubin of 2.0.
- **September 22, 1998. Dr. Robert L. Reed**, neurologist recommends complete immunological evaluation as objective findings are not significant and complete neurological work-up not likely to be fruitful. He found normal results in sensory and coordination exams and a normal gait. Family history only indicates mother has low blood pressure and headache and that parents are living.
- **Sept. 24, 1998.** Labs and MRI within normal limits;
- **Sept. 24, 1998.** Petitioner's phone message to **Dr. Nunlist-Young**: "Wants to see Robert Hiltz re his symptoms. Friend saw Dr. Hiltz for similar problem and was diagnosed with polymyocytis."[21] Left another message an hour later that he wants blood work for polymyocytis and is at "lab corp."
- **Sept. 29, 1998.** MRI of head normal except for partially empty cella;[22] sonogram of liver and gallbladder normal; chest X-ray normal.
- **Oct. 1, 1998.** Petitioner's phone message to **Dr. Nunlist-Young**: Illness getting more intense; Sat. eve began more muscle and joint pain plus headache. Wants

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[19] Hemochromatosis: a disorder due to deposition of hemosiderin (intracellular storage form of iron) in the parenchymal (essential elements of an organ, as opposed to its framework or stroma) cells, causing tissue damage and dysfunction of the liver, pancreas, heart, and pituitary. Other clinical signs include bronze pigmentation of skin, arthropathy, diabetes, cirrhosis, hepatosplenomegaly (enlargement of liver and spleen), hypogonadism, and loss of body hair. . . . *Id*. at 747, 751, 1231.

[20] Sclerosing cholangitis: a progressive chronic fibrosing inflammation of the bile ducts of unknown cause, most commonly in young men and frequently in association with chronic ulcerative colitis. *Id*. at 321.

[21] Polymositis: a chronic, progressive inflammatory disease of skeletal muscle, occurring in both children and adults, and characterized by symmetrical weakness of the limb girdles, neck and pharynx, usually associated with pain and tenderness, and sometimes preceded or followed by manifestations typical of scleroderma, arthritis, systemic lupus erythematosus, or Sjogren's syndrome. Sometimes associated with malignancy, and may be accompanied by characteristic skin lesions. *Id.* at 1332.

[22] Cella: lateral part of the lateral ventricle of the brain. *Id.* at 298.

appointment today.

- **Oct. 2, 1998. Dr. Michael E. Luggen**, internist. Reports Mr. Doe's account of his symptoms and Mr. Doe's assessment that his medical history is unremarkable with no allergies and an unremarkable family history except for a grandmother with arthritis of a certain type. Upon examination, found Mr. Doe to be normal with the following exceptions: walks slowly and seems to be in some distress, few pustules on chest and back, apithous ulcers in mouth, some conjunctival infection, tenderness in right upper quadrant abdomen, seemed to have pain when muscle strength tested. Lab test showed raised bilirubin. "It is difficult to explain Mr. Doe's severe pain. His arthralgias and myalgias are largely subjective. I can find little evidence of inflammation . . . [but symptoms] appear to be genuine and significant." Discussed possible diagnoses but ruled them out due to absence of objective markers**.** "The elevated bilirubin is the only clue that we have to date. I am not sure if this is new. It has been present since at least June perhaps longer. If this is not a congenital abnormality, then it may suggest an intrahepatic[23] process."
- **Oct. 3, 1998.** Note on **Nunlist-Young's** records. Largely illegible but appears to say Doe went to ER. "Left before call back"
- **Oct. 7, 1998.** Note from Mr. Doe to **Dr. Nunlist-Young**. Indicates he is attaching two abstracts he pulled from the internet. Suggests that his "partially empty cella is causing increased intracranial pressure and other symptoms such as joint pains, headaches, and gait ataxia." Asks for doctor's opinion.
- **Oct. 9, 1998.** Petitioner's phone message to **Dr. Nunlist-Young**: Would like referral to Bill Tobber (Mayfield Assoc.) – cranial pressure and partial empty cella.
- **Oct. 9, 1998. Dr. Starr Ford**, endocrinologist. Came in for endocrine consultation and reported history of several years of right upper quadrant abdominal pain. Finds that he walks more slowly when he has that abdominal pain. "His global somatic pain syndrome with headaches does not resemble any clinical entity that I can identify."
- **Oct. 13, 1998. Dr. Luggen** – "On closer questioning, the patient said that the parethesias[24] that he had reported have been brief, last only a few minutes and occur less than one time a week . . . last that he had was in August of any significance [sic]."
- **Oct. 19, 1998. Dr. Nunlist-Young** – Mr. Doe complains of joint pain, headache and right eye ache.
- **Oct. 20, 1998.** Petitioner's message for **Dr. Nunlist-Young** that he has headache, fatigue and achy joints and wants referral to Mayo Clinic.

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[23] Intrahepatic: within the liver. *Id*. at 849.

[24] Parethesia: an abnormal sensation, as burning, pricking, formication, etc. *Id*. at 1232.

- **Oct. 21, 1998** – Leaves another message that he wants referral to Mayo Clinic.
- **Oct. 22, 1998** – Leaves another message "He's dragging a little today; seems to be slipping backwards."
- **Oct. 26, 1998** – **Dr. Nunlist-Young** – notes an episodic poly arthralgia, cause unclear. "Association with oral ulcers, ocular inflammation, and perhaps abdominal pain . . . compatible with inflammatory bowel disease or Behcet's disease . . . [but] atypical presentation for either."
- **Oct. 26, 1998. Dr. Luggen** office visit. Patient reports feeling worse again, more pain in joints and muscles. Some myalgias but no definite decrease in his strength. Some improvement in GI distress.
- **Oct. 27, 1998 - Dr. Donald S. Jacobs**, ophthalmologist, – "Mr. Doe complains of an aching pain about the right eye . . . [and] bilateral head pain. He relates this to some autoimmune problems following a hepatitis vaccine." Found no ocular causes or signs related to his pain.
- **Nov. 9, 1998. Dr. Luggen** notes chronic polyarthralgias and myalgias – etiology unclear. No definite diagnosis. Patient is feeling better - symptoms wax and wane.
- **Nov. 16, 1998. Dr. Leonard Calabrese**, head of immunology at Cleveland Clinic rules out Behcet's syndrome.[25]
- **Nov. 16, 1998. Dr. Michael McClellen**, internist. Believes Bechet's disease is dx unless proven otherwise and suspects petitioner also has had aseptic meningitis."[26]
- Nov. 30, 1998. **Dr. Nunlist-Young** assesses condition as "possible undifferentiated connective tissue disease with polyarthralgias and myalgias . . . the exact nature of [which] is unclear." Thinks there is a better chance of making diagnosis now that prednisone has been tapered and discontinued.
- Alabama University, **Dr. Joseph Michalski, immunologist**, a Behcet's specialist **"had no clue."**
- Jan. 23, 1999. **Dr. Spickett** immunologist in London England who, at the time, found Bechet's unlikely.
- Jan. 29, 1999. **Dr. Luggen** office visit. Patient continues to have episodic symptoms. Quite a bit of joint pain, muscle pain and right upper quadrant abdominal pain with nausea. Mouth sores unchanged. No swelling or morning

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[25] Behcet's syndrome is described as a chronic inflammatory disorder involving the small blood vessels, which is of unknown etiology, and is characterized by recurrent aphithous ulceration of the oral and pharyngeal mucous membranes and the genitalia, skin lesions, severe uveitis, retinal vasculitis, and optic atrophy. It frequently also involves the joints, gastrointestinal system, and central nervous system. Called also Behc'et's disease. *Id*. at 111, 1631.

[26] Aseptic meningitis: the name given to a mild form of meningitis, most cases of which are caused by viruses. *Id*. at 1004.

stiffness. Been to UK to see a Dr. Spickett and to U. of S. Alabama to see Joseph P. Michalski who has exp. with Behcet's disease. No dx established. Dr. Luggen notes possible inflammatory bowel disease, Behcet's disease, Rider's or possibly nonarticular rheumatism as well.

- Feb. 1, 1999. **Dr. Steven Fessler, gastrologist** did an upper GI series re: results all normal.
- Feb. 4, 1999. CT (test) of pelvis – within normal limits.
- **Dr. Adam Kaufman** ophthalmologist dx **possibly Behcet's** or possibly episcleritis.[27]
- **Feb. 15, 1999. Dr. Luggen** office visit. Patient continues to have difficulties and myalgias. Also considerable trouble with fatigue. Pain is moderate to severe at times, and waxes and wanes but is there somewhat all the time. Said he saw Dr. Kaufman who thought might have Behcet's. "Mr. Doe raised once again the possibility that this could be a complication to hepatitis B vaccine. He has been searching the internet and has had a number of cases that are similar. He has also talked to a number of patients who have had similar complications and maintained very well the consequence of his vaccinations two years ago . . . I told him that I did not recognize this as a possibility. He brought in literature which I reviewed from a web site for the National Vaccine Information Center. It also provided me with a number of references. I told him I still felt it was unlikely but that if he wanted to pursue it, perhaps he should go see one of the experts in the area if there was such a person."
- **March 1999. Dr. Salem Ford & Dr. Daniel Wallace** – neither could make a definite dx.
- **May 1999.** Month of treatment at **Santa Barbara College for Oriental Medicine and Acupuncture.**
- **June 1999. Dr. Brent Kovacs**, gastroenterologist. Office visit.
- **June 1999. Dr. Tom Woliver**. Office visit.
- **July 1999. Dr. Scheuner** for medical genetics consult. Several tests, all in normal limits. No genetic dx.
- **August 8, 1999. Petitioner files claim under the Program.**
- Sept. 1999. **Dr. Burton Waisbren:** Office visit. Suspects postvaccinal encephalomylitis and acquired autoimmunity.
- **Jan. 21, 2000.** Again in London **Dr. Spickett:** although uncertain, dx post-vaccination chronic fatigue syndrome or Bechet's.
- **Feb. 17, 2000. Dr. McClellan** became convinced of dx: autoimmune RX to Hep B vaccination.
- March 2000. **Dr. De Meirleir**, professor - University of Brussels. Performed and evaluated a RNA-sel, which is a protein determination test.

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[27] Episcleritis: inflammation of tissues overlying the sclera (the tough white outer coat of the eyeball); also inflammation of the outermost layers of the sclera. *Id*. at 570.

- **June 9, 2000. Dr. Byron Hyde** in Ottawa, Canada. SPECT scan showed reduced uptake in the temporoparietal[28] lobes of the posterior fossa[29] and pons.[30] The report stated that these findings have been described in chronic fatigue syndrome ("CFS").
- **June 2000. Dr. Sheila Bastien**. Performed a neuropsychological examination.
- **July 2000. Dr. Poser** diagnosed him as suffering from chronic fatigue syndrome.
- August 4, 2000. **Dr. McClellan** , petitioner brought a PET scan which showed abnormal results consistent with some type of encephalitis presumably autoimmune.
- **Aug. 27, 2000.** Dx papillary carcinomas of thyroid: final dx after biopsy was Hashimoto's thyroiditis (an autoimmune disease) and a perithyroidal cancer of thyroid. **Dr. Padma Mangu**, endocrinologist, treated the cancer. The cancer was surgically removed successfully by **Dr. James Fidler**.
- **August 2000. Dr. McNamara**, professor of radiological sciences at UCLA School of Medicine. Reviewed MRI of brain and advised it was "abnormal."
- **October 2000. Dr. Hyde** concluded that petitioner suffers from an autoimmune disease caused by the hepatitis A & B immunizations.
- **March 20, 2001. Dr. Dalvi,** psychiatrist. Petitioner was referred to Dr. Dalvi for treatment of what was thought to be a psychologically-induced neurologic syndrome.
- **December 3, 2002.** Petitioner was examined by **Dr. Warren**, a urologist, for a prostate/testicular problem identified as epididymitis.

Mr. Doe's own opinion, prior to seeing any doctor post-vaccination, was that he had an allergic reaction to the hepatitis vaccines and that his condition would not have occurred but for his hepatitis B vaccination. He reports that he was a high-functioning individual, very well educated, and a highly successful business man. At the time of this writing, Mr. Doe is approximately 43 years old.

IV. THE ISSUES

The outcome of this case rests on three central issues: 1. Was petitioner's condition in progress at the time of the vaccination, and is his present state the natural progression of that

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[28] Temporoparietal lobes: temporal (at temples on either side of head) and parietal (pertaining to the walls of a caviety (in this case skull)) portion of the brain. *Id.* at 949, 1232, 1670.

[29] Posterior fossa: a pit situated on the lateral portion of the bone in the back of the head. *Id.* at 1164, 655.

[30] Pons: the brain stem. *Id.* at 1336.

condition? 2) But for the hepatitis vaccinations, would petitioner's current condition exist? 3) Do alternative causes account for petitioner's condition? None of these issues bear consideration, however, without first addressing the nascent issue: *Can* the hepatitis vaccine cause CFS? If the court finds that petitioner has not successfully provided a generic nexus between the vaccine and the injury, the remaining issues bear no examination.

Petitioner's Position

Petitioner maintains that the hepatitis B vaccine either caused his injuries and/or substantially aggravated an existing underlying condition that is likely to persist for the foreseen future. Petitioner claims further that he is entitled to compensation provided for by the Act for his injuries and his condition for the following reasons: (1) it is medically plausible that the hepatitis B vaccine caused chronic fatigue syndrome; (2) peer-reviewed medical literature provides confirmation of medical plausibility from the medical community; (3) he has proof that he has an injury recognized as medically plausible in the literature; (4) there is proof of a medically acceptable temporal relationship between the vaccination and the onset of his injury; and (5) he has provided proof of elimination of other causes of the injury. Tr. 6-8.

Petitioner relies upon two cases decided by the Chief Special Master to define the standard he proposes be satisfied for him to prevail in his claim. *See*, *Stevens v. Secretary HHS*, No. 99-594V, W L387418 (Fed. Cl. Spec. Mstr. March 30, 2001) (ruling that petitioner is denied summary judgment, having failed to satisfy a five-prong criteria for analyzing actual causation claims under the Program); *Watson v. Secretary HHS*, No. 96-639V, 2001 WL 1682537, at *8 (Fed. Cl. Spec. Mstr. Dec. 18, 2001).[31] First, to support the notion that it is medically plausible that the hepatitis B vaccine can cause CFS, petitioner offers the testimony of his experts and package inserts from the manufacturers of the vaccine, in which are listed several symptoms experienced by petitioner. Petitioner looks to four experts, three of them treating physicians, who are of the opinion that a causal link exists between hepatitis B vaccine and CFS. From this evidence, petitioner maintains he has demonstrated medical plausibility.

Second, petitioner asserts that the medical literature filed provides confirmation of medical plausibility from the medical community. To this end, he offers several published writings from which he intuits demonstration of a medically plausible causal relationship between hepatitis B vaccine and chronic fatigue syndrome, as set forth by the medical

[31] The Stevens standard was criticized by Judge Braden in *Althen v. Secretary HHS*, 2003 U.S. Claims LEXIS 269 (Fed. Cl., Sept. 30, 2003). *See also*, *Capizzano v. Secretary HHS*, 2003 U.S. Claims, LEXIS 219, (August 5, 2003), *reaffirmed Capizzano v. Secretary HHS,* 2004 U.S. Claims, LEXIS 149 (June 8, 2004).

community.

Third, petitioner, relying upon his treating physicians, argues that he has successfully demonstrated he has CFS, as described in the filed literature. Using the method of differential diagnosis, petitioner's physicians arrived at what is essentially a diagnosis of exclusion. This is achieved by having considered and eliminated reasonable alternate causes.

Fourth, petitioner argues that the temporal relationship between the vaccine and his CFS is supportive of a causal relationship. He points to symptoms developing within hours of the vaccination, abating for only a day and then returning and getting progressively worse.

Finally, petitioner argues that examination of his medical records makes clear that no alternative cause for his injury exists. Furthermore, he looks to the testimony of his medical experts for support this assertion.

Respondent's Report Summary in Opposition

In response to petitioner's allegations, respondent maintains that petitioner is not entitled to compensation, having failed to establish a logical sequence of cause and effect showing that the hepatitis B vaccine, or both hepatitis B and A vaccines caused his condition. Respondent argues that the medical records are inconsistent with petitioner's claim. Respondent first proposes that there is a discrepancy as to the timing of the onset of symptoms, and second, that it is not clear whether the immunizations were administered on June 18, 1997 or on June 16, 1997. *See*, R. Rule 4 at 3; Pet.'s MR at 690.

This factor is of importance inasmuch as the Vaccine Injury Table requires that the first symptoms of anaphylaxis or anaphylactic shock, which is the manifestation of onset or significant aggravation, be evident within 4 hours of administration of the vaccine.[32] Respondent further argues that not only has petitioner failed to establish a case for a Table injury, but that he has not demonstrated actual causation as neither the medical records nor medical literature support the allegation that the hepatitis B vaccination caused, in fact, petitioner's present condition. Furthermore, petitioner's medical records reveal significant factors having nothing to do with the vaccine, that may affect his health, past, present and future.

Respondent argues that the opinions of Drs. McClellan, Geier, Waisbren, Spickett, and Hyde are legally insufficient to prove causation. Moreover, respondent points out that petitioner's treating immunologist, Dr. Luggen, "offered several clinical impressions but did not feel that his patient's illness was caused by the vaccine." R. Pre-Hearing Memo at 6-7; *See*, Med. Rec. 36-37, 99. Respondent maintains that petitioner must demonstrate some independent validation of his experts' methodology, e.g., supporting scientific literature to support a prima

[32] The only Table injuries associated with the hepatitis B vaccine are anaphylaxis or anaphylactic shock within four hours of vaccination. 42 C.F.R. § 100.3 (as amended).

facie case.

V. TESTIMONY AT HEARING

Petitioner, John Doe

The petitioner, John Doe, was the first to testify. He describes his state of health prior to the June 1997 vaccinations as "generally excellent" his whole life, explaining that "other than [Rocky Mountain Spotted Fever as a child], from a physical point of view, I was probably about as good as you can imagine." Tr. at 14. When asked about gastrointestinal problems, he said he had them, "but nothing to the point of being debilitating by any stretch" and that he doesn't remember how he treated them but thinks he "took some antacid thing." *Id.* He describes reacting to the vaccination within several hours, while en flight to Dallas on a business trip, feeling feverish and just not well. Tr. at 18. He felt fine the next day and around a week later, suffered a blinding headache, pains "bouncing" throughout his body, with pain and burning in his face. The sensations continued on and off for around ten days, during which time he was away on vacation. He said he "ended up getting better after that," but remembered that a short time later, while traveling to Vail, Colorado he experienced his right side feeling "asleep." Tr. at 19-20. He was completely recovered the following day and "felt so good [he] went white water rafting." *Id*. The pains waxed and waned, becoming a constant pattern. Tr. at 20. During these "episodes" of pain, petitioner describes himself as going into a "brain fog."

On cross-examination, Mr. Doe testified that, on the day of his vaccinations, he visited his doctor complaining of having had a sore throat for three weeks. He said he doesn't remember having expressed concern to his doctor that he had been exposed to somebody with Scarlet Fever.[33]

He discussed having had a lump, a lipoma, surgically removed from his deltoid muscle, at the site of the injection; the doctor said it was "some kind of intramuscular lump that happens after vaccination sometimes." Tr. at 30. He said that starting the week after being vaccinated he was very lethargic and that at times he required naps and didn't have "nearly the same energy level that [he] had prior to the vaccination." Tr. at 31. When asked whether he recalls calling his doctor on July 9, 1997 and leaving a message that he was "feeling fine . . . changing insurance companies and wants these recent episodes explained as an allergic reaction," petitioner said he doesn't recall calling but is sure that it's probably correct. Tr. at 32. The message is documented on page 158 of petitioner's medical records. Petitioner provided little additional testimony, stating that he wasn't sure of, or couldn't remember, much detail having to do with his injury.

[33] Dr. Nunlist-Young's records indicate that petitioner did express concern regarding exposure to Scarlet Fever. *See*, Nunlist-Young records, June 16, 1997.

For petitioner, Dr. Byron Marshall Hyde

Dr. Byron Marshall Hyde, for petitioner, practices primarily in Ottawa, Canada. He is not board certified in any area, and for seventeen years served as a family practitioner until 1984 when he began studying what he calls "poorly defined" disease such as chronic fatigue syndrome (CSF). He is the principal editor of a textbook on chronic fatigue syndrome and myalgic encephalomyelitis, THE CLINICAL AND SCIENTIFIC BASIS OF MYALGIC ENCEPHALOMYELITIS, CHRONIC FATIGUE SYNDROME. He testified that the book "constituted his attempt to figure out chronic fatigue syndrome" after his daughter and numerous physician friends of his fell ill with a chronic fatigue syndrome-like illness. Tr. at 39. Currently, Dr. Hyde is not on staff or affiliated with any healthcare institution, and considers himself "basically a lab and research-oriented physician." He is self-funded in his research on post-hepatitis B immunization patients. As a general practitioner, he calls himself "an investigative physician as opposed to a treating physician." Dr. Hyde studied at the University of Toronto and the University of Ottawa. He founded the Nightingale Research Foundation and continues to reside in Ottawa, Canada. During the past 14 years, he has served a large number of patients with problems following recombinant hepatitis immunization cases, or "ill-defined" diseases such as chronic fatigue syndrome, also called encephalomyelitis in some countries, which is similar but not identical to CFS.

Dr. Hyde is of the opinion that John Doe suffered and continues to suffer from an autoimmune disease caused by the hepatitis B vaccination. Dr. Hyde has examined Mr. Doe on two separate occasions and has closely followed Mr. Doe's illness since their initial meeting in June of 2000. On June 9, 2000, Dr. Hyde arranged for Mr. Doe to have a SPEC scan[34] in Ottawa, Canada. The SPEC scan showed reduced uptake in the temporo-parietal lobes of the posterior fossa and pons. The report stated that these findings are indicative of chronic fatigue syndrome.

Dr. Hyde maintains that petitioner suffers from a "general and severely abnormal immune dysfunction exhibited through his inflammatory reaction to the arteries of the brain and . . . an inflammatory reaction to the thyroid." Third Set Med. Rec. Dr. Hyde at 3. Based on his examinations and a review of the medical records, Dr. Hyde concluded that petitioner had no history of any serious illness or chronic ongoing disability until he received the two hepatitis vaccinations. Dr. Hyde observed that within a time period consistent with an adverse immune type reaction, Mr. Doe developed a series of problems that Dr. Hyde has observed in a large number of patients following recombinant hepatitis B immunization. Those problems include the development and persistence of memory and speech dysfunction, various cognitive dysfunctions, loss of anticipated pre-illness intelligence levels, rapid fatiguability, neuropsychological abnormalities and other cognitive changes. Other symptoms include loss of

[34] A Spectrum is a charted band of wave-length of electromagnetic radiation obtained by obtained by refraction or diffraction; by extension a measurable range of activity as the range of bacteria or the complete range of manifestations of a disease. DORLAND'S POCKET MEDICAL DICTIONARY, 24th ed. at 551

stamina, intractable pain, retina problems, skin lesions and other problems following the hepatitis B vaccine. *See, e.g.,* Pet. Ex. Third Set of Med. Recs. Dr. Hyde maintains there was a close temporal relationship between petitioner's vaccinations and the onset of his illness.

Upon examination, Dr. Hyde found "an inflammatory reaction to the thyroid, a minor thyroid irregularity." Upon discovering that the abnormal amount of autoimmune antibodies was of major proportions, Dr. Hyde postulated that the body was attempting to reject or attack its own thyroid gland. Further testing revealed a follicular cell carcinoma described as "Hashimoto's Thyrotoxicosis." The gland was removed and the carcinoma duly excised.

Dr. Hyde testified that he's done a partial assessment of petitioner and believes he has a major brain stem injury that is measurable. He believes that Mr. Doe's symptoms and the pattern of his illness are consistent with both autoimmune and CNS vasculitis disease. He explains that

> . . . what possibly happened is that the immunizations caused the immune system not to be able to recognize the infection [petitioner] already had in his throat. And it probably became chronic, and destroyed his brain or injured his brain to the extent it has been injured. And I think this is the way, how I read it, how the immunization works.[35]

Dr. Hyde is of the opinion that petitioner was at risk for an adverse reaction to the hepatitis vaccines for three reasons. First, he believes that those with an acute infection should be not administered the hepatitis B vaccine; second that it should not be administered when the recipient is overtired, and third that it should not be given to those who, in addition to the first two contraindications also have a history of immune dysfunction.

For petitioner, Dr. Charles M. Poser

Dr. Charles M. Poser, M.D., is a neurologist practicing medicine for 52 years. Tr. at 98. He is currently a professor of neurology at the Boston University School of Medicine and a

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[35] Dr. Hyde maintains that it is medically improper to give an immunization, and particularly a multiple immunization to any patient with an active infectious disease. This is particularly so if one does not first ascertain the nature of this primary infection. "Since [sic] in my experience, many of the severe and permanent adverse immune reactions resulting from Recombinant Hepatitis B immunization have occurred when the patient already had a primary acute, subacute or chronic infection at the time of immunization." P. Med. Rec. at 1348. *See also*, Tr. at 49.

lecturer in neurology at Tufts and a visiting professor neurology at Harvard Medical School. In addition, Dr. Poser is a consultant in neurology to the Office of the Surgeon General for the Army and the Office of the Surgeon General for the Navy, as well as a consultant to the Veterans Administration Medical Center in Boston He testified that he has published about 240 articles in scientific journals, some 85 chapters in reviews, has written five books and done some editing. Tr. at 99. Petitioner was referred to Dr. Poser by Dr. Hyde. Although his Dr. Poser's initial examination of petitioner was "completely normal, Dr. Poser wasn't terribly surprised as, he explained, periods of being asymptomatic were consistent with a diagnosis of CFS. Dr. Poser testified that "The temporal relationship to the vaccination with a recombinant hepatitis A and B vaccine is such that to strongly suggest a causal relationship." Tr. at 104. He added that he has "seen several cases of classical CFS immediately following, and almost certainly resulting from such vaccination." *Id.* Moreover, he does not believe the thyroid carcinoma is related to this condition. *Id.*

For petitioner, Dr. Mark I. Geier

Dr. Mark R. Geier, M.D., Ph.D., is a medical doctor practicing in Maryland and Virginia, and is certified by the American Board of Medical Genetics. He is a Board Certified Forensic Examiner, a Board Certified Medical Examiner, and a specialist in both obstetrics and genetics and has published 30 peer-reviewed publications. Approximately ten of these articles involve hepatitis B vaccine but his publications studied the safety and efficacy of many different types of vaccines. He has appeared on many occasions before the special masters of the Vaccine Compensation Program as an expert witness testifying to the adverse effects of various vaccines. Dr. Geier has reviewed the reports of both parties in this case. Testifying for petitioner, Dr. Geier argues that his own research and the peer-reviewed findings published by others show a causal link between hepatitis vaccine and serious adverse reactions. Specifically, Dr. Geier posits that the hepatitis B vaccine can compromise the auto-immune system. It is his opinion that petitioner, more likely than not, was injured by the hepatitis B vaccination and that his claim should be compensated. *See*, P. Med. Rec. at 1909.

For petitioner, Dr. Michael McClellan

Dr. Michael McClellan is board certified in internal medicine and is in practice providing both primary care, and treatment and management of acute and chronic illness. Dr. McClellan first saw the petitioner approximately a year and a half after administration of the hepatitis vaccines, and continues to see him on a regular basis. At the time petitioner first saw Dr. McClellan, he had been seen by several different doctors in addition to his primary care physician and was seeking yet another opinion regarding his various symptoms. Tr. at 481. During that initial visit, petitioner reported symptoms including headaches, arthralgias, myalgias, weakness, cognitive dysfunction, and night sweats. Petitioner acknowledges that some of the symptoms pre-dated his vaccination

Dr. McClellan testified that several symptoms "actually sort of predated [petitioner's] complaints of all of the other systemic symptoms . . . and that they would be a recurring feature

of his illness" every time he saw petitioner. *Id*. Dr. McClellan argues strongly that Mr. Doe does not fit the profile of a malingerer and is a credible patient. Tr. at 485.

For respondent, Dr. Steven H. Lamm

Dr. Steven H. Lamm, an epidemiologist, argues that there is no known association between the hepatitis B vaccine and chronic fatigue syndrome, "let alone causation." R. Ex. CC at 2. Dr. Lamm specializes in the fields of medical epidemiology, pediatrics, and occupational and environmental health. He is board-certified in pediatrics, public health, and occupational medicine, and is a charter fellow of the American College of Epidemiology. He is currently on the clinical or attending faculties of Georgetown University School of Medicine (pediatrics), the Johns Hopkins-Bloomberg School of Public Health (health management and policy), and the Uniformed Services University of the Health Sciences Ebert School of Medicine (Preventive Medicine and Biometrics. He has published approximately one hundred articles in his fields. In addition, Dr. Lamm is the founder and president of Consultants in Epidemiology and Occupational Health, Inc., a consulting and research company dedicated to the assessment of health risks from exposure to various chemicals and biological substances. A special area of his research has been to identify the roles that biological and chemical exposures as well as medical diseases have in the development of certain health outcomes. Tr. at 199. The court found Dr. Lamm to be a credible witness, with impressive credentials.

Dr. Lamm defers to petitioner's treating doctors as to the diagnosis of chronic fatigue syndrome. His role in this case is not to diagnose Mr. Doe's symptoms, but to review the medical literature regarding whether there is an association between Hep B immunization and CFS. He identifies the fundamental question before him as "whether the medical evidence, the professional literature, indicates to a reasonable degree of medical certainty that [CFS] is a consequence of hepatitis B immunization." Tr. at 204. He identifies a secondary issue as the relevancy of the Geier reports as they apply to this case. *Id.* He draws upon the report of the Canadian panel and the publications by Dr. Salit and Dr. Pennie. Tr. at 205; *See*, R. Ex. CC. Having reviewed Mr. Doe's medical records and the affidavits of treating physicians along with those of testifying experts, as well as peer-reviewed literature, Dr. Lamm has concluded that the evidence in the literature does not support the proposition that CFS is related to the hepatitis B vaccination, nor does the testimony of petitioner's doctors. Tr. at 205.

For respondent, Dr. Burton Zweiman

Dr. Burton Zweiman is the only board certified immunologist testifying in this case as to the likelihood that CFS and the vaccine are causally related. He was director of the allergy and immunology division of the University of Pennsylvania Medical Center for almost thirty years. He is a professor of medicine and neurology. Dr. Zweiman has conducted neuroimmunologic research for more than twenty years, investigating experimental and clinical diseases of presumed autoimmune etiology, including experimental allergic encephalomyelitis, experimental allergic neuritis, multiple sclerosis, ADEM, Guillain-Barr, and other immune diseases. R. Ex.C. He testified for respondent as an expert in clinical immunology, arguing that no causal mechanism

exists between the hepatitis B vaccine and CFS and maintains that the causal mechanism theorized by petitioner's expert is simply not scientifically valid. R. Ex. A, B.

Dr. Zweiman asserts there is no evidence that Mr. Doe's condition is due to a defense defect. "The way that one determines whether or not an individual has a true host-defense defect is twofold . . . [first] is whether or not they have those types of recurrent infections, et cetera, that are typical for an immune defect of a particular type. And second, to actually measure the functional capacity of an individual to manifest the host defense." Dr. Zweiman explained that in this case, that would be the capacity to make antibody responses to immunization, "the capacity to exhibit what's called delayed hypersensitivity." This can be done by a series of skin tests and other tests, none of which were performed on Mr. Doe. Tr. at 310. Dr. Zweiman concludes that without these tests, he could not say that Mr. Doe had a "host-defense defect that made him more predisposed to getting a particular infection or adverse reaction to an immunization, et. cetera." *Id*.

For respondent, Dr. Arnold Safran

Dr. Arthur Safran, a board certified practicing neurologist, concurs with respondent's other experts that Hep B vaccine **is not** the cause of Mr. Doe's condition. R. Ex. Z, AA. He points to petitioner's medical history prior to administration of the hepatitis vaccines and argues that many of petitioner's symptoms predated those immunizations. *Id.* Dr. Safran also considers thyroid cancer, diagnosed after immunization, but possibly growing prior to that, as a probable cause of many of petitioner's post-vaccination symptoms.

VI. DISCUSSION

This analysis of the long and extensive record of this case begins with an a priori assumption: Petitioner is suffering. Several doctors agree that he suffers from chronic fatigue syndrome, an ongoing and disabling condition, and even those who don't agree with that diagnosis, acknowledge his multiple symptoms. Mr. Doe initiated litigation against his insurance company, and prevailed with a finding of disability.[36] That Mr. Doe is disabled, however, is not the issue at hand. It is the cause of his condition that is the focus of the deliberation at hand. Specifically, the undersigned is charged with deciding whether, as petitioner claims, administration of the hepatitis vaccine caused chronic fatigue syndrome, or whether, as respondent argues, Mr. Doe would be in the same condition without having been exposed to the vaccine, and that the vaccine was not a significant factor in the development of those symptoms. Before going any further, the central issue must be explored, whether a causal nexus exists between hepatitis B vaccine and CFS.

Issue One: Can hepatitis B vaccine cause chronic fatigue syndrome?

[36] The disability payments would be offset against any award under the Program. §300aa-15 g(1).

Having carefully reviewed the record, which includes reams of medical literature along with the affidavits of many doctors, the court has not been persuaded that hepatitis B vaccine can, in fact, cause chronic fatigue syndrome. The conclusions of those doctors who found a causal relationship between the vaccine and CFS have not been supported to a reasonable degree of medical probability.

If the court is to accept that hepatitis B vaccine can cause CFS, petitioner would have to present more compelling evidence than he has in this case. In fact, none of the medical literature submitted by petitioner addresses a most basic inquiry: whether hepatitis B vaccine can cause CFS. The strongest evidence provided by petitioner's experts is that of a temporal association. It is well-settled that temporal association alone is not probative in vaccine cases. *See, Grant v. Secretary HHS*, 956 F.2d 1144, 1148; *Strother v. Secretary HHS*, 21 Cl. Ct. 365,370 (1990), *aff'd*, 950 F. 2d 731 (1991); *accord Hasler v. U.S.*, 718 F. 2d 202, 205 (6th Cir. 1983), *cert. denied*, 469 U.S. 817 (1984). Temporal association between administration of the vaccine and the onset or worsening of a condition does not suffice to prove that the vaccine is the actual cause of injury. *Grant*, 956 F. 2d at 1148; *Hasler*, 718 R. 2d at 205. Other than concentrating on the non-probative temporal relationship, petitioner's experts relied upon medical literature that addresses the relationship between vaccines other than hepatitis B and various injuries, between hepatitis B vaccine and injuries not claimed by petitioner, and vaccine injury in general.

Only one study entered into evidence specifically investigates the relationship between hepatitis B vaccine and CFS, a Canadian study filed by respondent. *See*, "Canada Communicable Disease Report of the working group on the possible relationship between hepatitis B vaccination and chronic fatigue syndrome." CAN. MED. ASSOC. J. 1993: 149 (3). Petitioner criticized the study as unreliable, pointing to everything from sample size to the purportedly unimpressive government offices from which the study was issued. Tr. at 90. Petitioner's objections to a study's reliability based upon office size are new to this Program and are unpersuasive.

Dr. Lamm responded to each of petitioner's negative allegations that called into question the Canadian study. Dr. Lamm testified that there are three study groups in the Canadian report, the first with a sample of 69, the second of 700, and the third of 134. He explained that Dr. Geier's testimony criticizing the study was limited to only the first group, and that Dr. Geier's statement that only ten of the sample were contacted is incorrect.[37] In fact, out of the 69 cases in that group, 59 had been contacted, of which 30 were identified as CFS cases and it was those 30 reported in that first study group. Tr. at 213-214. Dr. Lamm testified that since the initial report done in 1993, two subsequent publications came out of that report, but that recent investigation shows that, as of two days before he testified in this case, those were the only reports specifically looking at the hepatitis B vaccine and CFS. Tr. at 215-216. Significantly, those reports found no causal relationship between the hepatitis B vaccine and CFS. Furthermore, petitioner's challenge of Dr. Lamm's most recent research is of little value here.

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[37] The undersigned was not persuaded by Dr. Geier's testimony. *See*, p. 27 *infra.*

Petitioner insists that Dr. Lamm missed the Gerard report published in BRAIN 2001. In that study, all of the 50 patients with macrophagic mild bursitis ("MMB") had been inoculated with hepatitis B or tetanus toxoid vaccine before biopsy. Tr. at 250. The court raised the same question as did Dr. Lamm: what is the relevance to petitioner's CFS? Petitioner quickly explained that MMB is a variant of CFS. Tr. at 251. The explanation was insufficient for Dr. Lamm, as it is for the court. The court is interested in those studies that address the specific relationship between hepatitis B vaccine and CFS, not that of the vaccine and other conditions, or of other vaccines and CFS.

Review of the Canadian study that examined the interplay of hepatitis B and CFS provides persuasive evidence that there is no scientific basis in this record supporting an association between hepatitis B vaccine and chronic fatigue syndrome, let alone one of causation. Another study published in 1997 reported that hepatitis B vaccine was not a precipitating factor for CFS. Moreover, Dr. Lamm found Dr.Geier's research and testimony irrelevant to this case as it does not address the diagnosis of CFS. The court notes, as does Dr. Lamm, that Dr. Geier's reports are not concerned with CFS, but with arthritis and the symptoms of acute arthritic reactions. Dr. Lamm criticizes Dr. Geier's studies for their lack of reliability. They were, he reports, "internally inconsistent with his individual reports and inconsistent across the reports." Dr. Lamm explains that even if Dr. Geier had used a reliable methodology, he did not apply it in a reliable manner.

Testifying for respondent, Dr. Lamm points again to Dr. Geier's erroneous determination of incidence rates from the reporting rates (case reports per 10 million dosages) compiled in a "passive surveillance system, VAERS."[38] Dr. Lamm emphasizes the significance of the difference between incidence rate and reporting rate. Furthermore, he faults Dr. Geier's methodology for its dependence on two assumptions that have not been validated. First, that the reporting rate (i.e., the percentage of cases that actually get reported to VAERS for a particular symptom or diagnosis) is the same for all vaccines, and second, that the age distributions of the vaccines are similar. Dr. Lamm argues that reliance on these false assumptions results in risk estimates that are far removed from the subsequently demonstrated actual risk and therefore devoid of predictive value. Accordingly, Dr. Lamm finds the Geier report neither relevant nor valid. The court finds Dr. Lamm to be better qualified than Dr. Geier in the areas discussed here.

The court finds Dr. Lamm's criticisms relevant and valid in that regard. The court does not find Dr. Geier's testimony probative, adding the present matter to a long line of vaccine cases finding little or no value in Dr. Geier's testimony. As has been the case with several special masters in the

[38] VAERS is the Vaccine Adverse Events Reporting System database. It has followed adult hepatitis B vaccine from 1997. It is an epidemiologic database maintained by the Centers for Disease Control and Prevention (CDC) since 1990.

Program,[39] the undersigned discounts Dr. Geier's testimony for several reasons. First, Dr. Geier is an obstetrician and geneticist. He has been trained in those specialties but not in epidemiology. Accordingly, Dr. Geier does not meet the AMA's guidelines for expert witnesses.[40] The guidelines clearly set forth the minimal requirements a doctor must fulfill to be considered an expert witness. Of primary importance is that the testifying doctor be an expert in the field for which he opines, and that formal training in that field is essential.

Counsel for petitioner, Mr. Shoemaker, began his direct examination of this witness with a thinly veiled and ineffective series of questions designed to establish that although Dr. Geier's research employs the use of numbers and P values, he is not involved in epidemiological endeavors. Tr. at 140-141. Several special masters in the Program have afforded little substance to Dr. Geier's testimony, the most frequent criticism being that he is not an epidemiologist. Mr. Shoemaker's attempt here is to forestall similar criticism by the undersigned, by suggesting Dr. Geier is simply using comparative statistics frequently employed by any medical doctor performing research. To be succinct: the undersigned is not persuaded. Elsewhere in the transcript, Mr. Shoemaker even refers to Dr. Geier's work in this case as epidemiological. Tr. at 10. Dr. Geier presented papers he

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[39] Dr. Geier's testimony has been accorded no weight in other vaccine cases: *Thompson v. Secretary HHS*, No. 99-0436, 2003 WL 22143972 (Fed. Cl. Spec. Mstr. May 23, 2003); *Haim v. Secretary of HHS*, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993) (Dr. Geier's testimony is not reliable, or grounded in scientific methodology and procedure. His testimony is merely subjective belief and unsupported speculation."); *Marascaloco v. Secretary of HHS*, No. 90-1571V, 1993 WL 277095 (Fed. Cl. Spec. Mstr. July 9, 1993) (where the special master described Dr. Geier's testimony as intellectually dishonest); *Ormechea v. Secretary of HHS*, No. 90-1683V, 1992 WL 151816 (Cl. Ct. Spec. Mstr. June 10, 1992) ("Because Dr. Geier has made a profession of testifying in matters to which his professional background (obstetrics, genetics) is unrelated, his testimony is of limited value to the court.") *Daly v. Secretary of HHS*, No. 90-590V, 1991 WL 15473 (Cl. Ct. Spec. Mstr. July 26, 1991) ("The court is inclined not to allow Dr. Geier to testify before it on issues of Table injuries. Dr. Geier clearly lacks the expertise to evaluate the symptomatology of the Table injuries and render an opinion thereon.").

[40] American Medical Association (AMA) guidelines for expert witnesses: H.265-994 Expert Witness Testimony: (3)(a) "Existing policy regarding the competency of expert witnesses ... (BOT Rep. SS A-89) is reaffirmed, as follows: The AMA believes that the minimum statutory requirements for qualification as an expert witness should reflect the following: (i) that the witness be required to have comparable education, training, and occupational experience in the same field as the defendant; (ii) that the occupational experience include active medical practice or teaching experience in the same field as the defendant; and (iii) that the active medical practice or teaching experience in the same field as the defendant; and (iii) that the active medical practice or teaching experience must have been within five years of the date of the occurrence giving rise to the claim." American Medical Association, *Policy Compendium* (1999).

wrote that addressed the relationship between hepatitis B vaccine and arthritis, not CFS; and of tetanus toxoid and hepatitis B vaccines' relationship to Guillain-Barr, not CFS. Accordingly, except for that which addresses genetics, the court discounts Dr. Geier's testimony here.[41]

The court is required to review and consider all issues raised and all matters submitted. The undersigned has done so without exception. The court has found the medical literature filed by petitioner to be of little value to his claim. Among the articles submitted in support of his allegations is: S. Guis et al., " Identical Twins With Macrophagic Myofascitis: Genetic Susceptibility and Triggering by Aluminic Vaccine Adjuvants," 47 ARTH. & RHEUM. 543 - 545 (2002), providing an anecdotal report of a single set of twins who developed macrophagic myofascitis (MMF) after the third and final administration of hepatitis B vaccine. The article concludes that "this observation illustrates the importance of the genetic background in MMF, and its possible triggering by aluminic vaccines." *See*, R. Ex. 6 at 33. The value of this article in determining causation in the present case eludes the court in three ways. First, Mr. Doe is not diagnosed with MMF. His diagnosis is CFS. MMF is described as "an inflammatory myopathy, recently described." *Id*. Unlike CFS, the diagnosis of which is one of exclusion, MMF is diagnosed based on "deltoid muscle biopsy that usually shows specific histologic abnormalities including infiltration of connective tissue structures by densely packed large and grossly rounded CD68+ histiocytes." Although Mr. Doe developed a mass in the area of his deltoid muscle, there is no evidence that a biopsy revealed the abnormalities described in the article. Second, the article refers to a situation in which the complete sequence of hepatitis B vaccination was completed; that is, the twins received three doses. If anything – the article suggests a possible causal relationship between hepatitis B vaccine and MMF as evidenced by positive rechallenge. Finally, for the same reasons explained above, the article provides no indication that aluminic vaccines cause CFS.

Petitioner filed another exhibit for the purpose of showing "that even as early as 1988, it was recognized that myalgic encephalomyelitis, or chronic fatigue syndrome (CFS), has been associated with vaccinations as an initiating event, and . . . demonstrat[ing] that it has long been known that it involves immunological dysfunction." *See*, P. Ex. 3. A.R. Lloyd et al., "What is Myalgic Encephalomyelitis?" THE LANCET 1286-1287 (June 4, 1988). For several reasons, this particular exhibit carries little weight in the deliberations at hand. First, it is a letter to the editors of THE LANCET , not a peer-reviewed article, and is therefore lacking the rigorous scrutiny of peer-reviewed articles published in that highly regarded journal.

The LANCET letter serves to stress the importance of having a single name to describe a particular disorder for which "reproducible diagnostic criteria are agreed." *Id*. at 1286. To that end, the authors express their agreement with the Center for Disease Control ("CDC") that the "best term" for the condition [known as myalgic encephalomyetlitis] is CFS." *Id.* Next, the letter provides

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[41] For example, as a geneticist, Dr. Geier provided a credible explanation of why petitioner could not have Usher's disease, based on the chromosome pattern for that condition. Tr. at 156-157.

no probative evidence that hepatitis B vaccine bears a causal relation to that condition, regardless of its name. The court's efforts are not directed at naming petitioner's condition, but at determining whether that condition has been caused by his hepatitis B vaccination. Finally, the authors make clear, in the letter's opening paragraph, that a diagnosis of CFS is based upon a "characteristic history (especially muscle fatigue), a normal physical examination (excluding the findings of lymphadenopathy, muscle tenderness, or pharynigitis), and negative investigations to exclude other chronic infectious or immuno-impairing diseases."*Id.* Using those criteria, and considering petitioner's thyroid disease and alternate diagnosis of Behcet's syndrome, the letter serves little purpose in the instant case other than to cast doubt upon a diagnosis of CFS.

Nor does it escape the attention of the court that the vaccines mentioned in the article are tetanus, cholera, influenza, and typhoid, but not hepatitis B. The letter proposes that the vaccines mentioned have been associated with the onset of CFS in several cases, thereby "suggest[ing] that antigenic challenge, not necessarily in the form of an infection, may be the prerequisite for the development of the disorder." *Id.* Not only is the argument speculative for the specific vaccines mentioned, but to extend such speculation to vaccines not even considered by the authors, amounts to little more than guesswork on the part of petitioner.

An even more puzzling submission is petitioner's Exhibit 2 in which a case of Reiter's syndrome and one of reactive arthritis were reported after the second and first dose of hepatitis (Engerixe) B vaccine were administered. W. Hassan, R. Oldham, "Reiter's syndrome and reactive arthritis in health care workers after vaccination," BRITISH MEDICAL JOURNAL 1994: 309; 94-5. Petitioner posits that "this article provides evidence of positive rechallenge, which is strong evidence of a causal relationship, for developing joint symptoms after hepatitis B vaccination." P. Ex. 2. But, the article does not link "joint pain" in general to vaccination, but joint pain symptomatic of Reiter's Syndrome and reactive arthritis, neither of which petitioner suffers. Accordingly, the article's relevance is weak. The court is ill-disposed to find credence in exhibits proffered for the stated purpose of providing evidence but, upon close examination, simply does not exist, and more tellingly, bear no indication that any information relevant to this case was contained therein.

Testifying for petitioner, Dr. Poser posited that CFS, or disseminated encephalomyelitis is a "common complication of vaccinations." Yet, he fails to present compelling scientific evidence supporting that opinion. Tr. at 107-108.

When confronting difficult medical issues such as those before the court today, the special masters frequently rely on the Institute of Medicine's conclusions as a sound source for answering questions regarding plausibility and causation.

> Due to the IOM's statutory charge, the scope of its review, and the cross-section of experts making up the committee reviewing the adverse events associated with vaccines, the court considers their determinations authoritative and subject to great deference.

See, *Althen v. Secretary of HHS*, U.S. Claims LEXIS at *42, n. 28; citing Watson v. Secretary of *HHS,* 2001 U.S. Claims LEXIS 268, No. 96-639V, 2001 WL 1682537, at *5, n. 11 (Fed. Cl. Spec. Mstr. Dec. 18, 2001). In its 1994 report entitled, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality: Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality 8, 14 (hereinafter "IOM 1994 Report"), the IOM concluded that "the evidence favors rejection of a causal relationship between hepatitis B vaccine and incident multiple sclerosis" as well as multiple sclerosis relapse. Notably, the IOM report made no mention of CFS as it relates to the hepatitis B vaccine, although it discussed various other conditions in relation to the vaccine, concluding that the evidence is inadequate to accept or reject a causal relationship between any of them and the hepatitis B vaccine. IOM report at 80. The committee seems more concerned with monitoring the incidents of various disorders as they relate to general vaccine administration, than to the relationship between those incidents and the hepatitis B vaccine itself. Specifically, the committee does not recommend a policy review of the hepatitis B vaccine by any of the national and federal vaccine advisory bodies, but recommends specific surveillance of hepatitis B disease and increased surveillance of secondary diseases such as cirrhosis and hepatocellular carcinoma (emphasis added). In sum, the IOM report lends no credibility to petitioner's theory of causation in this case.

Having considered the testimony regarding the existence of a causal relationship between hepatitis B and CFS, the court has been more favorably impressed with the opinions of respondent's experts than with those of petitioner. Respondent's experts are better qualified and more convincing in their arguments against vaccine-related causation. Moreover, they have effectively rebutted all of petitioner's arguments. None of the articles submitted by petitioner in support of his position have been relevant to the issues at hand; the studies do not support a finding of causation. Petitioner has simply not shown that hepatitis B vaccine can cause CFS or petitioner's injuries.

Although the court is not satisfied that petitioner has affirmatively established a causal association between hepatitis B vaccine and CFS, the undersigned will continue with its analysis, hypothesizing whether the vaccine, *were* it shown that it could cause CFS, did so in this case.

Issue Two: EVEN IF it were established that the Hep B vaccine COULD cause CFS, DID it cause Mr. Doe's condition?

At hearing, in his opening remarks for petitioner, Mr. Shoemaker invoked the rule of Occam's Razor, an age-old dictum advancing the proposition that the simplest explanation is usually the best.[42] Tr. at 5. After months of excruciating review of the record, the court would welcome

[42] Occam's Razor: (also Ockham's razor): A rule in science and philosophy stating that entities should not be multiplied needlessly, which is interpreted to mean that the simplest of two or more competing theories is preferable and that an explanation for unknown phenomena should first be attempted in terms of what is already known {After William of Ockham (1285?-1349).}

a simple explanation for petitioner's condition, but cannot countenance an explanation that is not only simple, but simplistic. The apparent explanation Mr. Shoemaker wants this court to adopt is that because petitioner's decline allegedly began within days of his hepatitis B vaccination, any symptoms existing after the vaccination were caused by the vaccine. But the statute under which petitioner's claim was filed, assures that no special master will be led into such temptation as temporal association or an apparent absence of alternative causation. On the contrary, although temporal association and lack of alternative causation may be considered, neither one, nor the two together, are sufficient evidence for petitioner to successfully carry his burden of proof. *See*, *Grant v. Secretary of HHS*, 956 F. 2d 1144 (Fed. Cir. 1992); *Thibaudeau v. Secretary of HHS*, 24 Cl. Ct. 400 (1991); *Lunn v. Secretary of HHS*, No. 970436, 2000 WL 246237 (Fed. Cl. Spec. Mstr. Feb. 17, 2000).

The court understands well Mr. Shoemaker's desire that the court look to that most simple of explanations: Mr. Doe was vaccinated; Mr. Doe thereafter suffered; ergo, Mr. Doe's suffering was caused by the vaccine. The undersigned is not the first to point out the logical fallacy inherent in such reasoning. The Federal Circuit has adopted the principle that "inferring causation solely on the basis of a proper temporal sequence is the logical fallacy of *post hoc ergo propter hoc* (literally, 'after this, therefore because of this')." IOM 1994 Report at 23. This logical fallacy exists even in the absence of alternate causes. Nor does biologic plausibility lend substance to a temporal relationship. *Huston v. Secretary of HHS*, 39 Fed. Cl. 632, 636 (1997), for the proposition that a showing of biologic plausibility and temporal association is insufficient to prove actual causation; *Hasler,* 718 F. 2d 202, 204-205, for the propositions that a proximate temporal relationship alone will not support a finding of causation and that evidence supporting the notion that "A" can cause "B" does show that "A" actually did cause "B."

Moreover, were temporal relationship cause enough to establish causation, the court is not convinced that temporal association has been successfully demonstrated here. A careful review of petitioner's medical records indicates that several of the symptoms he suffered post-vaccination were documented prior to the vaccination. Moreover, these same symptoms have been referenced as indicative of CFS. This information begs the question, but for the vaccine, would petitioner's condition be different today? The court emphatically professes its inability to say, with any degree of certainty, that but for the vaccine, petitioner would be a healthy man today. Even if the court was persuaded that but for the vaccine, petitioner would at least be healthier than he now is, the court cannot say that the vaccine was a substantial factor in bringing about his present condition. According to the Federal Circuit in *Shyface* 165 F.3d 1344, a logical sequence of cause and effect must lead to the conclusion that there is no other explanation or competing cause for the injury. A natural place to look for guidance as to whether the vaccine was a substantial factor in petitioner's case would be his treating doctors.

The American Heritage Dictionary at 860 (2nd College ed. 1985).

Treating Doctors

In the instant case, however, petitioner's medical records reveal two camps of treating physicians, those who make clear their opinion that petitioner's condition is not related to the vaccine, and those who attribute his condition to it. The latter, it appears, were visited when petitioner prepared for litigation. Understandably, petitioner submits only the opinions of those who attribute his condition to the vaccine. But a review of petitioner's medical records reveals alternate opinions of at least six doctors not called upon to testify. As stated above, the observations of those doctors testifying for petitioner reveal a shaky foundation upon which to build a theory of causal association. For example, Dr. Luggen, who examined petitioner in the fall of 1998, testified that lab results showed several abnormal readings, including elevated bilirubin levels. Dr. Luggen noted that he has no idea whether this abnormal reading is a new symptom, and attests to the fact that he is "not certain how long [petitioner] has experienced that symptom," speculating that it may be for more than a year. The medical records show that, at the time, more than a year had passed since petitioner was vaccinated, and that he had elevated bilirubin levels for at least a year prior to vaccination. Considering the voluminous records of the many examining doctors who reached no consensus of opinion as to causation in this case, the undersigned is reluctant to entrust the opinions of treating doctors with any greater weight than the experts who have not seen petitioner. Contrary to what petitioner's counsel advocates, there are no easy answers to be had. Evidence of a causal connection to the hepatitis B vaccine has not been established.

Throughout the years, the undersigned has reviewed clinically-based testimony on a case by case basis. In a 1991 case, the undersigned found the testimony of a treating physician to be more probative than that of an epidemiologist. *Robinson v. Secretary HHS*, No. 91-1V, 1991 WL 268650 at *6 (Cl. Ct. Spec. Mstr. Nov. 27, 1991) (for the proposition that epidemiological studies are relevant, but not necessarily the standard by which the court is required to render its decision in vaccine vases, as it would be virtually impossible for claimants to prove off-Table cases were that the standard). Yet, six years later, the undersigned found that clinically-based testimony may be unpersuasive. *See e.g, O'Leary v. Secretary, HHS*, 1998 U.S. Claim LEXIS 91 (for the proposition that clinical diagnosis, care and treatment can also be unpersuasive). Specifically, the undersigned found that, "Too many unknowns exist, and as [physician] admits, other causes are possible. . . . Something more is needed in an off-Table case to tip the balance."*Id*. at *3. And so it is in the instant matter before the court: Too many unknowns exist and petitioner has not provided enough to tip the balance in his favor; he has not provided convincing evidence that the vaccination is a more likely cause of CFS than is the virus petitioner suffered at that same time.

It appears, however, that petitioner had diagnosed himself as suffering an allergic reaction to the hepatitis vaccines within hours of administration. *See*, P. Ex. 4 Med. Rec. at 83. When various specialists made clear their disagreement with that diagnosis, petitioner traveled far and wide to doctors who subscribed to a hepatitis B theory of causation. From that time on, petitioner visited those doctors with whom the special masters are so familiar – several doctors who have testified time and again that myriad conditions are probably vaccine-related. The court faces a very sensitive question at this time, discussion of which must be premised by the understanding that the

undersigned is sympathetic not only to the plight of petitioner, but to anyone who suffers from an idiopathic condition, and especially those whose conditions are without positive diagnosis. That being said, it is understandable that if able to, the afflicted *will* travel far and wide to find a diagnosis, cause, and - hopefully - treatment.

There is evidence throughout Mr. Doe's records that he proposed his theory of causation to many of his doctors, and time and again, they refuted the possibility. A look back at the chronology of petitioner's symptoms, post-vaccination, reveals the notations made by at least six doctors that Mr. Doe discussed his theory of causation with them. Mr. Doe continued his search and stopped only when he found those doctors who subscribed to the theory of causal relationship between the vaccine and his condition. This is not surprising in light of a dominating fact in this case: Mr. Doe filed his claim for entitlement under the Act on August 4, 1999 – five months before any doctor affirmed his suspicion. It appears that he studied the statute and the guidelines for the Program and filed in good faith, although he heard many doctors challenge his belief that his condition at that time was attributable to the vaccine.

Only Dr. Nunlist-Young, his primary doctor for many years, initially agreed with Mr. Doe that he experienced serum sickness. It is interesting that testifying for petitioner, Dr. Poser makes a distinction between serum sickness and a neurologic response to vaccination. He states that CFS is the result of a neurologic response to the vaccine, but that serum sickness is a different type of response in that it is humeral, not cellular. Furthermore, in answer to Mr. Shoemaker's question as to whether serum sickness can lead to a more debilitating auto-immune condition, Dr. Poser testified that he really doesn't know, but would say "probably." Tr. at 109. He then emphasized that his basis for concluding that the CFS was caused by the vaccination is because he could find "no other cause that could be implicated in causing this." Yet none of the specialists to whom petitioner was referred in the first year and a half following vaccination, indicated the vaccine as a cause of his symptoms. Dr. Nunlist-Young wrote a brief statement that he believed his patient's symptoms were vaccine-related, but he was not called upon to testify on his behalf. The court finds no evidence of causation in temporal association and lack of alternative causes.

Also worth noting is the report of Dr. Harold T. Pretorius, dated August 5, 2003 – post-hearing. *See*, P. Reply Post-Hearing Memo at 9; P. Rep. Dr. Pretorius. Dr. Pretorius performed a baseline acetazotamide Brain SPECT on petitioner and concluded that he had "[d]ecreased metabolic (FDG) vs. stimulated perfusion (HPAO) tracer distribution in the left parietal, left frontal, right parieto-occipital and either temporal cortex and cerebellum, consistent with immune cerebritis." He states the condition is "likely due to prior hepatitis B vaccine injection and worsening after repeated hepatitis B vaccine injections." See, P. Rep. Dr. Pretorius. The court, however, was privy to information regarding his patient, of which Dr. Pretorius was unaware: following the initial hepatitis B vaccination, petitioner received no additional hepatitis B vaccination. *See*, P. Aff. Dec. 2002 at 2 ¶ 5 (attesting to the fact that petitioner received no further hepatitis B vaccinations). Accordingly, the court finds no probative value in Dr. Pretorius's conclusion.

Again, the undersigned has full appreciation for what Mr. Doe has experienced and his quest

for definitive answers and acknowledges that Mr. Doe finally found doctors to support his theory. He consulted with Dr. Hyde and Dr. Poser and the undersigned found both doctors to be pre-disposed to accept a causal relationship between the vaccine and CFS. The court does not come to this case with any predetermined notions; it behooves the court to reflect on the testimony of all the doctors.

The Experts

The credibility of several of petitioner's experts has been called into question repeatedly by several special masters and judges.[43] For example, in *Gardner-Cook v. Secretary HHS*, the undersigned's colleague, Special Master Millman, found that Dr. Byron Hyde, testifying for petitioner, "devotes his time to litigation and helping people who assert that hepatitis B vaccine has injured them . . . [and he appears to be] alone against the mainstream of the medical establishment, a status he regards as a mark of honor." *Gardner-Cook v. Secretary HHS*, No. 99-480V, 2003 U.S. Claims LEXIS , 296, August 3, 2003; *aff'd* U.S. App. LEXIS, 9981 (Fed. Cl. May 11, 2004). As is evident in the matter before this court, Dr. Hyde, in the Gardner-Cook case, associates himself "with some like-minded people . . . and by a process of misdiagnosis and misinterpretation, has cast aspersions on hepatitis B vaccine in the legal area. *Id*. at 22. The undersigned agrees that "[i]t may well be that hepatitis B vaccine causes adverse reactions, but Dr. Hyde's opinion in this case is highly suspect and not credible." *Id.* The court found Dr. Hyde's credentials are unpersuasive in that his research is derived mainly from his own lab's findings with little support from outside studies. As stated earlier, the results of his studies are published by his own foundation. In sum, the testimony of Drs. Hyde, Weisbren, and Geier provides little to advance petitioner's case. Not only do these doctors fail to establish an affirmative and probative diagnosis of vaccine causation, but they fail to overcome the evidence of alternative causation. On the other hand, respondent's experts provided a convincing challenge to petitioner's assertions of causation.

For example, in response to Dr. Hyde's testimony that Mr. Doe had a "predisposition to having problems," Dr. Zweiman reminds the court Mr. Doe stated that prior to this time, he had no problems with recurrent infections. In the absence of either recurrent infections or positive test results, it follows that Mr. Doe had no evidence that he had a host-defense defect. Tr. at 311. As to Mr. Doe's slightly decreased CD-4, Dr. Zweiman observes that should a host-defense condition exist, one would have expected to see a much more profound abnormality or defect in the CD-4 levels. For example, he informed the court that people with CD-4 counts of around 400 still have "absolutely no increased incidence of infection"and that individuals with compromised immune

[43] The court has already set forth its opinion as to Dr. Geier's credibility. *See*, p. 27, 37, *supra*. *See also*, *Ormechea v. Secretary of HHS*, No. 90-1683V, 1992 WL 151816 (Cl.Ct. Spec. Mstr. June 10, 1992) ("Because Dr. Geier has made a profession of testifying in matters to which his professional background (obstetrics, genetics) is unrelated, his testimony is of limited value to the court.")

systems, such as HIV-infected patients, "do not start getting into trouble with major infections until the CD-4 count is down around 200." Tr. 313. Mr. Doe's count was 629. *Id.* Dr. Zweiman emphasizes that Mr, Doe apparently displayed no immune dysfunction that would make him susceptible to an adverse reaction to the hepatitis B vaccine, and exhibits nothing that suggests his immune system has been affected by the vaccine. The court found Dr. Zweiman's testimony well-supported by medical science. His explanation of why he discredits a causal association between the vaccine and CFS is clearly stated presenting the mechanisms of immune defenses, insult antibodies, cell-mediated immunity, the interaction of certain cells, and the flexibility of the immune system. Tr. at 310. While petitioner failed to present a cogent and logical theory of causation, respondent was persuasive in presenting a logical theory of alternative causation. Especially effective was Dr. Zweiman's explanation of the significance of the results of tests assessing petitioner's effective immunity. *See*, Tr. at 311-313, 334-336. Moreover, Dr. Zweiman also found insufficient independent validation of the opinions of Drs. McClellan, Waisbren, Spickett and Hyde. *See*, Med. Rec. 1881-1882.

Dr. Zweiman questions the expertise of several of petitioner's witnesses. He discounts the opinions of Drs. Hyde and Waisbren because they base their opinions on case reports and not on published epidemiological literature. See R. Ex. at 5-6. The court acknowledges, however, that epidemiology is not required to prove entitlement in the program, and that case reports can be considered as evidence. *See*, *Capizzano,* 2003 U.S. Claims, LEXIS 219, (August 5, 2003), *reaffirmed Capizzano v. Secretary HHS,* 2004 U.S. Claims, LEXIS 149 (June 8, 2004); *see also*, Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 27 (1994) (IOM Report on Causality). Still, the court finds little value in the testimony of Drs. Hyde and Waisbren for several reasons.

Dr. Hyde's credentials do not compare favorably with those of respondent's experts. His training and clinical experience are as a general practitioner. Tr. at 69. He is without any board certification. *Id*. Dr. Hyde refers frequently to his published book, but on cross-examination the court learned that the book was self-published. "We published the textbook through the Nightingale Foundation and various pamphlets."[44] Tr. at 71. Throughout his testimony, and expert report, Dr. Hyde maintains that CFS can be precipitated by a viral infection. Moreover, he acknowledges that petitioner had a viral infection for three weeks at the time he was vaccinated. To intuit that petitioner's CFS was caused by the vaccine rather than by the viral infection is speculative, and therefore of no probative value to the court.

When questioned about his understanding of the Center for Disease Control's (CDC) 1994 definition of CFS, Dr. Hyde was, at best, evasive.

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[44] According to Dr. Hyde, the Nightingale Research Foundation is "one of the poorest charitable institutions in Canada. . . [e]veryone volunteers; no one is paid a salary." Tr. at 70. Dr. Hyde is founder and chairman of the foundation. *See*, http://www.nightingale.ca/nightb.html August 16, 2004.

> It's not a very useful definition; it's very complex. . . . My first understanding is it's not useful. . . . Well, that definition goes on for several pages, as you probably know. There's no way I would even attempt to give you that by memory. And this is one of the problems with that definition. It's literally unuseable, because it just goes on forever. I wouldn't comment on that definition without it right in front of me. Tr. at 73.

Petitioner's experts argue that ample evidence exists to support a causal relationship between hepatitis vaccine and CFS. Dr. Weisbren, an immunologist, diagnosed Mr. Doe on September 14, 1999, as having chronic debilitating post-vaccinal encephalomyelitis and acquired autoimmunity. Dr. Spickett, another immunologist Mr. Doe visited in London, England on two occasions, is of the opinion that Mr. Doe suffers from chronic fatigue syndrome. Yet not only do these doctors fail to provide the court with a logical progression of causation, but they fail to address petitioner's pre-existing condition, those symptoms troublesome enough to warrant multiple visits to his doctors. These pre-vaccine symptoms include oral ulcers for several years, abdominal pain that was so severe at times as to inhibit walking, nonspecific eye symptoms, and dizziness and disorientation.

Although petitioner presented several experts, including treating doctors, to testify on his behalf, his medical records reveal at least as many doctors who do not support his theory of vaccine-related causation, namely Drs. Deborah A. Fritz, Robert L. Reed, Michael E. Luggen, Starr Ford, Daniel C. Jacobs, Leonard Calabrese, Joseph Michalski, Steven Fessler, Adam Kaufman, Salem Ford, Daniel Wallace and Dr. Scheuner. These doctors all examined petitioner, and while they represent a range of medical specialties, none indicated that petitioner suffered from CFS caused by, or even possibly caused by the hepatitis vaccine.

Alternate Causes

While unnecessary to decide given the court's resolution of this case, based on petitioner's failure to prove the vaccine capable of causing CFS, a significant question of alternate causation persists. The undersigned cannot sweep away the ample evidence that presents possible alternate causes of Mr. Doe's problems. Petitioner's medical records are replete with multiple factors that may have caused his current condition. Given the various alternate causes considered by petitioner's doctors, the court is not satisfied that petitioner has convincingly demonstrated the elimination of reasonable alternative causes. Dr. Luggen, petitioner's treating immunologist, offered several clinical impressions, but did not feel that his patient's illness was caused by the vaccine. *See*, R. Prehearing Memo at 6-7, citing Med. Rec. 36-37, 99. Although Dr. Poser, another of petitioner's experts, testified that in his opinion, petitioner suffers from CFS triggered by the hepatitis B vaccination, the court finds it telling that he also testified that there is no single cause of CFS and that there is a basic mechanism that can be activated by a number of factors. Tr. at 112, 24.

In addition to the affidavits and oral testimony of certain treating doctors and experts, the court found the comments on petitioner's medical records revealing. As noted earlier, it appears that most of petitioner's doctors did not have a complete family history. Dr. Fritz knew that petitioner's sister has what is possibly lupus and that his grandmother suffers from reactive arthritis. Dr. Fritz

indicated her impressions on petitioner's chart, that Mr. Doe has "generalized myalgias and atypical myofascial pain felt to represent a chronic benign pain syndrome, most likely related to his lifestyle as he does a lot of traveling overseas, flying around." She notes that he admits to a fair amount of stress in his life and to a habitual alcohol use pattern. She found no evidence of an inflammatory arthropathy, myopathy, or other connective tissue disease and notes that he "apparently had a 6-week illness last summer which was felt to represent a viral syndrome by Dr. Dunn who evaluated him at that time." No mention is made of the hepatitis vaccinations. *See*, Pet. Ex. 4 Med. Rec. Dr. Fritz at 38-39.

Similarly, with regard to family history, Dr. Deckter, a gastroenterologist, who saw petitioner on several occasions prior to administration of the hepatitis vaccines, on March 30 and April 7, 1995, notes an **"unremarkable"** family history. Although petitioner testified that he had insignificant gastrointestinal problems that never interfered with his lifestyle, and were treated with antacids, Dr. Deckter recorded the following impressions: "Hepatobiliary[45] imaging study indicates normal liver. Impression: right upper quadrant pain with radiation to left upper quadrant and lower abdomen, not decreased with Zantac or Bentyl; Elevated bilirubin with normal LFT's. Probable Gilbert's [disease]." A week later, after seeing petitioner again, Dr. Deckter noted that the "abdominal pain is so severe that it wakens [petitioner] at times but that pain is decreased with rest. [He] [u]nderwent pandendoscopy[46] with a final diagnosis of slight hiatal hernia, mild duodenitis and probable irritable bowel syndrome." *See*, Pet. Ex. 4 Med. Rec. Dr. Deckter at 47-55.

The record is notable for its contradiction of petitioner's testimony that he suffered only mildly from gastrointestinal problems. The doctor's notes regarding the degree of pain suffered by petitioner, could only reflect petitioner's account of that pain. Not only did the pain awaken him from sleep, but it seemed to abate with rest, raising the question of whether physical manifestations of fatigue have been an ongoing problem for petitioner.

Also in 1995, the month illegible in the record, petitioner visited his primary care physician, Dr. Nunlist-Young. The notes from that office visit reveal the following: "[Petitioner is] [h]ere because of chest congestion and coughing for last several weeks. [His] [f]riend prescribed amoxicillin which helped initially. Has also been feeling 'funny' – described as having hot flashes, disorientated slightly, pain up back of neck (sharp and shooting, sporadic)." Noteworthy, is the description of 'funny' feelings. Although petitioner avers that prior to vaccination, he suffered none of the symptoms he experienced after vaccination, it appears that in 1995 at least, he experienced disorientation and pains that sound similar to those he experienced following the vaccination: shooting pains up and down his body – pains that waxed and waned. Cf. Pet. Reply to Res. Post-Trial Brief at 4-8. *See*, 6-8*, supra;* Res. Post-Hearing Memo at 4; tr. at 14, 405-406, 445-450, 481;

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[45] Hepatobiliary: pertaining to the liver and the bile or the biliary ducts. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY, 27th ed. 1997 at 753.

[46] Pandenoscopy: [use of a pandenscope (cytoscope)] that permits wide-angle viewing of the urinary bladder and urethar. *Id*. at 1217.

Med. Rec at 1-4. 82-83, 144, 159, 164-72, 186-87, 866-886, 1106, 1107.

The court is simply not convinced that petitioner has borne his burden by demonstrating a causal link between hepatitis B vaccine and CFS. Moreover, petitioner has not persuaded the court that administration of hepatitis B vaccine was a but-for cause of, or significant factor in his case.

VII. CONCLUSION

The court stresses yet again that to prevail in the instant case, petitioner's burden is not to merely convince the court that he is disabled, but that administration of the hepatitis B vaccine caused his disability. The court does not question petitioner's credibility regarding his condition. Although that question was the focus of prior litigation, it does little to address the issue with which the court grapples – causation.

The undersigned has reviewed and carefully considered the opinions of every expert testifying in this case, the complete filed records of every medical doctor who treated Mr. Doe, and the medical literature provided by both parties. In coming to a decision in this case, the undersigned finds the opinions and reasoning of respondent's experts most persuasive. Dr. Lamm and Dr. Zweiman not only presented superior credentials and expertise in the issues most relevant to this case, but they provided compelling arguments against a causal relationship between hepatitis B vaccine and CFS. In addition, their testimony compromised petitioner's assertion that, assuming a causal relationship, the hepatitis B vaccine more likely than not was the cause of petitioner's CFS in this case.

That Mr. Doe, an accomplished professional, should have to end his career prematurely and suffer the ravages of so debilitating a condition is indeed a tragedy. The undersigned is empathetic to his plight. Such empathy, however, cannot find a demonstration of causation where none exists. It may well be that in the not so distant future, medical science will establish the precise etiology of chronic fatigue syndrome and similar conditions. At this time, however, the court may only consider the existing explanations. In the absence of evidence that the hepatitis B vaccine caused Mr. Doe's CFS, the court comes to a single conclusion: petitioner is *not* entitled to compensation under the Program.

In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgement in accordance herewith.

IT IS SO ORDERED.

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E. LaVon French
Special Master