

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

JOHN DOE 54,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

* No. 99-454V
* Special Master Christian J. Moran
*
* Filed: May 28, 2009
* Issued for Publication: December 22, 2009
*
* Entitlement, hepatitis B, chronic
* fatigue syndrome, lack of records
* created contemporaneously, failure
* to present evidence in timely manner,
* reliability of expert’s theory,
* temporal relationship.

Clifford J. Shoemaker, Shoemaker & Associates, Vienna, VA., for petitioner;
Heather L. Pearlman, United States Dep’t of Justice, Washington, D.C., for respondent.

PUBLISHED DECISION ON ENTITLEMENT*

Petitioner alleges that a hepatitis B vaccine, which he received on September 17, 1998, caused him to suffer an adverse reaction, which petitioner categorizes as chronic fatigue syndrome. A preponderance of the evidence demonstrates that petitioner is not entitled to compensation. The primary, but not only, flaw in petitioner’s proof is that the facts, as found in this decision, do not match the assumptions made by petitioner’s expert.

I. Facts

The parties do not agree that petitioner’s medical records set forth the problems experienced by petitioner. Specifically, petitioner submitted an affidavit, describing problems that are not listed in a medical record created during the periods of time being described in the affidavit. This discrepancy occurs, in part, because petitioner did not see a medical doctor for many years.

* After this decision was filed on May 28, 2009, the petitioner made a timely motion to redact the decision pursuant to 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b). This motion is granted and the petitioner’s name is changed to “John Doe 51.” Except for this footnote, no substantive changes have been made.

This section finds facts based upon the entire record, including the testimony of petitioner. Section III analyzes these facts in the context of the elements petitioner is required to establish.

A. Standards for Finding Facts

The Vaccine Act permits a finding of when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. See 42 U.S.C. § 300aa-13(b)(2) (2006). The preponderance of the evidence standard requires that the Special Master “believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence.” In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. James, Civil Procedure 250-51 (1965)).

In weighing divergent pieces of evidence, contemporaneous written medical records are usually more persuasive than oral testimony. Cucuras v. Sec’y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, compelling oral testimony may be more persuasive than written records. Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); Camery v. Sec’y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (this rule “should not be applied inflexibly, because medical records may be incomplete or inaccurate”); Murphy v. Sec’y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff’d, 968 F.2d 1226 (Fed. Cir. 1992). Whether contemporaneous medical records or later-given oral testimony is more persuasive is a determination that “is uniquely within the purview of the special master.” Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

B. Demeanor

In determining the credibility and persuasiveness of witnesses, special masters may consider the demeanor of the witnesses. Snyder v. Sec’y of Health & Human Servs., 117 F.3d 545, 548-49 (Fed. Cir. 1997); see also Easley v. Cromartie, 532 U.S. 234, 262-65 (2001) (citing Anderson v. City of Bessemer, 470 U.S. 564, 574 (1985)). These determinations are entitled to deference. Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993); see also Leatherbury v. Dep’t of the Army, 524 F.3d 1293, 1304-05 (Fed. Cir. 2008) (reversing decision of Merit Systems Protection Board because the Board failed to defer to credibility determinations made by the administrative judge). Determinations about the credibility and persuasiveness of witnesses “are by nature impressionistic.” Tweten v. Sec’y of Health & Human Servs., 26 Cl. Ct. 405, 410 (1991).

Here, petitioner’s demeanor indicated that he had a less than meticulous concern about the accuracy of his testimony. Describing exactly how long petitioner paused in answering questions and his demeanor is difficult. Nevertheless, petitioner’s overall appearance suggested

that his testimony was not always truthful.

Other aspects increase the concern with the accuracy of petitioner's testimony. His memory fluctuated – he could describe some events in great detail. But, he could not remember at all other events from approximately the same time. This variability suggests that petitioner's memory was selective. In addition, details in his story varied from one account to another. This lack of consistency suggests that the events are not fixed in petitioner's memory. For example, in preparing a chronology (probably in late 1999), petitioner stated that he did not “know exactly the time I started getting symptoms, but it was definite[ly] around” the date he received the hepatitis B vaccination. Exhibit 12. But, in contrast, he testified that the symptoms began within one or two days after receiving the vaccination. Tr. 19, tr. 87. Petitioner did not explain why his recollection, while testifying in 2008, was much more specific than his statement prepared in 1999. Cf. Monsanto Co. v. David, 516 F.3d 1009, 1015 (Fed. Cir.) (holding that finder of fact may consider inconsistencies in witness's testimony when determining the reliability of that witness's testimony), cert. denied, ___ U.S. ___, 129 S.Ct. 309 (2008).

For these reasons, when petitioner's testimony conflicts with other evidence, petitioner's testimony is generally discounted.¹ The findings of fact, set forth below, are drawn primarily from the medical records created contemporaneously with the events being described.

C. Findings of Fact

As mentioned earlier, the parties dispute certain facts about petitioner. These disputes are resolved in this section, which is divided into six periods of time.

¹ The finding that petitioner was not credible does not depend upon his failure to file tax returns. Governments rely upon individuals to comply with tax reporting requirements voluntarily. Petitioner did not. Tr. 128.

Courts have generally considered the failure to file tax returns as having some relevance to the witness's credibility. See Chamblee v. Harris & Harris, Inc., 154 F. Supp. 2d 670, 681 (S.D.N.Y. 2001) (denying motion to exclude evidence because plaintiff's failure to pay taxes “bears directly on her propensity for truthfulness”); but see O'Brien v. Chaparro, No. 05-80342, 2005 WL 6011248 *2 (S.D. Fla. Dec. 8, 2005) (granting motion to exclude evidence about plaintiff's failure to file tax returns on the ground that potential prejudice outweighed probative value for credibility).

However, it is not entirely clear that petitioner was under a legal duty to file a tax return. Conceivably, his status as an immigrant from Australia could affect any obligation to file a tax return. Given that respondent has not pursued this issue in his brief by, for example, citing any laws from either the United States or Australia, that obligated petitioner to file a tax return, Petitioner's failure to file a tax return will not be considered in evaluating his credibility. First American Bank v. Western DuPage Landscaping, Inc., No. 00 C 4026, 2005 WL 2284265 *2 (N.D. Ill. Sep. 19, 2006).

1. Before Vaccination

Petitioner was born on December 25, 1960. Exhibit 23 ¶ 4. He grew up on a farm in Australia. He had a great amount of exercise as a child, participating in sports such as soccer, football, and volleyball. As a child, he had some intermittent problems with allergies. Tr. 8-9.

Petitioner moved to the United States, settling in the area around Los Angeles, California, in 1987. Tr. 49. Petitioner did not submit any medical records for treatment before he received the vaccinations in September 1998. However, petitioner did receive some medical treatment.

In 1992, he had an accident while surfing, resulting in a cut over his eye. Petitioner sought medical attention from a clinic. Tr. 49.

In 1996, petitioner was involved in a car accident in which his back and, possibly, his neck were hurt. (Although petitioner testified that this accident happened in 1994 or 1995, tr. 50; a medical record places the accident in 1996. Exhibit 7 at 2.) Petitioner saw a doctor in Beverly Hills, but could not provide any additional information. Petitioner resolved any possible injuries he had with his regular exercise routine. Tr. 50.

Also, before 1998, petitioner periodically sought treatment from an acupuncturist and a chiropractor. These treatments were to maintain petitioner's health, not due to any particular injury. Tr. 52-53, tr. 152. Again, petitioner did not file any medical records from these providers.

By the summer of 1997, petitioner was earning a living as a personal trainer. Tr. 54. He often trained clients for three to four hours per day. Tr. 15. He had approximately five regular clients. Tr. 54. He did not file any tax returns with the government that could substantiate his income. Tr. 128.

Besides his employment as a personal trainer, petitioner had another professional interest. He was developing a television show. (Eventually, this show was televised as The Aquanauts.) Petitioner did not receive any income for his work on this enterprise until at least July 1998.

In August 1997, an actress asked petitioner to attend the filming of a movie in Borneo, Indonesia. The production company required petitioner to obtain various vaccinations as a condition for his participation. Tr. 15.

2. Vaccinations

Petitioner received vaccinations for tetanus/diphtheria, typhoid, hepatitis A, and Japanese encephalitis on August 28, 1997. On September 3, 1997, petitioner received another dose of the

Japanese encephalitis vaccine and a dose of the IPVE.² Exhibit 2 at 4. Petitioner does not allege that any of the vaccinations listed in this paragraph caused him any harm.

Petitioner received a third dose of the Japanese encephalitis vaccine and his first (and only) dose of the hepatitis B vaccine on September 17, 1997. Exhibit 2 at 4. Petitioner contends that the hepatitis B vaccine caused his subsequent health problems. Pet'r Post-Hearing Br., filed Dec. 18, 2008, at 8. Petitioner does not ascribe any causative role to the Japanese encephalitis vaccine, which is not listed on the Vaccine Injury Table. 42 C.F.R. § 100.3. Incidentally, petitioner did not respond to the hepatitis B vaccine, that is, he did not develop antibodies to the hepatitis B surface antigen. Exhibit 16 at 5.

The parties dispute the state of petitioner's health in the days, weeks, and months immediately following the September 17, 1997 vaccinations. Petitioner provided different accounts of his problems at different times, including in statements prepared for this litigation. Respondent challenged the accuracy of petitioner's testimony and contended that "he is not credible." Resp't Post Hearing Br., filed Jan. 15, 2009, at 24.

Respondent raised many concerns about the accuracy of petitioner's statements. *Id.* at 24-27. At a minimum, respondent's arguments have a facial validity, such that an explanation was expected. Yet, petitioner failed to file a reply within the time permitted. See Order, filed Aug. 20, 2008 (setting deadline for filing reply brief); see also Vaccine Rule 20 (setting default deadlines for filing briefs). Thus, petitioner has left unanswered respondent's questions about the accuracy of his statements.

Respondent's brief set forth inconsistencies among petitioner's statements and also inconsistencies between petitioner's testimony and his actions. One example demonstrates the problem. In petitioner's affidavit, dated Feb. 27, 2006, petitioner asserts that "during the initial stages after the vaccination," he could "barely bend forward over the bathroom sink to brush my teeth due to lower back pain and spasming." Exhibit 24 ¶ 11; accord tr. 92. Petitioner described someone who was in a large amount of pain and who was having difficulty performing a relatively easy physical task.

In contrast, petitioner testified that around the same time, he worked full-time as a physical trainer. He did not reduce the amount of training he did with people. Tr. 59.³ He also

² The meaning of "IPVE" is not clear. It may stand for "inactivated polio vaccine - enhanced."

³ Petitioner did not increase the number of clients during this time. Tr. 24. However, he explained that "There was no real need for it. We also were working heavily on putting the show together." Tr. 126-27; see also tr. 59. Thus, a preponderance of the evidence indicates that the lack of increase in the list of Petitioner's number of clients was not due to any physical limitations for him.

continued to work on developing The Aquanauts television show and obtained a certification in scuba diving. He also traveled to different auditions in the Los Angeles area. Tr. 59-62. These actions show that petitioner's physical abilities were not severely impaired after the vaccinations.

Additional support for finding that petitioner could function relatively normally derives from petitioner's failure to see a doctor during this time. Petitioner stated that he did not seek medical attention. Tr. 62. But, if petitioner were suffering from significant physical impediments, the reasonable expectation is that petitioner would have sought medical attention from a doctor. Petitioner's expert, Dr. Yehuda Shoenfeld, implicitly, recognized the expectation that people suffering from persistent or relapsing fatigue seek medical attention. According to Dr. Shoenfeld, before he sees a patient suffering from chronic fatigue syndrome, the patient has seen many doctors. Tr. 162, tr. 165-66. An expectation that an ill person would seek medical attention is strengthened by the fact that petitioner's livelihood depended upon his work as a physical trainer. Tr. 55. In addition, one explanation for not seeking medical care, a concern about the ability to pay for the medical care such as due to lack of medical insurance, was not present for petitioner. He could have obtained medical attention. Tr. 124-26.

During the hearing, petitioner attempted to explain why he did not seek medical attention. According to him, people from Australia seek medical attention less readily. But, even this attempted explanation makes little sense. He stated:

I think I come from a different culture and a different background that if somebody stepped on a rusty nail here, they would just all freak out, and we would like just clean the wound out and just continue working. It's just a different way of doing stuff. There is no cause for alarm unless there was a cause for alarm. So it just didn't seem -- it was something I noted that I would keep an eye on. If it like persisted that, you know, I would have done something. Absolutely. It was a little concern because of all these other symptoms, but it's just like just weird stuff every now and again. Okay, now it's this, let me pay attention.

Tr. 123. The difficulty with accepting petitioner's testimony is that he testified about having medical problems that allegedly "persisted" and about which he "would have done something." But, petitioner did not.

In terms of seeking medical assistance, the most that petitioner did during the fall 1997 was telephone the doctor who administered the vaccine. A chronology prepared by petitioner indicated that he telephoned the doctor twice. Exhibit 12 at 5.⁴ (Petitioner's testimony that he

⁴ This document, which was probably prepared in June 1999, tr. 84-86; has some assurances of reliability. It was prepared approximately 20 months after Petitioner received the vaccinations. It does not qualify as a document created contemporaneously with the events being

telephoned the doctor three times, tr. 59; is rejected for being inconsistent with a document that was prepared much closer in time to the events in question.)

Overall, the weight of the evidence favors a finding that petitioner's health deteriorated, to a small extent, for a relatively short period of time. Petitioner experienced some soreness at the site where the vaccine was injected into him. Exhibit 24 at 2, tr. 19. It seems logical to consider this soreness a reaction to the vaccine.

Petitioner also experienced a low grade fever, night sweats, joint pain, muscle aches, and headaches. Exhibit 12 (chronology) at 5. A simple summary of these problems is that they were "flu-like symptoms." Exhibit 24 (affidavit) ¶ 9. Dr. Kovner, the doctor who administered the vaccines to petitioner, told him over the telephone that he probably had the flu. *Id.* ¶ 10; tr. 20, tr. 56. A preponderance of the evidence supports a finding that these flu-like symptoms lasted as long as two weeks after the vaccination. Petitioner said that Dr. Kovner told him that if the symptoms lasted longer than a week to call again. Petitioner was having more problems, so that Dr. Kovner said to wait another week. If there were more problems, then petitioner should call again. Tr. 21. Petitioner's failure to seek additional medical attention, such as an in-person visit, suggests that his health improved. Although much of his testimony is internally inconsistent, petitioner did testify that he "could function okay." Tr. 21.

In September 1997, the production company cancelled the trip to Borneo. Tr. 21. As previously explained, petitioner's source of income in the fall 1997 was his work as a personal trainer. Tr. 59.

Another interest was developing The Aquanauts. Tr. 22. Petitioner did a variety of tasks, some of which involved physical exertion. Petitioner did not seek care from a medical doctor during this time. Tr. 62.

Petitioner testified that between September 1997, and January 1998, he was gradually worsening. Tr. 25. However, petitioner's actions during this time contradict his testimony. He continued training other people and continued developing The Aquanauts. He did not see a doctor. It is very difficult to understand how a person with an illness that persisted, let alone worsened, for three months would not seek attention from at least one medical doctor.

described. On the other hand, the formal Federal Rules of Evidence do not restrict the admissibility of evidence in the Vaccine Program. 42 U.S.C. § 300aa-12(d)(2)(B). Petitioner appears to have created the document for purposes of seeking medical care from Dr. Raisen, although this finding is based upon the fact that the document appears in Dr. Raisen's records. Yet, oddly, Petitioner's chronology is the only document from Dr. Raisen's records that was filed as an exhibit in this case. See exhibit 12.

Petitioner usually returns to Australia in December each year. In 1997, he did not return that month. The reason for not returning was that petitioner was working on The Aquanauts. Tr. 25, tr. 63.

3. Trip to Australia - February 1998

In early February 1998, petitioner returned to Australia for vacation. Exhibit 24 ¶ 13; tr. 26. The primary purpose was a vacation to refresh him. Tr. 26, tr. 108-09.

While in Australia, petitioner went to see a chiropractor referred to him by friends. Petitioner filled out a questionnaire in which he requested help for “lower back / knee / spine / neck.” Petitioner did not respond to the question on the questionnaire, which asked about other problems. Exhibit 7 at 2; see also tr. 28; tr. 66-67.

Also, in February 1998, petitioner saw Dr. Skapinker. Dr. Skapinker’s notes are short (only about two dozen words) and illegible. Exhibit 16 at 4. Petitioner testified that he told Dr. Skapinker that he was feeling tired, having pain in his joints, and having pain in his back. Tr. 27; see also exhibit 16 at 1. Petitioner also testified that he told Dr. Skapinker that he believed that one of the vaccines caused his health problems. Tr. 64. Dr. Skapinker recommended an X-ray and blood tests. Exhibit 12 at 5; tr. 27. The X-ray showed that petitioner had spondylolisthesis⁵ in his lumbar spine. Exhibit 7 at 3. The results from the blood tests were apparently normal or close to normal, although petitioner did not create antibodies to the hepatitis B surface antigen. Exhibit 16 at 5-6. Petitioner testified that Dr. Skapinker believed that he had the flu. Tr. 65.

Petitioner remained in Australia until March 8, 1998. Exhibit 12 at 6.

4. Return to United States - March 1998

According to petitioner, the trip to Australia did not reinvigorate him. He felt the same flu-like symptoms, and also felt lightheaded. Tr. 29-30; exhibit 12 at 6.

In the spring 1998, petitioner was training three clients. He also went scuba diving periodically. Tr. 70. He also was working on trying to develop The Aquanauts. His tasks appear to have been less physical than in the previous fall. In the spring 1998, he met with people either by telephone or in person. Tr. 71. Petitioner explained that he could perform activities associated with his work because he was saving his energy by not performing other tasks. Tr. 30.

The situation described by petitioner is odd because from March 1998 to July 1998, petitioner did not see any doctor. He maintains that, for at least some time, he was able to work

⁵ Spondylolisthesis is defined as a “forward displacement (olisthy) of one vertebra over another, usually of the fifth lumbar over the body of the sacrum, or of the fourth lumbar over the fifth, usually due to a developmental defect in the pars interarticularis.” Dorlands at 1743.

only from his bed. Tr. 31. But, it is reasonable to expect that a person with health so poor that he cannot leave his bed would seek medical attention.

The vagueness in some aspects of petitioner's testimony makes crediting his testimony difficult. For example, petitioner stated that he was "always researching and talking to people in the know to find out anybody who might know something about" his health problems in general, and a link to the vaccines specifically. Tr. 33; accord tr. 68-69. But, when asked to identify these "people in the know" with whom he spoke, petitioner could not. Tr. 68-69. Petitioner admits that "he didn't go to doctors. . . . [He] would do all the research first." This approach is very strange. People consult doctors because doctors have learned about medicine.

A preponderance of the evidence supports the finding that between March and July 1998, petitioner felt flu-like symptoms at least once. He was not continuously fatigued, although he may have experienced some episodes of fatigue.

5. July 1998

In July 1998, two events of some consequence happened. The Aquanauts was picked up by a production company and petitioner saw a chiropractor.

The Aquanauts did not progress as petitioner had hoped. An intermediary for the Discovery Channel, Village Roadshow, purchased The Aquanauts in July 1998. Tr. 70, tr. 138-39. In doing so, petitioner surrendered any rights he possessed in the show to Village Roadshow. The other people with whom petitioner had worked in developing The Aquanauts were retained and received credit (and royalties). Petitioner appeared disappointed in being excluded from the continued development of The Aquanauts. Tr. 138-42.

Around this same time, a marine biologist recommended that petitioner see a chiropractor, Edward Wagner. Tr. 32, tr. 68. Petitioner told Dr. Wagner that he was "very healthy until Sept 97, had 7-8 vaccinations and started having low grade fevers and increasing fatigue." Exhibit 20 at 4. Dr. Wagner's notes begin with a notation "chronic fatigue synd[rome]" - Due to vaccines - Sept 1997." Exhibit 20 at 2. The basis for Dr. Wagner's notation is not clear. No evidence was presented to establish that chiropractors generally or Dr. Wagner specifically possess the professional training to diagnose chronic fatigue syndrome. As discussed in section III.B.1.a below, a medical doctor would properly diagnose chronic fatigue syndrome only after excluding other possible causes of the patient's symptoms. No evidence indicates that Dr. Wagner followed this diagnostic procedure. Dr. Wagner's plan appears to be recommending the use of homeopathic medicines. Tr. 33; see also exhibit 20 at 3.

6. More Recent Doctors' Visits

In 1999, petitioner saw Beverly Heller, whose letterhead identifies her as a practitioner of traditional Chinese medicine. The letterhead also states that Ms. Heller is a "C.A. and M.Ac.,"

probably meaning “certified acupuncturist” and “masters in acupuncture.” Petitioner reported that he wanted “to be healed of chronic fatigue – Candida – adverse reaction to the vaccines – allergies.” Exhibit 3 at 2. Ms. Heller’s record of treatment of petitioner is difficult to understand.

Petitioner saw Dr. Shera Raisen at some point in the latter half of 1999.⁶ Tr. 36. Petitioner called her a “medical doctor,” who took a holistic approach to medicine. Tr. 37. Dr. Raisen’s records add almost nothing to the case. The records contain the chronology prepared by petitioner, but nothing else. There are no notes from treatments. There are no letters. There is not a diagnosis or a plan for treatment. Exhibit 12.

In April 2001, petitioner saw Dr. Kevin Cahill, a specialist in tropical diseases, in New York City. Petitioner’s stool was tested, but the results are not included in the record. Exhibit 19. Petitioner was in New York City only temporarily to assist the same actress that he was supposed to assist in Borneo years earlier. Tr. 73-74, tr. 118.

The medical records suggest that in the middle of 2001, petitioner returned to Australia. Except for Dr. Braun, the doctors who cared for petitioner after April 2001 and whose records were filed reside in Australia. Although petitioner testified that he returned to Australia in 2004, tr. 40, tr. 118; his recollection is poor. Tr. 117 (“the dates are pretty blurry for me.”).

In October 2001, petitioner saw Dr. Ranjit Thomas of the Rouse Hill Medical Centre in Australia. The purpose of his treatment with Dr. Thomas is not explained in the record. Petitioner filed only the results of laboratory tests, not any notes or reports from Dr. Thomas. Exhibit 17, tr. 75. In addition, petitioner did not file any records from Rouse Hill.

In November 2002, petitioner saw Dr. Lindsay Gazal, a general physician in Sydney, Australia. Tr. 39; exhibit 18. Petitioner’s treatment with Dr. Gazal is relevant to whether petitioner satisfies the criteria for suffering from chronic fatigue syndrome. See section III.B.1.b.

In approximately May 2003, petitioner saw Dr. Braun at an urgent care facility in Hawaii. He was in Hawaii because he was helping another actor train for a movie role. Tr. 76. The particular reason that petitioner saw Dr. Braun is also difficult to understand, but the history notes a long history of “CF” and other conditions that are also difficult to read. Exhibit 5. Dr. Braun prescribed antidepressants. Tr. 104.

In June 2004, petitioner saw Dr. Peter Aftanas. Exhibit 21. He specializes in acupuncture and Chinese herbs. Pet’r Status Rep’t, filed Feb. 21, 2006.

⁶ The inference that Petitioner saw Dr. Raisen in the latter half of 1999 comes from the fact that Dr. Raisen’s records contains a chronology that ends in June 1999. Exhibit 12 at 6.

Petitioner also stated that a roommate from Redondo Beach referred him to Dr. Raisen. Tr. 37. Petitioner was living in Redondo Beach in 1999. Exhibit 14 at 6; tr. 114.

In 2005, petitioner saw Dr. Gluck. Exhibit 15. Dr. Gluck referred petitioner to Dr. Paul Ameisen. Dr. Ameisen appears to be a doctor who recommends taking various nutritional supplements to cure illnesses. Exhibit 13, tr. 73, Pet'r Status Rep't, filed Feb. 21, 2006.

Today, petitioner feels better but not 100 percent recovered. Tr. 47, tr. 149. His source of income is inheritance. Tr. 142.

D. Commentary on Evidence

The quality of information about petitioner's medical history is poor. Two factors contribute to this state.

First, petitioner may be a person – for whatever reason – who does not see doctors often. To some extent, this attitude may explain why there is relatively little information about petitioner's health before he received the vaccinations in 1997. After the vaccinations, which is when petitioner alleges that he became seriously ill, petitioner's reluctance to see doctors is difficult to square with his purported state of health. People who are sick usually see doctors, because doctors can make them feel better. While there may be some reasons for a sick person not to see a doctor, such as an inability to pay for medical care or a mental illness that prevents the person from seeking care, petitioner has not alleged that he could not see a doctor.⁷ See Boley v. Sec'y of Health & Human Servs., 86 Fed. Cl. 294, 302-03 (2009) (affirming special master's determination that an adverse reaction to a vaccine did not last six months when the petitioner did not see a doctor for periods of time).

Second, petitioner – and his attorney – did a poor job of collecting information about his health. Represented by an attorney, petitioner filed his petition on July 13, 1999. This date is near the end of the time permitted to file claims that a hepatitis B vaccination caused an injury before August 6, 1997. See 63 Fed. Reg. 25777 (May 11, 1998).

When petitioner filed his petition, he did not comply with 42 U.S.C. § 300aa-11(c), which requires medical records and other information to be filed with the petition. The failure to file medical records with the petition can be excused because petitioner's attorney may have believed that a petition was required to be filed before August 6, 1999.⁸ If petitioner filed his

⁷ In response to a leading question from his attorney, petitioner indicated that he did not see doctors because they could not help him. Tr. 38. This testimony is not credible. Petitioner did not see doctors with any frequency after the vaccinations. Petitioner cannot say that the doctors were not effective when petitioner did not give any doctor much opportunity to care for him.

⁸ Actually, because petitioner alleged that the September 17, 1997 hepatitis B vaccination caused him an adverse reaction, his injury must have developed after August 6, 1997. Thus, the period for filing a petition was not set forth in the notice published in the Federal Register.

petition after the expiration of the statute of limitations, this Court would lack jurisdiction to adjudicate his claim. Brice v. Sec’y of Health & Human Servs., 358 F.3d 865 (Fed. Cir. 2004). The process of collecting medical records often takes two months after the request for medical records is sent. If petitioner first consulted an attorney in July 1999 (and some evidence shows this to be true, exhibit 16 at 1-3), petitioner was justified in filing the petition without medical records.

This justification does not extend to the failure to file an affidavit from petitioner. Petitioner was knowledgeable about his health from September 1997, when he was vaccinated, to July 1999, when he filed his petition. Petitioner could have prepared an affidavit in July 1999, to support his petition. The affidavit would have the advantage of being prepared closer in time than any affidavit prepared later. A well-prepared affidavit would explain what symptoms petitioner was experiencing, when he first started to experience those symptoms, how long those symptoms lasted, whom petitioner has seen for his problems, and what those doctors told petitioner. Petitioner’s case is weaker because he failed to file an affidavit with, or shortly after, his petition.

At best, petitioner prepared a questionnaire for Bonnie Dunbar on June 22, 1999. Petitioner lists approximately 20 different problems, including fatigue, that began “almost immediately” after the hepatitis B vaccination. Exhibit 14 at 3. This questionnaire, which petitioner filed more than six years after he prepared it, on January 17, 2006, does not replace the need for an affidavit. Dr. Dunbar’s questionnaire is relatively cursory. It does not ask petitioner to explain when each symptom began. It also does not ask petitioner to explain the duration of the symptoms.

The lack of factual development appears to be exacerbated by a delay in obtaining medical records. See Pet’r Status Rep’t, filed June 18, 2004 (describing efforts to obtain medical records). It appears likely that petitioner delayed obtaining medical records. For example, petitioner signed an authorization for Dr. Raisen to produce records on July 16, 2003. Exhibit 12 at 3. Petitioner’s attorney actually issued the request on May 17, 2004, ten months later. Exhibit 12 at 1.⁹

The delay in requesting records seems to have caused a loss of information. For example, before petitioner received the vaccinations, he was in a car accident for which he received medical treatment for whiplash. Exhibit 7 at 2, tr. 50-51, tr. 124. However, petitioner did not file any medical records from this doctor. One reason may be that petitioner could not remember

⁹ Petitioner’s attorney stated that obtaining medical records from Australia was difficult. Pet’r Status Rep’t, filed Aug. 20, 2004. Except for Petitioner’s treatment in February 1998 with Dr. Skapinker and the chiropractor, the records from Australia are relatively less important. Petitioner began seeing doctors in Australia many years after he received the hepatitis B vaccine. Therefore, these records are less likely to contain meaningful information about Petitioner’s symptoms in the fall of 1997.

the name of the doctor. But, if petitioner submitted the document referencing this accident earlier (exhibit 7 was filed in June 2004), then petitioner's memory would have been better.

Furthermore, records from some medical care providers appear incomplete. For example, the record for Dr. Cahill is only a two-page form to claim health insurance benefits. Exhibit 19. The record for Dr. Thomas is only a report on blood tests, which runs six pages. Exhibit 17. Petitioner did not file other documents that commonly appear in a doctor's file, such as a patient intake form, the doctor's handwritten notes, a nurse's handwritten notes or a dictated report from the doctor. The same concern about the completeness of records applies to the records from Dr. Raisen. Exhibit 12. Notably, both Dr. Cahill and Dr. Raisen work in the United States, not Australia. Thus, petitioner's counsel should not have had much difficulty in obtaining complete medical records from these providers.

The problem with obtaining information that could have been available extends to subjects other than medical records. For example, petitioner recorded his schedule for clients to train in an appointment book. Tr. 111-12. But, petitioner did not possess this book in 2008. Id.; see also Pet'r Status Rep't, filed Oct. 20, 2008. To date, it has not been filed. The information in the appointment book could have been relevant to show that the number of petitioner's clients decreased, a fact that could support an inference that the decrease was due to a decline in health. The information in the appointment book could also have been relevant to establishing the amount of compensation by providing a measure of his income. This secondary source of information about income is especially important because petitioner did not file any tax returns. Tr. 128.

Eventually, petitioner did obtain statements regarding his medical condition from some associates, which he filed on June 25, 2004. Exhibits 8-10. These are dated between March and May 2002. (The date on which they were signed raises a separate question of why they were actually filed about two years later.) These statements are not helpful.

For example, the statement of Janice Hirsch stated that petitioner's condition changed in September 1997. Ms. Hirsch noted that "he couldn't rock climb, he couldn't hike, he couldn't surf." Exhibit 8. Ms. Hirsch's assertion stands in contrast with petitioner's testimony that in the fall of 1997, he performed various physical tasks, such as scuba diving, to develop The Aquanauts. Tr. 59-62. Scuba diving is probably as physically taxing as surfing, and, given that scuba diving takes places underwater, scuba diving is probably more challenging. Thus, Ms. Hirsch's statement is contradicted by petitioner's own testimony.

Ms. Hirsch failed to explain why she believes that petitioner's health deteriorated in September 1997, as opposed to September 1998. Her ability to recollect the distinction between different periods of time would have been important to explain, especially because she wrote her affidavit more than four years after petitioner received the vaccinations. If petitioner had obtained an affidavit from Ms. Hirsch in 1999, shortly after he filed his petition, there would be less question about the accuracy of Ms. Hirsch's memory.

Similarly, a statement from Robert Pecel is not helpful. Mr. Pecel states that he was away from petitioner from 1997-2003, which is the time most pertinent to the issues raised in this case. Exhibit 30.

The relative weakness in the statement by Ms. Hirsch and in the statement by Mr. Pecel contrasts with another statement from Gia Carides. Ms. Carides asserted that petitioner “was suffering from a lack of energy, back pain, and general fatigue.” Ms. Carides placed these problems in connection with a movie that she was filming. Ms. Carides also recounted another time in which petitioner trained her as a special favor because she was getting married in 1998. Exhibit 29. Although Ms. Carides wrote her statement in January 2007, her reference to a particular movie as well as the date of her wedding anchors her statements much more powerfully than the unexplained statements by Ms. Hirsch.

Nevertheless, despite Ms. Carides’s statement having some value, it is not persuasive. These reasons for this finding are explained in section III.B.1.b, below.

II. Procedural History

Petitioner filed his petition on July 13, 1999. He did not file any medical records with his petition.

On August 30, 2001, a special master ordered petitioner to file medical records by March 29, 2002, or to face dismissal for lack of prosecution. On March 1, 2002, petitioner filed two medical records, including a document evidencing his vaccinations. In substance, the two records totaled fewer than 10 pages. Exhibit 1-2.

In February 2003, the special master stayed this case. Although not reflected on the docket, the stay reflected efforts to develop a method to resolve the numerous cases in which petitioners alleged that the hepatitis B vaccine caused them an injury. Ultimately, these attempts did not succeed.

Petitioner periodically filed additional medical records in 2004 and 2005. In 2006, the pace of litigation increased. Petitioner filed 10 exhibits on January 17, 2006. He filed an amended affidavit from himself on March 28, 2006.

Petitioner submitted a report and curriculum vitae from Dr. Yehuda Shoenfeld on October 24, 2006. Exhibits 25-26.

In January 2007, respondent asserted that an independent medical examination would be helpful in determining petitioner’s “current condition.” Resp’t Status Rep’t, filed Jan. 19, 2007. Petitioner saw a doctor, Stuart Silverman, in Beverly Hills, California on April 18, 2007. Dr. Silverman specializes in rheumatology. Respondent filed Dr. Silverman’s report on July 3, 2007,

as exhibit A. Dr. Silverman requested additional information, specifically the results of a sleep study and also that petitioner have an evaluation of his immune system. Exhibit A at 9.

Petitioner reported that he has not obtained “the sleep apnea test or any additional records from Dr. Lindsay Gazal. Efforts are still being made to get a copy of this test, but it is quite possible that these records are no longer available.” Pet’r Status Rep’t, filed Sep. 6, 2007. As mentioned earlier, petitioner saw Dr. Gazal in Sydney, Australia, starting in November 2002. Exhibit 18.

Respondent filed the report and curriculum vitae of Dr. Raoul L. Wientzen on December 20, 2007. Exhibit B-C. Dr. Wientzen questioned whether petitioner has been properly diagnosed as having chronic fatigue syndrome. Dr. Wientzen also stated that he believed that the hepatitis B vaccine did not cause petitioner’s health problems, regardless of the name given to them. Exhibit B at 5.

A hearing was scheduled for August 18, 2008, during an unrecorded status conference. In this same status conference, the special master expressed concerns, again, about the completeness of the medical records in the case. Both parties filed a memorandum in advance of the August 18, 2008 hearing.

At the August 18, 2008 hearing, three witnesses, petitioner, Dr. Shoenfeld, and Dr. Wientzen, testified. Following the hearing, both parties were ordered to file additional documents, primarily medical articles. Each party filed one brief after the hearing. Although petitioner was entitled to file a reply brief, he has not done so. Thus, the case is ready for adjudication.

III. Analysis

A. Standards for Adjudication

To receive compensation under the Program, petitioner must prove either: (1) that he suffered a “Table Injury”--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to the hepatitis B vaccination, or (2) that he suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, petitioner does not claim that he suffered a table injury. Pet’r Post Hearing Br. at 13. Thus, he must prove causation in fact.

A petitioner may not be given an award through the Vaccine Program based solely on the petitioner’s claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record. 42 U.S.C. § 300aa-13(b)(1). This universe necessarily includes “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the

petitioner's illness." 42 U.S.C. § 300aa-13(b)(1)(A). Here, because the medical records do not uniformly support petitioner's claim, petitioner has offered the opinion of Dr. Shoenfeld. Respondent countered with an opinion from Dr. Wientzen.

In this case, the evidence includes conflicting opinions from each side's experts. The persuasiveness of the experts must be evaluated and the testimony of one side's expert may be rejected when a reasonable basis supports such a rejection. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). A decision about the persuasiveness of an expert is virtually not reviewable on appeal. Energy Capital Corp. v. United States, 302 F.3d 1314, 1329 (Fed. Cir. 2002); Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

To prove causation in fact, a petitioner must establish at least three elements. The petitioner's

burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

B. Temporal Relationship

Althen requires that petitioners establish, by a preponderance of the evidence, that there is a proximate temporal relationship between vaccination and injury. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). In this case, petitioner has not met his burden on this factor. This failure to establish a temporal relationship means that petitioner is not entitled to compensation. Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1358-59 (Fed. Cir. 2006).

Petitioner presented relatively little information to support a finding that the temporal relationship is appropriate. On this point, petitioner's brief contains 24 words. The entirety of the brief on this point is: "Dr. Shoenfeld stated that the timing of his flu-like symptoms was appropriate and so was the onset of his other symptoms. Tr. at 194-195." Pet'r Post Hearing Br. at 16. By way of contrast, respondent's brief regarding timing runs more than three pages. Resp't Post Hearing Br. at 21-24. Of course, the length of the brief does not necessarily determine the quality or the persuasiveness of the argument. But, here, the shortness of

petitioner's brief shows that it is conclusory and lacks an appreciation for the challenges in determining whether there is an appropriate temporal relationship.

For analysis, the temporal prong can be divided into two different components. The first part is when did the condition for which the petitioner seeks compensation begin. The second component is whether the onset falls within the time medical science believes is appropriate. The determination of when the condition began, the first element, will vary by petitioner. Each petitioner develops symptoms at different times. The second element, regarding the appropriate window, should remain relatively consistent across cases involving the same vaccine and the same disease.¹⁰ Here, petitioner's proof regarding both aspects of the temporal relationship prong is not persuasive.

1. When Did Petitioner's Disease Begin

Petitioner seeks compensation for suffering from chronic fatigue syndrome. Pet'r Post Hearing Br. at 8.

a. Criteria for Diagnosing Chronic Fatigue Syndrome

Determining when a person began to experience chronic fatigue syndrome is somewhat difficult. "Chronic fatigue is defined as self-reported persistent or relapsing fatigue lasting 6 or more consecutive months." Exhibit 27 (Keiji Fukoda et al., The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study, 121 Ann. Intern. Med. 953, 954 (1994)) at 115. Dr. Shoenfeld agreed that one symptom of chronic fatigue syndrome is fatigue lasting more than six months. Tr. 163.

In addition to chronic fatigue, a person fulfills the diagnostic criteria for chronic fatigue syndrome by having four or more of eight different problems lasting for more than six months. The list of eight problems is (1) impaired memory or concentration, (2) sore throat, (3) tender cervical or axillary lymph nodes, (4) muscle pain, (5) multi-joint pain, (6) new headaches, (7) unrefreshing sleep, and (8) post-exertion malaise. Exhibit 27 (Fukoda at 155) at 116. Dr. Shoenfeld appears to agree that these additional problems are part of chronic fatigue syndrome. Tr. 164 (mentioning problems in lymph nodes and unrefreshing sleep).

The presence of chronic fatigue, by itself, and the presence of four of the eight other factors are not sufficient to qualify as chronic fatigue syndrome. To diagnose chronic fatigue syndrome properly, the doctor must exclude other medical conditions "that may explain the presence of chronic fatigue, such as untreated hypothyroidism, sleep apnea, and narcolepsy, and

¹⁰ If medical science believes that a particular vaccine (for example, hepatitis B vaccine) can cause a particular reaction (for example, demyelination), and if medical science believes that the demyelination will occur between 14 and 28 days after vaccination, then this 14-28 day window should be the same in all cases involving the hepatitis B vaccine and demyelination.

iatrogenic conditions such as side effects of medication.” Exhibit 27 (Fukoda at 955) at 116. Dr. Shoenfeld’s opinion about sleep apnea was a little unclear. Dr. Shoenfeld seemed to agree that a person with sleep apnea would not qualify as suffering from chronic fatigue syndrome, although Dr. Shoenfeld seemed to resist the suggestion that a particular test must be performed to rule out sleep apnea. Tr. 169, tr. 201-3, tr. 206. Dr. Wientzen stated that sleep apnea is a condition that rules out the diagnosis of chronic fatigue syndrome. Tr. 252.

b. Petitioner’s Experience

As suggested by its name, a primary criterion for chronic fatigue syndrome is a problem with fatigue. When petitioner began to experience fatigue is far from clear. As explained at length in section I above, petitioner has not presented much probative evidence about his health.

A preponderance of the evidence supports a finding that petitioner was not suffering chronic fatigue in February 1998. During this month in Australia, petitioner saw Dr. Skapinker and a chiropractor. The chiropractor’s records indicate that petitioner was concerned about back pain and knee pain. Petitioner did not tell the chiropractor that he was having trouble with fatigue. Exhibit 7 at 2; see also tr. 28; tr. 66-67.

The lack of a notation in the chiropractor’s records that petitioner was suffering from fatigue creates an inference that he was, in fact, not suffering from fatigue. Patients are likely to tell health care providers all their problems because providing as complete information as possible is likely to increase the effectiveness of any assistance given by the health care provider. Cucuras v. Sec’y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Special masters may reject oral testimony that a particular problem existed when the problem is not included in a medical record created contemporaneously. Snyder v. Sec’y of Health & Human Servs., 117 F.3d 545, 547-49 (Fed. Cir. 1997).

Petitioner (or more precisely, petitioner’s attorney) did relatively little to assemble the different pieces of evidence providing information about when petitioner experienced (or did not experience) fatigue. Petitioner’s brief summarized the medical records. But, the brief failed to account for petitioner’s activities that suggest a level of health that is inconsistent with petitioner’s assertion of chronic fatigue. Pet’r Post Hearing Br. at 2-8. As to when petitioner first developed persistent or relapsing fatigue, Dr. Shoenfeld provides no insights. He explained that it does not matter to him when the fatigue began. Tr. 221.

Some evidence supports a finding that petitioner began to experience fatigue in the fall of 1997. In chronological order beginning with the earliest-created record, the list includes:

- 1) Petitioner’s statement to Dr. Wagner in July 1998. Exhibit 20 at 2, 4.
- 2) Petitioner’s response to Bonnie Donbar’s questionnaire, completed on June 22, 1999. Exhibit 14 at 3.
- 3) Petitioner’s letter to Dr. Skapinker, dated June 23, 1999. Exhibit 16 at 1.

4) Statement by Gia Carides, signed Jan. 12, 2007. Exhibit 29.

The best source of information is Dr. Skapinker's records because Dr. Skapinker was the first doctor petitioner saw after receiving the hepatitis B vaccination. But, Dr. Skapinker's records do not assist petitioner. They are unreadable. Exhibit 16 at 4. Petitioner bears the burden of submitting medical records. 42 U.S.C. § 300aa-11(c)(2). Petitioner does not fulfill this burden by filing medical records that are not understandable. Petitioner should have requested Dr. Skapinker to dictate his notes into a written report – a task that numerous petitioners have used previously.

Petitioner's testimony about the information he provided during his visit with Dr. Skapinker is not credited. Although petitioner said he told Dr. Skapinker that he was feeling tired, this testimony is not persuasive. Petitioner's activities are also not consistent with someone who was allegedly experiencing continuous fatigue. Before traveling to Australia, petitioner was active in developing The Aquanauts television show. He also continued to work with his clients as a personal trainer. While in the United States, petitioner did not seek any medical attention. These factors suggest that in the months before petitioner went to Australia, he was relatively healthy. Petitioner may have had periodic episodes of fatigue, like virtually all adults have from time to time. But, isolated instances of fatigue differ from the persistent or relapsing fatigue that is a part of chronic fatigue syndrome. Additionally, as discussed in section I.B above, petitioner's general demeanor suggested that his testimony was less than scrupulous.

These reasons, by themselves, are sufficient to reject petitioner's testimony about his conversation with Dr. Skapinker. Separately, a policy reason supports rejecting petitioner's testimony. Petitioners should not be allowed to disregard their obligation to file medical records and to replace contemporaneously created documents with oral testimony. Such an approach would allow petitioners to manipulate the information filed with the court.

The next piece of evidence that minimally supports a finding that petitioner was experiencing chronic fatigue is his statements to a chiropractor, Dr. Wagner, in July 1998. This statement has some probative value because petitioner was communicating in July 1998, about events that took place after September 1997. Fewer than eleven months elapsed. So, petitioner's memory should be stronger than at times more distant from September 1997. On the other hand, ten months is not such a short amount of time that it qualifies as "contemporaneous" statement.

In June 1999, petitioner made two writings relevant to his assertion of chronic fatigue. In requesting records from Dr. Skapinker, petitioner stated that Dr. Skapinker had seen him in February 1999, for, among other problems, fatigue. Exhibit 16 at 1. Petitioner also told Bonnie Dunbar that he experienced several problems, including fatigue, immediately after his hepatitis B vaccination. Exhibit 14 at 3.

These statements hold only minimal persuasive value. They were not created contemporaneously, so their accuracy depends, in part, on petitioner's memory. Petitioner's

memory is not accurate. Tr. 46. In addition, petitioner's statements to Dr. Skapinker and Dr. Dunbar were not given for the purpose of seeking medical attention. The statement to Dr. Skapinker was in a request for documents to prosecute the present litigation. Bonnie Dunbar is not a medical doctor, but has testified on behalf of people seeking compensation in the Vaccine Program. E.g., Stevens v. Sec'y of Health & Human Servs., No. 99-594V, 2006 WL 659525 *13-14 (Fed. Cl. Spec. Mstr. Feb. 24, 2006). Because it appears that petitioner's statements in June 1999 were prepared as part of this litigation, they are not as unbiased as statements given to doctors when seeking medical assistance. See Buchanon v. Nicholson, 451 F.3d 1331, 1337 (Fed. Cir. 2006) (finder of fact may consider bias in evaluating statements not supported by documents created contemporaneously); Interstate General Gov't Contractor, Inc. v. West, 12 F.3d 1053, 1060 (Fed. Cir. 1993) (affirming rejection of conclusory, self-serving assertion from contractor's witness that was contradicted by other evidence).

The final piece of evidence having some support for petitioner's assertion that he was experiencing chronic fatigue close in time to the September 17, 1997 hepatitis B vaccination is the statement by Ms. Carides. She stated that she observed petitioner being fatigued in 1997 and 1998. Exhibit 29.

Collectively, there is not sufficient evidence to support a finding that petitioner suffered chronic fatigue in 1997. Two facts predominate. First, petitioner did not seek medical attention. If petitioner actually suffered from the fatigue found in patients with chronic fatigue syndrome, he probably could not leave his bed. There is a qualitative difference between episodes of fatigue (or tiredness) that everyone experiences and the persistent and deep fatigue that characterizes chronic fatigue syndrome. Petitioner may have had the former, but he did not have the latter. The second fact relates to the first fact. There is almost no evidence that petitioner was physically unable to perform his duties in the latter portion of 1997. An abundance of evidence shows the opposite – petitioner continued to train people. He took on the additional (unpaid) responsibilities in developing The Aquanauts. He went scuba diving. He traveled to Australia. A person with debilitating fatigue could not perform these activities. In this sense, petitioner's actions, which show a relatively healthy, physically active person, are more meaningful than petitioner's words.

Consequently, a preponderance of the evidence supports a finding that petitioner was not experiencing persistent or relapsing fatigue between September 1997 and January 1998. This finding necessarily means that any persistent or relapsing fatigue started after January 1998.

For reasons discussed in the following two sections, determining if petitioner ever fulfilled the diagnostic criteria for chronic fatigue syndrome is not necessary. Although petitioner claims compensation for chronic fatigue syndrome, Pet'r Post Hearing Br. at 8; respondent disputed whether petitioner actually suffers from that condition. Resp't Post Hearing Br. at 11-14.

The evidence about petitioner's diagnosis of chronic fatigue syndrome is sparse. Petitioner is not sure when a medical doctor first diagnosed him as suffering from chronic fatigue syndrome. Tr. 72. Dr. Shoenfeld examined petitioner in 2006, and concluded that petitioner was suffering from chronic fatigue syndrome. Tr. 167-68; tr. 202-06; exhibit 25 at 10.¹¹ Dr. Shoenfeld ruled out another possible cause of petitioner's chronic fatigue, sleep apnea, because petitioner told him that he had previously had a sleep study. Similarly, a doctor retained by respondent to examine petitioner, Dr. Silverman, also determined in 2007 that petitioner was suffering from chronic fatigue syndrome. But, inconsistently, Dr. Silverman reached this conclusion without reviewing a sleep study. Exhibit A at 8.¹² Dr. Wientzen could not state whether petitioner suffered from chronic fatigue syndrome because petitioner did not have a comprehensive medical examination, which could have identified other causes of his fatigue. Tr. 251-52; exhibit B at 3.

The evidence about the sleep study is, again, limited. Petitioner testified that Dr. Lindsay Gazal tested him for sleep apnea in 2003 or 2004. Tr. 39, tr. 105-07. So, the results from a sleep apnea study should be included in Dr. Gazal's records.

Dr. Gazal's notes, which are a little difficult to read, show that petitioner first visited Dr. Gazal in November 2002. Petitioner saw Dr. Gazal periodically in 2002 and 2003. In one visit, which may have been on July 28, 2003, Dr. Gazal notes that petitioner has been having difficulty sleeping. The last line for this entry appears to say "sleep apnea." Exhibit 18 at 2. But, there are no results from any sleep study.

¹¹ Dr. Shoenfeld's report did not reveal that he had examined petitioner in person. This fact should have been disclosed in the report.

After Dr. Shoenfeld stated that he examined petitioner, petitioner was ordered to produce Dr. Shoenfeld's notes. Order, filed Aug. 20, 2008. However, Dr. Shoenfeld informed petitioner's attorney that he had lost his notes. Exhibit 38.

Doctors, of course, should care for their notes of treatment and not lose them. The obligation to retain notes is, if possible, higher for doctors who are retained to testify in court. An expert's failure to produce relevant materials could cause adverse consequences for the party retaining him or her. United Medical Supply Co., Inc. v. United States, 77 Fed. Cl. 257, 263-64 (2007); see also Trigon Insur. Co. v. United States, 204 F.R.D. 277, 286-287 (E.D. Va. 2001).

It is assumed that Dr. Shoenfeld's loss of notes relating to petitioner was accidental and an experience that will not be repeated.

¹² Respondent observed that both parties questioned Dr. Silverman's knowledge about chronic fatigue syndrome. Resp't Post Hearing Br. at 13 n.7.

Respondent is encouraged to consider the qualifications of a particular doctor before retaining that doctor to examine a petitioner. A more thorough review of Dr. Silverman's qualifications could have obviated any arguments about his expertise.

Whether petitioner was, in fact, tested for sleep apnea is, in the final analysis, not relevant to determining whether he is entitled to compensation. Even if petitioner's version is accepted, his visits to Dr. Gazal suggest that he may have been suffering from persistent fatigue perhaps as early as November 2002. Even if any fatigue in November 2002 were the first manifestation of chronic fatigue syndrome, which might have been diagnosed in July 2003, fatigue in November 2002 is outside of the temporal window expected by medical science. Thus, a factual determination of when petitioner started having persistent or relapsing fatigue is not necessary. For purposes of this case, it is sufficient to find that petitioner was not having fatigue in September 1997 to January 1998.

2. What is the Time Expected by Medical Science

Dr. Shoenfeld's testimony about the appropriate temporal relationship was inconsistent, somewhat contradictory, and, ultimately, not persuasive.

Initially, Dr. Shoenfeld's report stated that "One month after receiving the vaccine [petitioner] entered into a long phase (9 years) of CFS represented by the classical clinical manifestations. . . . The time relationship in this case is remarkable to indicate that the CFS was induced by the vaccine." Exhibit 25 at 4-5. The basis for Dr. Shoenfeld's assertion that within one month of the September 1997 vaccinations, petitioner was displaying the "classical clinical manifestations" of chronic fatigue syndrome is unclear. The primary source of information discussed in Dr. Shoenfeld's report is the set of three letters written in 2002. Exhibit 25 at 3. However, as explained in section I.D. above, these letters are not persuasive. Dr. Shoenfeld did not discuss petitioner's failure to seek assistance from any medical doctor when he was allegedly experiencing the classical clinical manifestations of chronic fatigue syndrome.

Regardless of why Dr. Shoenfeld believed that petitioner was experiencing problems within one month of the vaccination, it is implicit that Dr. Shoenfeld believes that one month is an appropriate temporal relationship. Dr. Shoenfeld testified that a reasonable time to expect an adverse reaction to the hepatitis B vaccine to occur is "one month to three months." Tr. 211. But, on further questioning, Dr. Shoenfeld reduced the reasonable amount of time to as little as one week because petitioner had received other vaccinations around the same time as he received the first dose of the hepatitis B vaccine. These other vaccines, according to Dr. Shoenfeld, contained a similar adjuvant as the hepatitis B vaccine. Tr. 211-12, tr. 231-33, tr. 238.

The lack of a clarity about the expected time for a reaction to the hepatitis B vaccine reduces the persuasive value of Dr. Shoenfeld's opinion. How soon a person would experience an adverse reaction to the hepatitis B vaccine appears to be a question whose answer would be a relatively defined range. For example, the Vaccine Injury Table establishes a presumption that a measles vaccine causes thrombocytopenic purpura when the thrombocytopenic purpura develops within 7-30 days after the measles vaccination. 42 C.F.R. § 100.3 ¶ V.A.

Here, one month was the shortest amount of time from vaccination to onset given by Dr. Shoenfeld. But, after hearing petitioner testify that he had symptoms much earlier than one month, Dr. Shoenfeld changed his testimony to one week. This change left the impression that Dr. Shoenfeld was altering his opinion about the temporal window expected by medical science to fit petitioner's case. Dr. Shoenfeld could have avoided this result if his report had explained with more clarity the medically accepted time frame. See exhibit 25. Given that petitioner bears the burden of establishing the medically appropriate time frame, Pafford, 451 F.3d at 1358-59; Althen, 418 F.3d at 1278; petitioner should have obtained a more definite statement from Dr. Shoenfeld on this point. A conclusory statement that "the timing does not disturb me," tr. 195; is not persuasive.

3. Summary Regarding Temporal Relationship

From various perspectives, the evidence allegedly demonstrating an appropriate temporal relationship between petitioner's receipt of the hepatitis B vaccination and the onset of chronic fatigue syndrome was very weak. A preponderance of the evidence establishes that petitioner was not experiencing persistent or relapsing fatigue between September 1997 and January 1998.

At best, Dr. Shoenfeld's opinion is that persistent fatigue, which was caused by the hepatitis B vaccine, would develop as soon as one week and as long as three months after the vaccine. Tr. 211.¹³ Petitioner received the first dose of the hepatitis B vaccine on September 17, 1997. Exhibit 2 at 4. This date means that, according to Dr. Shoenfeld's testimony about the temporal window, the persistent or relapsing fatigue should have been present three months later, or December 17, 1997. For reasons explained earlier, a preponderance of the evidence indicates that petitioner was not suffering from persistent or relapsing fatigue in December 1997. See section III.B.1.b.

Consequently, petitioner has not established, by a preponderance of the evidence, that there was an appropriate temporal relationship between his receipt of the hepatitis B vaccine and the onset of his fatigue.

Although petitioner testified that he experienced other problems closer in time to the vaccination, these other problems do not assist petitioner. For example, petitioner said that he saw blood in his urine. Tr. 102, tr. 123. (Oddly, petitioner did not seek medical attention for this condition.) Even if this testimony were credited, this event would not be relevant. Blood in the

¹³ Whether medical science accepts that three months is the outer limit for hepatitis B to cause an adverse reaction is disputable. Other cases have awarded compensation based upon a more limited window. E.g. Griffin v. Sec'y of Health & Human Servs., No. 99-378, 2007 WL 4270698 at *16 (Fed. Cl. Spec. Mstr. Nov. 19, 2007) (compensation appropriate when symptoms occur one month after hepatitis B vaccination).

Resolving any dispute about the outer limit is not necessary because even if Dr. Shoenfeld's opinion is accepted, petitioner's persistent fatigue began after this date.

urine is not a sign or symptom of chronic fatigue syndrome. Tr. 174 (Dr. Shoenfeld), see also Exhibit 27 (Fukoda at 955) at 116.

Petitioner also said that he developed some problems within one day of receiving the hepatitis B vaccine. Tr. 19, tr. 56-57. This testimony also does not help petitioner. If petitioner's testimony is accurate, these problems occurred too quickly for the hepatitis B vaccine to be responsible. The shortest time proposed by Dr. Shoenfeld is one week. Tr. 211. The various theories proposed by Dr. Shoenfeld, which are discussed in section III.C below, all require some actions by the immune system. While the immune system, in theory, could develop an aberrant reaction in seven days, one day is an insufficient amount of time. Tr. 259-63. When petitioners experience an illness too close in time to a vaccination for the vaccination to have caused the illness, petitioners are not entitled to compensation. Bazan, 539 F.3d at 1352.

Petitioner's claim is that the hepatitis B vaccine caused him to suffer chronic fatigue syndrome. An essential part of chronic fatigue syndrome is fatigue. A preponderance of the evidence establishes that petitioner was not suffering persistent or relapsing fatigue in September 1997 through January 1998. Petitioner's development of chronic fatigue after January 1998, while unfortunate for petitioner, places the onset of the disease outside of the window proposed by Dr. Shoenfeld. Petitioner's failure to establish this element means that he is not entitled to compensation. However, for sake of completeness, the other Althen elements are reviewed as well.

C. A Medical Theory Causally Connecting the Vaccination and the Injury

As part of his case to establish entitlement, petitioner is required to establish a medical theory connecting the hepatitis B vaccine to chronic fatigue syndrome. Althen, 418 F.3d at 1278. "Theory" means a proposed explanation for how the vaccine caused the injury. Although Althen requires a "medical theory," the petitioner is not required to provide "proof of specific biological mechanisms." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994).

The theory connecting the vaccine to the injury "must be supported by a sound and reliable medical or scientific explanation." Knudsen, 35 F.3d at 548; accord Althen v. Sec'y of Health & Human Servs., 58 Fed. Cl. 270, 284 (2003), aff'd, 418 F.3d 1274 (Fed. Cir. 2005). In the Vaccine Program, an expert's opinion may be evaluated according to the factors identified by the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). As recognized in Terran, the Daubert factors for analyzing the reliability of testimony are:

- (1) whether a theory or technique can be (and has been) tested;
- (2) whether the theory or technique has been subjected to peer review and publication;
- (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and,
- (4) whether the theory or

technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2, citing Daubert, 509 U.S. at 592-95. After Terran, decisions from judges of the Court of Federal Claims have consistently cited to Daubert. E.g. De Bazan v. Sec’y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2000) (“A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness’s testimony regarding causation.”), rev’d on other grounds, 539 F.3d 1347 (Fed. Cir. 2008); Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006); Piscopo v. Sec’y of Health & Human Servs., 66 Fed. Cl. 49, 54 (2005).

Daubert lists several non-exhaustive factors that may be considered in assessing the reliability of an expert’s opinion. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 149 (1999). These factors include whether the expert’s opinion is well accepted in the relevant community. Daubert, 509 U.S. at 594; see also McDowell v. Brown, 392 F.3d 1283, 1299 (11th Cir. 2004) (affirming district court’s exclusion of expert whose theory lacked “testing, peer review, a potential error rate, and general acceptance.”); Sullivan v. United States Dep’t of Navy, 365 F.3d 827, 834 (9th Cir. 2004) (reversing exclusion of expert whose theory was generally accepted).

A closely related factor is how peer-reviewed articles have evaluated a theory. This point may also be considered in weighing the value of a medical opinion. Id.; see also Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364, 1374 (Fed. Cir. 2005); Libas v. United States, 193 F.3d 1361, 1366-67 (Fed. Cir. 1999); Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 354 (5th Cir. 2007) (stating a lack of textual support may “go to the weight, not the admissibility” of the expert’s testimony); Waleryszak v. Sec’y of Health & Human Servs., 45 Fed. Cl. 573, 578-79 (1999), appeal dismissed, 250 F.3d 753 (Fed. Cir. 2000). Although the presence or absence of peer-reviewed articles may affect the weight given to an expert’s theory, the admissibility of the expert’s opinion does not depend upon support of peer-reviewed articles. Althen, 418 F.3d at 1281. These factors are useful in evaluating the theory proposed by Dr. Shoenfeld.

Petitioner attempted to present a reliable medical theory by introducing the opinion of Dr. Shoenfeld. However, Dr. Shoenfeld’s opinion was not supported by a “sound and reliable medical or scientific explanation” as required by Knudsen, 35 F.3d at 548. In large part, Dr. Shoenfeld attempted to demonstrate the reliability of his theory by relying on medical literature with two themes: first, that the hepatitis B vaccine has been associated with chronic fatigue syndrome, and second, that chronic fatigue syndrome is a type of autoimmune disease. On both of these points, Dr. Shoenfeld’s opinion is not persuasive.¹⁴

¹⁴ Petitioner emphasized Dr. Shoenfeld’s credentials. Pet’r Post Hearing Br. at 10. Petitioner argued that these credentials make Dr. Shoenfeld more persuasive than Dr. Wientzen. Pet’r Post Hearing Br. at 18.

1. Literature Linking Hepatitis B Vaccine and Chronic Fatigue Syndrome

To establish the reliability of his theory, Dr. Shoenfeld cited various medical articles that purport to establish a causal connection between the hepatitis B vaccine and chronic fatigue syndrome. Dr. Shoenfeld stated:

Since a great variety of infection[s] can cause CFS it is not surprising that vaccines have also been reported to precede the development of CFS. Notorious among them is the Hepatitis B vaccine (42). It should also be mentioned that HBV and HCV vaccine were reported extensively to be associated with autoimmune conditions. (10,12).

Exhibit 25 at 10. This passage appears to be powerful support for Dr. Shoenfeld's underlying theory that the hepatitis B vaccine can cause chronic fatigue syndrome.

However, further examination shows that Dr. Shoenfeld's statement is in error. The most important authority is reference 42, which is given in support of the statement that the hepatitis B vaccine is "notorious" among vaccines reported to precede the development of chronic fatigue syndrome. Reference 42 is an article by Phillippe Duclos. Petitioner filed this article as part of exhibit 27.

Dr. Duclos stated something that was virtually the exact opposite of what Dr. Shoenfeld had written. The article states that "[i]n Canada, during 1993-1994, a rumour was also raised that vaccination against hepatitis B was responsible for chronic fatigue syndrome, but no epidemiological data have ever confirmed this allegation." Exhibit 27 (Philippe Duclos, Safety of Immunization and Adverse Events Following Vaccination Against Hepatitis B, 2(3) Expert Opin Drug Saf. 225, 227 (2003)) at 108 .

Further, the Duclos study relies upon another paper, which was submitted as court exhibit 201. This study indicates that hepatitis B vaccine does not cause chronic fatigue syndrome. Exhibit 201 (Report of the Working Group on the Possible Relationship between Hepatitis B Vaccination and Chronic Fatigue Syndrome, 149(3) Can Med Assoc J 314 (1993)); see also tr. 261-66 (testimony of Dr. Wientzen discussing this article). To be fair, petitioner raised some doubts about whether the Canadian study was definitive. Tr. 293. Even if petitioner weakened

Dr. Shoenfeld's background has been considered. But, his background is less important than the soundness of his reasoning. As discussed in the text, Dr. Shoenfeld makes assertions that are not supported even by the literature that he supplied. See Hathaway v. Bazany, 507 F.3d 312, 318 (5th Cir. 2007) ("without more than credentials and a subjective opinion, an expert's testimony that 'it is so' is not admissible") (citation and quotation marks omitted). Although Dr. Shoenfeld's opinion is part of the record, his opinion was not persuasive.

the evidentiary value of the Canadian study, this would mean only that there was little evidence showing that the hepatitis B vaccine does not cause chronic fatigue syndrome. There would still be no affirmative evidence that the hepatitis B vaccine can cause chronic fatigue syndrome.

When questioned about this portion of his report, Dr. Shoenfeld changed his meaning. He said that he intended “notorious” to refer to the association between the hepatitis B vaccine and many different types of autoimmune conditions. Tr. 218-19. Dr. Shoenfeld acknowledged that “there are no studies to show that chronic fatigue syndrome follow[s] vaccination.” Tr. 219. Consequently, Dr. Shoenfeld’s written report is misleading. The list of credentials on his curriculum vitae does not excuse errors in his report.

Dr. Shoenfeld’s concession that “there are no studies to show that chronic fatigue syndrome follow[s] vaccination,” tr. 219; might be enough to reject his opinion as unreliable pursuant to Terran, which endorsed the special master’s use of Daubert factors to evaluate the reliability of an expert’s opinion. But, in light of other Federal Circuit precedent, which arguably could relax the Daubert standards, Dr. Shoenfeld’s other points will be considered.

2. Comparison between Chronic Fatigue Syndrome and Autoimmune Conditions

Dr. Shoenfeld’s report discussed what is known about the cause of chronic fatigue syndrome. Exhibit 25 at 8-9. The summary is that the “etiology is most probably multi-factorial and the condition [a]ffects genetically susceptible candidates.” Id. at 8. The cause of chronic fatigue syndrome is not known. Tr. 181 (Dr. Shoenfeld), tr. 267 (Dr. Wientzen).

Dr. Shoenfeld’s report also discussed autoimmune diseases. An autoimmune disease is a condition in which the body’s reaction to an outside substance, which is known as an antigen, becomes distorted and the body attacks itself. The body’s immune system confuses self with the foreign particle. Some diseases, such as Guillain-Barré syndrome, are generally considered to be autoimmune in origin. Dr. Shoenfeld’s report posited different explanations for how autoimmune diseases develop, including the theories of molecular mimicry and polyclonal activation. Exhibit 25 at 5-7.

Dr. Shoenfeld’s report implied that similar phenomena can explain the process of how chronic fatigue syndrome develops. See exhibit 25 at 7 (stating, under heading “HBV and CFS,” “it should be assumed that vaccines can also lead to autoimmunity.”)

Dr. Shoenfeld’s reasoning holds persuasive value only if chronic fatigue syndrome is a type of autoimmune disease. However, chronic fatigue syndrome is not considered an autoimmune disease. Dr. Shoenfeld stated “if you will ask me is it a classic autoimmune disease, the answer is not, because it does not fulfill all the criteria, but it may allude to autoimmune mechanism because of the autoantibodies that we found in the serum.” Tr. 191. On cross-examination, Dr. Shoenfeld made essentially the same point when he stated “There is no

information that chronic fatigue syndrome is an autoimmune disease.”

Nonetheless, Dr. Shoenfeld opined that “there is evidence that the immune system may be involved in I would say association or induction of the chronic fatigue syndrome.” Tr. 191. He also explained that he planned to present a lecture at an important conference in which he was going to “refer to chronic fatigue syndrome as [an] additional disease which may have a flavor of autoimmune disease.” Tr. 216-17; see also exhibit 36 (Dr. Shoenfeld’s slides).

Dr. Shoenfeld’s opinion that chronic fatigue syndrome may be a type of autoimmune disease is not persuasive. Dr. Shoenfeld’s language indicates an uncertainty or conjecture about this opinion. He stated that “the immune system may be involved in . . . [the] induction of the chronic fatigue syndrome.” Tr. 191 (emphasis added). He also testified that chronic fatigue syndrome “may have a flavor of autoimmune disease.” Tr. 216-17 (emphasis added). The emphasized words show that Dr. Shoenfeld’s opinion is inherently weak.

A “possibility” cannot establish the reliability of a medical theory. Van Epps v. Sec’y of Health & Human Servs., 26 Cl. Ct. 650, 654 (1992); Doe v. Sec’y of Health & Human Servs., 19 Cl. Ct. 439, 450 (1990) (“an assertion that something is ‘highly possible’ does not rise to the level necessary to establish causation by a preponderance of the evidence”); Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation does not establish a probability); Duncan v. Sec’y of Health & Human Servs., No. 90-3809V, 1997 WL 75429, at *4 (Fed. Cl. Spec. Mstr. Feb. 6, 1997) (“The court notes further that [petitioner's expert] is unwilling to state his opinion to a reasonable degree of ‘medical probability’ but as ‘a possibility’ only, a standard that cannot support a finding of a preponderance of evidence.”); Lacour v. Sec’y of Health & Human Servs., No. 90-316V, 1991 WL 66579, at * 5 (Cl. Ct. Spec. Mstr. Apr. 15, 1991) (“Expert medical testimony which merely expresses the possibility – not the probability – of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred.”).

Dr. Shoenfeld attempts to buttress his theory by relying upon articles that discuss the presence of autoantibodies.¹⁵ For example, in 1996, researchers analyzed the autoantibodies of patients with chronic fatigue syndrome. The authors, who included E.M. Tan, a well-known rheumatologist, concluded that “humoral autoimmunity against polypeptides of the [nuclear envelope] is a prominent immune derangement in [chronic fatigue syndrome].” Exhibit 32 (K. Konstantinov et al., Autoantibodies to Nuclear Envelope Antigens in Chronic Fatigue Syndrome, 98 J. Clin. Invest. 1888, 1888 (1996)); see also tr. 183-84 (discussing exhibit 32). But, the authors did not go so far as to say that people develop chronic fatigue syndrome as an autoimmune reaction. The authors say that the nuclear envelope “may be a target of the postulated ongoing immune system activation in CFS.” Id. at 1895. The reference to “ongoing

¹⁵ Dr. Shoenfeld did not refer to these articles in his report. Dr. Shoenfeld is expected to cite all relevant articles in his report to allow respondent and the undersigned an opportunity to prepare for his testimony.

. . . activation” suggests that people with chronic fatigue syndrome have overly active immune systems and this over-activity can turn into an autoimmune reaction. The article does not say that the origins of chronic fatigue syndrome are autoimmune.

After 1996, which is the year that the Journal of Clinical Immunology published the article by Konstantinov et al., articles about chronic fatigue syndrome have continued to assert that the etiology is not known. Various other causes for chronic fatigue syndrome have been proposed, including viral infections, bacterial infections, autonomic dysfunction, mental disorders and aberrant immune system reactions. Exhibit 25 at 8-10 (Dr. Shoenfeld’s report, citing various articles).

Scientists do not know what causes chronic fatigue syndrome. Tr. 181. There is not even a general consensus that chronic fatigue syndrome is an autoimmune disease.¹⁶

The finding that chronic fatigue syndrome is not a form of autoimmune disease eliminates any need to explore additional parts of Dr. Shoenfeld’s theory. Undiscussed parts of Dr. Shoenfeld’s theory include (1) whether receiving the hepatitis B vaccine, which contains only an inert portion of the hepatitis B virus, is comparable to developing an infection from the hepatitis B virus, and (2) whether the theories proposed to link the hepatitis B virus to autoimmune diseases, such as molecular mimicry and polyclonal activation, are reliable theories. These portions of Dr. Shoenfeld’s theory lose their relevance after the finding that chronic fatigue syndrome is not a type of autoimmune disease.¹⁷

For these reasons, petitioner has not met his burden of establishing, by a preponderance of the evidence, a medical theory causally connecting the hepatitis B vaccine to chronic fatigue syndrome. This failure of proof is another reason not to award petitioner compensation.

D. A Logical Sequence of Cause and Effect Showing That the Vaccination Was the Reason for the Injury

Given the lack of persuasive evidence as to timing (section III.B above) and theory (section III.C above), it follows that petitioner has also failed to demonstrate a logical sequence of cause and effect showing that the hepatitis B vaccination was the reason that he developed

¹⁶ Daubert permits the gate-keeping adjudicator to consider whether a theory has reached “general acceptance” as part of the process for determining whether the theory is reliable. Daubert, 509 U.S. 579, 594-95.

¹⁷ A theory that an aberrant immune system causes chronic fatigue syndrome may not explain much about petitioner’s condition. When his immune system was tested in October 2001, the results were within normal limits. Exhibit 17 at 4-5. Dr. Shoenfeld did not address whether a normal immune system in October 2001, provides any information about whether petitioner’s immune system was normal in October 1997.

chronic fatigue syndrome for the same reasons described above. Two additional points about petitioner are worthy of some attention, although these points do not affect the outcome of this case.

Interestingly, petitioner did not respond to the hepatitis B vaccination by developing the expected antibodies. Exhibit 16 at 5, exhibit 21 at 2. Neither Dr. Shoenfeld nor Dr. Wientzen discussed this fact in their reports. See exhibit 25 and exhibit B.

When asked about petitioner's failure to respond, Dr. Shoenfeld explained that petitioner probably reacted to the adjuvant contained in the hepatitis B vaccine. Tr. 234-40. (An adjuvant is a nonspecific stimulator of the immune system. Dorland's Illustrated Medical Dictionary 32 (30th ed. 2003).) If Dr. Shoenfeld believed that the problem with the hepatitis B vaccine was the adjuvant, then his opinion and report should have focused on this portion of the vaccine. A report more tightly crafted to the specifics of petitioner would have been more persuasive than the report, which was mostly generic, submitted by Dr. Shoenfeld. (The undersigned has reviewed reports by Dr. Shoenfeld in other cases.)

Whether any adverse reaction was caused by the hepatitis B surface antigen or the adjuvant affects the reliability of the theory offered by Dr. Shoenfeld. For example, if molecular mimicry were a reliable theory, then Dr. Shoenfeld would need to offer some evidence that there is similarity (sometimes known as homology) between part of the human body and the adjuvant in the hepatitis B vaccine. Likewise, if Dr. Shoenfeld believes that the most reliable theory is polyclonal activation, then Dr. Shoenfeld should have explained why the adjuvant used in the hepatitis B vaccine is considered a polyclonal activator. See Rotoli v. Sec'y of Health & Human Servs., No. 99-644V, 2008 WL 4483739 *18-22 (Fed. Cl. Spec. Mstr. Oct. 2, 2008) (discussing petitioner who failed to respond to hepatitis B vaccine), motion for review filed (Oct. 14, 2008).

A second unusual factor about petitioner's case is that he received nine doses of vaccines in a three-week period. Petitioner received three doses of the Japanese encephalitis vaccine and one dose of the typhoid vaccine. Exhibit 2 at 4. The Vaccine Program does not compensate people who are harmed by the Japanese encephalitis vaccine or the typhoid vaccine. 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3 (Vaccine Injury Compensation Table).

Again, neither expert particularly considered whether petitioner could have reacted to these vaccines. See exhibit 25 and exhibit B. Dr. Shoenfeld stated that the combination of all the vaccines (including the adjuvants in those vaccines) caused the chronic fatigue syndrome. Between the first dose of the hepatitis B vaccine and the third dose of the Japanese encephalitis vaccine, which petitioner received on the same day, Dr. Shoenfeld believes that the hepatitis B vaccine is more likely to be responsible because the hepatitis B virus causes fatigue. Tr. 212, tr. 231-32, tr. 237-40.

Ultimately, these two facts about petitioner do not affect the outcome of his case. Even if he were assumed to have developed an appropriate response to the hepatitis B vaccine and even

if he received only the hepatitis B vaccine, his development of chronic fatigue occurred outside the expected temporal window. Furthermore, the theory proposed by Dr. Shoenfeld to explain a causal connection between the hepatitis B vaccine and chronic fatigue syndrome was not reliable and was not persuasive.

IV. Conclusion

Petitioner has not established that he is entitled to compensation. In the absence of a motion for review filed pursuant to Vaccine Rule 23, the Clerk's Office is directed to enter judgment according to this decision.

IT IS SO ORDERED.

S/ Christian Moran
Christian J. Moran
Special Master