IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

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JANE DOE 60,	*	
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Petitioner,	*	No. XX-XXXV
	*	Special Master Christian J. Moran
v.	*	
	*	Filed: January 29, 2010
	*	Reissued: March 26, 2010
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	Entitlement, hepatitis B vaccine,
	*	transverse myelitis, chronic fatigue
Respondent.	*	syndrome, systemic lupus
* *		erythamatous, "possibilities"

Clifford Shoemaker, Esq., Shoemaker & Associates, Vienna, Virginia, for Petitioner; Heather R. Pearlman, Esq., United States Dep't of Justice, Washington, DC, for Respondent.

PUBLISHED DECISION DENYING ENTITLEMENT[*]

Petitioner claims that a series of vaccinations against hepatitis B, which she received in 1997, caused her to suffer various injuries. Petitioner's experts claim that she suffers from transverse myelitis, chronic fatigue syndrome, or systemic lupus erythamatous. She seeks compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10 et seq. (2006).

A preponderance of the evidence establishes that petitioner is not entitled to compensation. Petitioner has not established that she suffers from any of the three conditions that are the basis for her experts' opinions. The reasons for this decision follow.

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[*] After this decision was issued, Ms. Doe filed a motion to redact her name. This motion is GRANTED. See Vaccine Rule 18(b). The decision is made available to the public with minor typographical errors corrected.

I. Facts

Petitioner was born in 1946. Certain portions of her medical history before her hepatitis B vaccinations affect her claim for compensation.

At age 25, petitioner became a vegetarian. Exhibit 3 at 1. In October 1989, petitioner began working for Abbott Laboratories, first as a device assembler and later as an area coordinator. Tr. 9. Her weight was 112 pounds. Exhibit 12 at 35. Her initial job duties included packaging medical devices and working with a chemical called cyclohexane. Exhibit 34 at 113. Her employer offered the hepatitis B vaccine to its employees. However, for a period of time, petitioner refused to be vaccinated. Id.; exhibit 12 at 10 (statement declining vaccination, dated April 10, 1996).

In 1990, petitioner's son died under tragic and unexpected circumstances. She did not work for six months during which she was on a leave of absence.

On April 1, 1997, petitioner received the first dose of the hepatitis B vaccine. Exhibit 12 at 2-3, at 56. She did not have any adverse reaction to the first dose of the hepatitis B vaccine. Exhibit 12 at 2 (note stating "no [reaction] to first injection," dated May 6, 1997); see also exhibit 9 at 11. During her testimony, petitioner affirmatively stated that she did not have a reaction to the first two hepatitis B vaccinations. tr. 12.[1]

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[1] A note from the files of Dr. Andrew Campbell indicated that petitioner started to feel like she had the flu after receiving the first and second doses of the hepatitis B vaccine. See exhibit 34 at 113 (notes from July 12, 1998). The information presented in Dr. Andrew Campbell's note about petitioner's condition after the first and second doses of the hepatitis B vaccine is not persuasive for several reasons.

The primary reason is that medical records created closer in time to the vaccinations (when petitioner's memory is more likely to be accurate) are inconsistent with the information in Dr. Campbell's records. For example, a nurse's note created with the second vaccination indicates that petitioner stated that she did not have an adverse reaction. Exhibit 12 at 3. If petitioner did feel flu-ish, she probably would have reported her condition, especially given the context that petitioner previously refused the vaccination. Therefore, the contemporaneously created medical record is more persuasive. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Furthermore, when petitioner applied for Social Security benefits in May 1998, she stated that her problems began on November 6, 1997, with severe pain in her right side. She did not mention feeling flu-ish in the spring of 1997. Exhibit 7 at 44-50, see also exhibit 7 at 12 (decision of administrative law judge, stating petitioner was disabled on November 6, 1997).

Finally, petitioner testified that she suffered no problems after the first and second hepatitis B shots. Tr. 12. Thus, a preponderance of evidence indicates that Dr. Andrew Campbell's note is not accurate.

Petitioner was given the second dose of the hepatitis B vaccine on May 6, 1997. Exhibit 12 at 3. She, again, reported that she received this second vaccination "with no effect" and confirmed that statement when she testified during the hearing in this case that she had no adverse effects after this second shot. Exhibit 9 at 11; tr. 12.[2]

On October 28, 1997, petitioner received the third dose of the hepatitis B vaccination. Exhibit 12 at 3.

On November 8, 1997, petitioner began experiencing pain in her right flank radiating into her right chest. The next day, she reported to the emergency room at Mount Carmel Medical Center where various tests were performed. She was discharged the same day with a diagnosis of atypical chest pain. Exhibit 11 at 15-17. On November 14, 1997, petitioner again had pain in her right side and returned to the emergency room. Tests at the Mount Carmel Medical Center again failed to detect any problems. Exhibit 11 at 4-14.

The pain in petitioner's right side continued for the next two weeks. She sought treatment from Dr. Michael Conaway on January 15, 1998. In addition to the pain in her right side, petitioner also reported that she was very weak and fatigued. Exhibit 2 at 8-9. This appears to be the first reference to weakness and fatigue in petitioner's medical record. Her weight on January 15, 1998, was 157 pounds. Petitioner informed Dr. Conaway that she had gained 40 pounds in the last five years. Exhibit 2 at 17.[3]

Dr. Conaway reviewed results from various tests performed on petitioner's blood, which had been drawn two days earlier. One test showed that petitioner had a positive antinuclear antibody (1280) with a speckled pattern. Exhibit 2 at 14. Dr. Conaway decided to run additional tests to determine whether she had systemic lupus erythematosus (SLE or lupus). Exhibit 2 at 18.

Petitioner also saw a rheumatologist, Dr. Teresa George, who evaluated petitioner to determine whether she had lupus. Dr. George noted petitioner's history and reviewed the results of various tests. Dr. George stated petitioner "essentially has a right chest pain, which is of unclear etiology, arthralgias and fatigue with a positive ANA. I do not think there is enough evidence for systemic lupus erythematosis or another autoimmune process at this time." Exhibit 40 at 103.

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[2] See footnote 1.

[3] Petitioner's statement implies that she weighed approximately 117 pounds on January 15, 1993. This weight is consistent with her weight (112 pounds) in 1989 when she began working at Abbott Laboratories. Assuming that she gained the same number of pounds (eight) each year for five years, then on January 15, 1997 (approximately three months before the first dose of the hepatitis B vaccination), she weighed 149 pounds.

Petitioner followed up with Dr. Conaway two times in February and once in March 1998. During these visits, she generally complained about pain in her right side, nausea, and weakness or fatigue. Exhibit 2 at 10, 16, 19. At the last visit, Dr. Conaway was "really at a loss to explain both her pain and her fatigue at this point, having put her through a fairly rigorous workup." Exhibit 2 at 16 (report dated March 2, 1998). Dr. Conaway did not diagnose petitioner with SLE. Petitioner asked for a referral to the Cleveland Clinic for a diagnostic evaluation. Id.

On March 16, 1998, petitioner saw Dr. John Campbell at the Cleveland Clinic. The notes from this visit are somewhat difficult to read. Nevertheless, it appears that petitioner was experiencing right flank pain. Dr. Campbell's impressions included "post hepatitis B fatigue." Exhibit 13 at 26. Dr. Campbell ordered blood tests, which indicated that petitioner's vitamin B12 level was at the low end of the "indeterminate range" and that she had an elevated amount of methylmalonic acid. Exhibit 13 at 15, 21. Dr. Campbell requested that petitioner have additional tests and also see a neurologist. Exhibit 13 at 26.

One of these tests determined that petitioner's bone density was decreased. The radiology report stated that petitioner's symptoms were consistent with osteopenia in her lumbar spine and osteoporosis in her left hip. Exhibit 13 at 9 (tests dated April 3, 1998). It appears that petitioner did not have an MRI or CT scan of her thoracic spine at any time during 1998.

Petitioner saw two specialists in the Cleveland Clinic on April 9, 1998. First was Dr. Lavery from the Colorectal Surgery Department. At the time, petitioner complained about right flank pain and lower abdominal pain. However, Dr. Lavery did not note any problems. Exhibit 13 at 29, 32. (In 2004, a doctor suspected that her recurrent right sided pain was caused by small kidney stones. Exhibit 36 at 47-48.)

The second specialist from the Cleveland Clinic was a neurologist, Dr. Sweeney, as a consultant for Dr. John Campbell. Petitioner told Dr. Sweeney that before November 1997, she was in good health. Then, she began to have pain in her right side. Petitioner also complained that she was fatigued. Dr. Sweeney's impressions included that petitioner was not likely to have a neurologic problem. Exhibit 13 at 33-34. (One of petitioner's experts, Dr. Tornatore, questioned Dr. Sweeney's report.)

After seeing Dr. Lavery and Dr. Sweeney, petitioner returned to Dr. John Campbell. Dr. Campbell, whose notes are again difficult to read, summarized much of the information presented above. His impressions included "post vaccine syndrome." He suggested that petitioner take B12 vitamins. He also recommended that she follow up with her local doctor. Exhibit 13 at 35-36.

After seeing these specialists in the Cleveland Clinic, petitioner returned to see Dr. Conaway a few weeks later. Dr. Conaway noted that petitioner stated that she was very fatigued and could only walk for about 10 minutes before being exhausted. Dr. Conaway planned to continue giving vitamin B12 to petitioner, although Dr. Conaway was not confident that her deficiency in this vitamin was causing her fatigue. Dr. Conaway also could not explain why petitioner was having pain in her right side. Exhibit 2 at 16 (notes from April 23, 1998).

The medical records indicate that petitioner was referred to Dr. Hurst for a psychological evaluation. No medical records from Dr. Hurst have been filed in this case. However, in one of Dr. Conaway's records, a note was made that petitioner was diagnosed with depression and would call for a referral to a mental health professional. Exhibit 34 at 384-385.

Petitioner went to Dr. Conaway on May 1, 1998. She had been prompted to go to her doctor because a friend had told her about a news report stating that the hepatitis B vaccine can cause rheumatological problems, leading to chronic fatigue. Petitioner and her husband told Dr. Conaway that after the hepatitis B vaccination, "her entire being changed." Petitioner was having severe chronic fatigue and severe nausea. Dr. Conaway did not express any opinion about the significance of the hepatitis B vaccine in his office notes. He requested that petitioner see Dr. Ian Baird, a specialist in infectious diseases. Exhibit 2 at 15. No records from Dr. Baird have been filed in this case.

On July 9, 1998, Dr. Conaway wrote a letter recommending that petitioner see Dr. Andrew Campbell in Texas because this Dr. Campbell had extensively evaluated chronic fatigue syndrome due to the hepatitis B vaccine. Exhibit 2 at 1.

Petitioner saw Dr. Andrew Campbell on July 12, 1998. (Another of petitioner's experts, Dr. Shoenfeld, relies extensively upon information found in Dr. Andrew Campbell's records.) She began by completing an immune dysfunction questionnaire in which petitioner indicated that she experienced a variety of problems starting in November 1997. The list of problems included fatigue, aches in her muscles and joints, weight gain, abdominal pain, shortness of breath, and sensitivity to food. She also indicated that she was taking vitamin B12 monthly. Exhibit 34 at 118-26. Apparently, in an interview, petitioner informed Dr. Campbell that she felt "flu-like" after receiving the first dose of the hepatitis B vaccine in May 1997. She also stated that she felt sick after the second and third doses of the hepatitis B vaccine. Exhibit 34 at 113.[4] Dr. Andrew Campbell's impression was that petitioner suffered from fatigue, chest pain, and polyneuropathy. Exhibit 34 at 112.

Dr. Andrew Campbell ordered a series of tests, including various types of blood tests and neurological testing. (These tests were repeated in virtually every visit to Dr. Andrew Campbell.) Petitioner's laboratory tests showed that her cholesterol was high at a level of 266 and that her vitamin B12 level was low. Petitioner again had a positive ANA test. Exhibit 34 at 182-184.

Dr. Andrew Campbell prescribed a course of vitamins for petitioner. Exhibit 16 at 260. Among other vitamins included in the regimen was a dose for a Vitamin B complex. Id.

Petitioner returned to see Dr. Andrew Campbell a few weeks later. Petitioner told Dr. Campbell that she was feeling much worse. She was having gastrointestinal problems and was

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[4] Petitioner later testified that this information was incorrect. She testified that she had no adverse reaction to the first and second hepatitis B vaccinations. Tr. 12.

tired all the time with no energy. Dr. Campbell again diagnosed petitioner as having fatigue and polyneuropathy. He also added the diagnosis of an adverse reaction to a vaccine. He continued petitioner's medications and requested a reassessment in 90 days. Exhibit 34 at 109-110; exhibit 15 at 2.

Petitioner actually saw Dr. Andrew Campbell more quickly, approximately three weeks later. Petitioner called his office because she was getting worse, specifically she said she was dropping things. Dr. Campbell again ordered a series of tests. He also prescribed gammaglobulin. Exhibit 34 at 104-07 (notes from visit on August 20, 1998). (It appears that petitioner actually received gammaglobulin in February 1999). Dr. Campbell summarized this visit as well as other treatment in a letter dated October 12, 1998. Dr. Campbell stated that petitioner's "decline in overall health and subsequent disability status is a direct result of her Hepatitis B vaccines." Exhibit 34 at 376.

On October 30, 1998, petitioner saw Dr. Joseph Plouffe, a specialist in infectious diseases. Blood tests that Dr. Plouffe ordered showed that petitioner had antinuclear antibodies. However, the specific antibodies that are diagnostic for lupus were negative. Dr. Plouffe's conclusion was that petitioner had a "possible immunologic process of questionable etiology[.] Hep B vaccine certainly possible." Exhibit 8.

On December 1, 1998, Dr. Conaway wrote a "To Whom It May Concern" letter. It appears that this letter was written to support petitioner's claim for disability benefits. This letter states that Dr. Conaway is treating petitioner for "chronic fatigue and chronic chest wall pain that initially arose immediately after her third Hepatitis B vaccine. . . . It is certainly possible that she is having a chronic severe reaction to the Hepatitis B vaccine as reported by a specialist in Texas." Exhibit 2 at 6.

In 1999, petitioner continued to see Dr. Andrew Campbell about every two months.[5] Petitioner's condition did not change in a meaningful way under his care. In a visit on December 20, 1999, Dr. Campbell diagnosed her with, among other problems, autoimmune disease, chronic inflammatory demyelinating polyneuropathy, fatigue, and an immune mechanism disorder. He continued to state that the hepatitis B vaccine was the cause of petitioner's health problems. Exhibit 34 at 71-72.

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[5] Because petitioner received her third and final dose of the hepatitis B vaccine in October 1997, most of the information derived from doctor's appointments from 1999 to the present is not relevant to determining whether the hepatitis B vaccine caused her health problems. Thus, some records are summarized succinctly and other records are omitted from this discussion. Although the recitation of facts may omit some records, all records have been considered. See 42 U.S.C. § 300aa–13(a) (special masters are obligated to consider "the record as a whole.")

Petitioner saw Dr. Sandra Stewart-Pinkham on August 26, 1999, and on September 22, 1999. Dr. Stewart-Pinkham concluded that petitioner's problems "are best explained by an adverse reaction to [the] Hepatitis B vaccine which contains 25 mcg of mercury in each injection." Dr. Stewart-Pinkham, however, also recognized that petitioner's "complaints are identical to individuals with chronic fatigue immune dysfunction, a disease of unknown etiology." Exhibit 3 at 3.

In January 2000, an administrative law judge in the Social Security Administration found that petitioner was totally disabled and entitled to benefits. The record before the administrative law judge included reports from the Cleveland Clinic, Dr. Conaway, Dr. Andrew Campbell, and Dr. Stewart-Pinkham. Based upon this information, the administrative law judge stated that petitioner's impairments included "depression, osteoarthritis . . ., sensory neuropathy secondary to hepatitis B vaccine, history of chronic fatigue syndrome with borderline fibromyalgia, positive ANA, somatization disorder and borderline intellectual functioning." Exhibit 7 at 5.

II. Procedural History

Petitioner filed a petition seeking compensation pursuant to the National Childhood Vaccine Injury Act on July 28, 1999. Petitioner did not file any medical records or affidavits with her petition. Instead, she filed her first collection of medical records in October 2000.

Over the next six years, petitioner periodically filed additional medical records. In this time, counsel for petitioner, counsel for respondent and the Office of Special Masters were attempting to establish a method of resolving the numerous cases in which petitioners alleged that the hepatitis B vaccine caused them an injury. Although this effort did not succeed, all parties acted in good faith. The need for adjudication of this case became apparent by 2006. The case was transferred to the undersigned, a previously entered stay was lifted, and the case began to progress.

In addition to filing medical records, petitioner submitted reports from three experts.[6] Petitioner filed, as exhibit 42, an expert report from Dr. Yehuda Shoenfeld on June 30, 2006. Petitioner also submitted Dr. Shoenfeld's curriculum vitae as well as a collection of medical articles on which Dr. Shoenfeld relied. Dr. Shoenfeld opined that Petitioner suffers from chronic fatigue syndrome. Dr. Shoenfeld also stated that the hepatitis B vaccine can cause chronic fatigue syndrome and that the vaccine did cause petitioner's chronic fatigue syndrome. Exhibit 42 at 11, 14.

On October 25, 2006, petitioner filed an expert report from Dr. Carlo Tornatore as exhibit 44. Dr. Tornatore stated that an MRI of the thoracic spine, which petitioner had not received previously, would assist him in understanding the nature and the cause of petitioner's condition. Exhibit 44 at 2-3. Petitioner had this procedure performed, the report of which was submitted as exhibit 49. Dr. Tornatore prepared a supplemental report, which Petitioner filed on January 28, 2007, as exhibit 49. Based upon the MRI, Dr. Tornatore stated that petitioner's thoracic spinal cord was atrophied. Dr. Tornatore opined that the cause of the atrophy was an inflammation of the spinal cord, known as myelitis. The inflammation, in turn, was caused by a reaction to the hepatitis B vaccine. Exhibit 49 at 2-3. Petitioner filed five articles that Dr. Tornatore cited in his report. Exhibits 50-54.

After petitioner concluded the process of filing written submissions from her experts, respondent addressed her petition and the evidence on April 9, 2007. Respondent's report, filed pursuant to Vaccine Rule 4, stated that petitioner was not entitled to compensation. Respondent also presented the reports and curriculum vitae of two experts, Dr. Lawrence Kagen, a rheumatologist, and Dr. Thomas Leist, a neurologist.

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[6] Petitioner submitted a report from and curriculum vitae of Dr. Sandra Pinkham as exhibit 41. Dr. Pinkham stated that she believes that mercury, which is part of some vaccines in the form of a preservative called thimerosal, effectively poisoned petitioner, who developed chronic fatigue syndrome as a result. Exhibit 41 at 3.

Petitioner does not rely upon the written report of Dr. Pinkham. Tr. at 5. Thus, this report is not discussed extensively.

Even if petitioner had relied upon the report of Dr. Pinkham, petitioner has not demonstrated the reliability of Dr. Pinkham's opinion. As a predicate for arguing that thimerosal in a vaccine caused an adverse reaction, the petitioner must establish, by a preponderance of the evidence, that the vaccine contained thimerosal. There is relatively little evidence that the particular doses of the hepatitis B vaccine that petitioner received contained thimerosal. Respondent indicated that the third dose of the hepatitis B vaccine contained some amount of thimerosal. However, respondent could provide no information about either the first or second doses. Resp't Status Rep't, filed Nov. 29, 2006. Petitioner has not offered any evidence to support Dr. Pinkham's assertion that the dose of the hepatitis B vaccines, which petitioner received, contained mercury.

Dr. Kagen's written report offers additional diagnoses. He stated petitioner suffers from (1) a mixed connective tissue disease with rheumatoid arthritis overlap, (2) osteoarthritis with spinal cord and nerve root compression, (3) a nutritional deficit due to a lack of vitamin B12 in her diet, (4) an allergic reaction to mold, and (5) depression. Dr. Kagen's report did not comment upon whether petitioner, in his opinion, suffers from chronic fatigue syndrome. He also did not discuss whether the hepatitis B vaccine could have caused the illnesses that he diagnosed. Exhibit A at 8-9.

Dr. Leist reaches conclusions to similar to Dr. Kagen. Dr. Leist stated that petitioner suffers from (1) a deficiency in vitamin B12, (2) an evolving mixed collagen vascular disorder, and (3) osteopenia with degenerative changes in her cervical spine. Dr. Leist's report also rejected, in a conclusory fashion, Dr. Tornatore's hypothesis that petitioner suffers from myelitis. Exhibit C at 16-17.

A hearing was conducted on November 1 and 2, 2007. On the first day, only petitioner testified. On the second day, Dr. Tornatore and Dr. Leist testified. A second hearing was held on April 9, 2008. At this hearing Dr. Shoenfeld and Dr. Kagen testified. During that hearing, Dr. Shoenfeld opined, for the first time, that petitioner met the diagnostic criteria for systemic lupus erythematosus and that the hepatitis B vaccination she received caused this condition. Thus, a third hearing was held on November 25, 2008, to take testimony from the experts as to whether petitioner met the diagnostic criterion for SLE. Petitioner presented the testimony of Dr. Shoenfeld and respondent presented the testimony of Dr. Kagen. Both parties submitted post-trial briefs. The last brief was filed on August 28, 2009. The case is now ready for decision.

III. Standards for Adjudication

There are at least three distinct parts to evaluating whether a petitioner is entitled to compensation. One part is to articulate the elements of petitioner's case. These elements are "what" petitioner must establish. A separate part of analysis is the quantum of evidence that a petitioner must introduce, which is the burden of proof. A final aspect is the process of weighing or evaluating the evidence that is submitted. These three portions are discussed separately.

A. Elements of Petitioner's Case

Petitioner is entitled to compensation if she establishes, among other elements, that she "sustained, or had significantly aggravated, any illness, disability, injury or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine [listed in the vaccine injury table]." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Here, petitioner does not argue that the vaccine "significantly aggravated" any illness. The question then becomes whether petitioner established that she "sustained . . . any illness, disability, injury or condition . . . which was caused by" the hepatitis B vaccine.

When a petitioner claims compensation for an injury not listed on the Vaccine Injury table, a petitioner must establish 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).

Typically, the Althen test sets forth the issues that the parties dispute. However, petitioner's case is unusual in the sense that the doctors have not reached any consensus about what condition affects her now, or affected her in 1997-98. Petitioner's treating doctors have not diagnosed her with one condition consistently. The two doctors whom petitioner retained in this litigation differ in their opinions. Dr. Tornatore proposes transverse myelitis. Dr. Shoenfeld offers two alternatives – chronic fatigue syndrome or systemic lupus erythematosus. The two doctors whom respondent retained offered other possibilities.

These circumstances fairly raise the question of whether petitioner must establish, by a preponderance of the evidence, that she suffers from a specific condition identified by one of her experts. The answer is yes. "For off-Table injuries such as the one claimed here, it is axiomatic that as a prerequisite to proving causation, a petitioner must prove by a preponderance of the evidence the existence of the injury she claims was caused by the vaccination." Devonshire v. Sec'y of Health & Human Servs., 76 Fed. Cl. 452, 454 (2007).

Petitioner's obligation to establish, by a preponderance of the evidence, that she suffers from a disease that her expert believes was caused by the hepatitis B vaccine derives, in part, from the special master's obligation to consider "relevant" evidence. Vaccine Rule 8(b)(1). For example, if petitioner does not suffer from transverse myelitis, then Dr. Tornatore's opinion — regardless of its persuasive force — that "molecular mimicry" constitutes a reliable theory to explain how the hepatitis B vaccine can cause transverse myelitis is not relevant. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 591 (1993) (explaining that, pursuant to Rule 702 of the Federal Rules of Evidence, proposed expert testimony must "fit" the case); see also Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (aff'g special master's use of Daubert standards in the Vaccine Program).

Requiring petitioner to establish, by a preponderance of the evidence, that she actually suffers from the condition that her own experts opine was caused by the hepatitis B vaccine is consistent with existing law. Although Althen establishes a three-part test, that test is used to determine whether a petitioner established that a vaccine caused a particular injury. The context of Althen indicates that there was no dispute that Margaret Althen suffered from acute disseminated encephalomyelitis. Althen, 418 F.3d at 1277. Thus, the Federal Circuit was not presented with a case in which the diagnosis was questioned. Without a binding decision from the Federal Circuit addressing whether a petitioner must establish the diagnosis offered by the

petitioner's expert, the undersigned finds Devonshire to be persuasive and follows its holding that a petitioner must establish, by a preponderance of the evidence, that she suffers from the condition discussed by her experts.[7]

B. Burden of Proof

For the elements that petitioners are required to prove, the petitioner's burden of proof is a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. See In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Petitioner's burden of proof – preponderant evidence – assists special masters in evaluating statements that "a vaccine may have cause an injury" or "it is possible that a vaccine caused this injury." These guidelines about "possibilities" will be used to evaluate some of the evidence in this case. Section IV.B.5 analyzes statements of three of petitioner's treating doctors. Two treating doctors expressed an idea that the hepatitis B vaccine caused petitioner an adverse reaction "possibly." A statement about "possibilities" that is unsupported by any other evidence cannot satisfy petitioner's burden of proof by itself because a statement expressed in terms of "possibilities" does not rise to the level of preponderant proof.

The concept of "relevance" also assists special masters in evaluating statements expressed as "possibilities." Rule 401 of the Federal Rules of Evidence defines "relevant evidence" as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the

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[7] Petitioner has not argued that the three conditions are so similar that doctors consider them to be conditions along a spectrum of diseases. Thus, petitioner's case is distinguishable from Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84, 100 (2005), in which a judge held that the chief special master had erred in distinguishing between Guillain-Barré syndrome and chronic inflammatory demyelinating polyneuropathy. See Broekelschen v. Sec'y of Health & Human Servs., 89 Fed. Cl. 336, 344 (2009) (aff'g special master's decision that determined the petitioner's diagnosis before determining causation), appeal docketed, No. 2009-5132 (Fed. Cir. Sept. 28, 2009).

evidence." Although the Federal Rules of Evidence do not restrict the admissibility of evidence in cases in the Vaccine Program, 42 U.S.C. § 300aa–12(d)(2)(B); the judges of the Court of Federal Claims have required special masters to consider "relevant" evidence. Vaccine Rule 8(b)(1).

Decisions of appellate authorities in the Vaccine Program recognize that statements expressed as "possibilities" are not the same as statements expressed as "probabilities." Moberly v. Sec'y of Health & Human Servs., F.3d , No. 2009-5057, 2010 WL 118661, at *5 (Fed. Cir. Jan. 13, 2010); 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). Special masters have also reached the same conclusion. See 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.").

Finding that opinions expressed as "possibilities" do not constitute preponderant evidence is consistent with Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1378 (Fed. Cir. 2009). In Andreu, the child, Enrique, received the DTaP vaccination and within one day had movements that were consistent with a seizure. Some evidence indicates that the DTaP vaccine can cause febrile seizures, that is, seizures associated with a fever. Thus, if Enrique had a fever immediately after receiving the DTaP vaccine, then more evidence would support his claim that the DTaP vaccine caused his seizure disorder. A medical record showed that when Enrique was hospitalized eleven days after his vaccination his temperature was 99.4 degrees. Id. at 1378. The Federal Circuit stated that "it is quite possible that [the child] had a low-grade fever in the period immediately after his vaccination." The Federal Circuit drew this conclusion from the documented evidence that Enrique's temperature in the hospital was 99.4 degrees. In any event, the Federal Circuit did not find, as a fact, that Enrique had a low-grade fever because this fact was extraneous to its analysis. The Federal Circuit explained, in the next paragraph, that even if there were no fever, the special master erred in denying compensation. Id. Thus, the Federal Circuit's discussion of a "possible" fever is dicta in that the discussion could have been eliminated without changing the outcome of the case. National American Ins. Co. v. United States, 498 F.3d 1301, 1306 (Fed. Cir. 2007).

After Andreu, the Federal Circuit further illustrated the need for an expert to state his or her opinions as probable. A veteran, Timothy Fagan, sought benefits for developing bilateral hearing loss while in the military. The examiner for the Department of Veterans' Affairs wrote a report stating "it is not possible to determine if [Mr. Fagan's hearing problem] is related to military service." Fagan v. Shinseki, 573 F.3d 1282, 1284 (Fed. Cir. 2009). The Court of

Appeals for Veterans' Claims affirmed a denial of compensation, reasoning that the examiner's statement "may be characterized as non-evidence." Id. at 1285, citing 2008 WL 2130166, at *3.

The Federal Circuit also affirmed the denial of compensation, although the Federal Circuit expressed that it was troubled by the description of the examiner's statement as "non-evidence." Id. at 1289 n.4. The Federal Circuit stated that "[t]he examiner's statement, which recites the inability to come to an opinion, provides neither positive nor negative support for service connection. . . . Therefore, it is not pertinent evidence, one way or the other, regarding service connection." Id. at 1289.

Cases from outside the Vaccine Program have also indicated that experts' opinions about "possibilities" do not meet a plaintiff's burden to present a preponderance of evidence. United States v. Frazier, 387 F.3d 1244, 1263-65 (11th Cir. 2004) (en banc) (affirming exclusion of a portion of the opinion of an expert whom a criminal defendant intended to call as a witness); Fedorczyk v. Caribbean Cruise Lins, Ltd., 82 F.3d 69, 75 (3d Cir. 1996) (following New Jersey law and stating that "The possibility of the existence of an event does not tend to prove its probability."); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1320 (11th Cir. 1999) (following Georgia law and affirming exclusion of expert's opinion); Bowers v. Norfolk Southern Corp., 537 F. Supp. 2d 1343, 1367-70 (2007) (granting motion to exclude expert). For a decision discussing several decisions by a Court of Appeals for various circuits that were issued before Daubert, see Schulz v. Celotex Corp., 942 F.2d 204, 208-9 (3d Cir. 1991); see also Mays v. Ciba-Geigy Corp., 661 P.2d 348, 360 (Kan. 1983).[8]

C. How to Weigh Evidence

The preceding sections explain what a petitioner is required to establish and what level of proof satisfies petitioner's obligation. The remaining issue is how to evaluate evidence submitted to meet the standard of proof on those elements. Two particular issues within this general topic are the value of statements by treating physicians and the evaluation of opinions by hired experts.

Three authorities generally instruct special masters in how to evaluate evidence. The first is Congress. In enacting the National Vaccine Injury Compensation Act, Congress provided some instructions about how special masters should analyze the evidence that are codified in section 13. Among other provisions, section 13 dictates that the special master should consider "the record as a whole." Section 13 also provides that the special master shall consider "any diagnosis, conclusion, medical judgment or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury,

[8] Several cases cited in the text caution against requiring "magic" words. E.g. Bowers, 537 F. Supp. 2d at 1369. Experts may express their opinion using various phrases, such as "it is more likely than not" or "it is probable that" or "to a reasonable degree of probability" or "to a reasonable degree of medical probability." But, these phrases differ from an expression that something "may" have happened.

condition or death." Nevertheless, "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court."

The second authority is the United States Court of Federal Claims. Congress authorized the Court of Federal Claims to promulgate rules of procedure for cases in the Vaccine Program. 42 U.S.C. § 300aa–12(d)(2). Collectively, the judges of the Court of Federal Claims have issued the Vaccine Rules. The Vaccine Rules, in turn, provide that the special master "must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b)(1).

The third authority is the United States Court of Appeals for the Federal Circuit. Decisions by the Federal Circuit are binding precedent. 42 U.S.C. § 300aa–12(e). In regard to weighing evidence, some Federal Circuit cases that reviewed decisions made by special masters were relatively silent. E.g. Lampe, 219 F.3d at 1359-62; Terran, 195 F.3d at 1316 (reviewing special master's evidentiary determination under the abuse of discretion standard). These decisions are in accord with how the Federal Circuit has reviewed challenges to causation in contexts outside of the Vaccine Program. See Southern California Fed. Sav. & Loan Ass'n v. United States, 422 F.3d 1319, 1337 (Fed. Cir. 2005) (affirming trial court's finding, despite some evidence to the contrary, that FIRREA caused the bank's recapitalization). Within the Vaccine Program, the Federal Circuit expected that special masters would "consider[] the relevant evidence of record, draw[] plausible inferences and articulate[] a rational basis for the decision." Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

Further explanation about how special masters should weigh evidence came in Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). The Federal Circuit emphasized that statements of treating doctors have a special value in the Vaccine Program. The Federal Circuit stated that "Althen III explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280).[9]

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[9] Although statements of treating doctors are "favored," there may be times when a statement of a treating doctor is not dispositive. The special master is required to evaluate the record, including any judgment of a treating doctor, as a whole. Section 13(b)(1); accord Althen, 418 F.3d at 1279. The entire record may prevent the report of one treating doctor from controlling the outcome in at least two situations.

First, the entire record may raise questions about the reliability of a conclusion reached by a treating doctor. For example, the treating doctor may have received inaccurate or incomplete information about the patient's medical history. In the context of reviewing claims for disability benefits processed by the Office of Personnel Management and the Merit Systems Protection Board, the Federal Circuit has acknowledged that those fact-finders may evaluate opinions of treating doctors by considering "doubts about professional competence, contrary medical evidence, failure of the professional to consider relevant factors, lack of particularity in relating

Therefore, consistent with Capizzano, the undersigned will consider with great care any statements made by treating doctors. Besides statements of treating doctors, another topic on which the Federal Circuit has instructed special masters is the method for evaluating the reliability of an expert's opinion.

In the Vaccine Program, an expert's opinion may be evaluated according to the factors identified by the United States Supreme Court in Daubert, 509 U.S. 579. Terran, 195 F.3d at 1316. 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. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 742-45 (2009); Cedillo v. Sec'y of Health & Human Servs., 89 Fed. Cl. 158, 182 (2009), appeal docketed, No. 2009-5004 (Fed. Cir. Oct. 7, 2009); De Bazan v. Sec'y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) ("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).

The Federal Circuit has recently made clear that after an expert's opinion has been admitted into evidence questions about the reliability of the expert's opinion may be considered by the fact-finder in weighing the opinion. i4i Ltd. Partnership v. Microsoft Corp., No. 2009-1504, 2009 WL 4911950, at *14 (Fed. Cir. Dec. 22, 2009); accord Nussman v. Sec'y of Health & Human Servs., No. 99-500V, 2008 WL 449656, at *16 (Fed. Cl. Spec. Mstr. Jan. 31, 2008), aff'd, 83 Fed. Cl. 111 (2008).

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diagnosis to nature and extent of disability." Vanieken-Ryals v. Office of Personnel Management, 508 F.3d 1034, 1042 (Fed. Cir. 2007). Similarly, the Federal Circuit has stated that an expert's opinion about causation in the Vaccine Program is only as strong as the underlying basis for the opinion. Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (1994).

Second, the entire record also may indicate that treating doctors differ in their evaluations. If so, "favoring" one doctor may be the equivalent of "disfavoring" another treating doctor.

In evaluating expert testimony and scientific literature, special masters should analyze scientific literature "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." Andreu, 569 F.3d at 1379. "In other words, a finding of causation in the medical community may require a much higher level of certainty than that required by the Vaccine Act to establish a prima facie case. The special master must take these differences into account when reviewing the scientific evidence." Broekelschen, 89 Fed. Cl. at 343.

Generally, the Federal Circuit expects that a special master will present a reasonable basis for rejecting the opinion of one expert. Lampe, 219 F.3d 1361; Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

These standards will be used to determine whether petitioner has established that she is entitled to compensation. For reasons explained in the following section, petitioner has not met her burden of proof. Therefore, she is not entitled to compensation.

IV. Analysis

Petitioner's case is complicated because she alleges that she suffers from three conditions. The first is transverse myelitis and she presents the report, testimony and medical literature of Dr. Tornatore to support this claim. Second, petitioner alleges that she suffers from chronic fatigue syndrome. She relies on the report, testimony and medical literature of Dr. Shoenfeld to support this diagnosis. Finally, petitioner alleges that she suffers from systemic lupus erythematosus, again, relying on the report, testimony and medical literature presented by Dr. Shoenfeld.

Petitioner's briefs filed after the hearing continue to present three alternatives. Petitioner has not argued that she seeks compensation for a condition other than transverse myelitis, chronic fatigue syndrome or systemic lupus erythematosus.[10] Thus, the next sections evaluate whether petitioner is entitled to compensation for transverse myelitis (section A), chronic fatigue syndrome (section B), and systemic lupus erythematosus (section C). For each condition, the evidence that petitioner fulfills (or does not fulfill) the diagnostic criteria is considered. As discussed below, petitioner has not proved, by a preponderance of the evidence, that she suffers from transverse myelitis, chronic fatigue syndrome or systemic lupus erythematosus. Consequently, this decision does not determine whether petitioner satisfied the additional elements necessary for

[10] As discussed in footnote 7, this case is distinguishable from Kelley.

compensation set forth in Althen.[11] See Doe v. Sec'y of Health & Human Servs., 76 Fed. Cl. 328, 334-35 (2007).

A. Transverse Myelitis

A preponderance of the evidence fails to establish that petitioner suffers from transverse myelitis. Petitioner's presentation, which is discussed in detail in section 2 below, does not match the diagnostic criteria for transverse myelitis, which is set forth in section 1 below.

1. Description of Transverse Myelitis

Transverse myelitis is "an acute inflammatory process affecting a focal area of the spinal cord." Transverse myelitis is "characterized clinically by acutely or subacutely developing symptoms and signs of neurological dysfunction in motor, sensory and autonomic nerves and nerve tracts of the spinal cord." Exhibit 72 (Douglas Kerr, Transverse Myelitis in Current Therapy in Neurologic Disease (R.T. Johnson et al., eds. 6th ed. 2001) at 1; accord tr. 99; tr. 111 (testimony of Dr. Tornatore).

As described by the Mayo Clinic, the symptoms of transverse myelitis are:

> **Pain.** Pain associated with transverse myelitis often begins suddenly in your neck or back. Sharp, shooting sensations may also radiate down your legs or arms or around your abdomen.
>
> **Abnormal sensations.** Some people with transverse myelitis report sensations of numbness, tingling, coldness or burning below the affected area of the spinal cord. You might notice that you're especially sensitive to the light touch of clothing or to extreme heat or cold.
>
> **Weakness in your arms or legs.** Some people with mild weakness notice that they're stumbling, dragging one foot or that their legs feel heavy as they move. Others may develop severe paralysis.

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[11] As mentioned earlier, exploring, pursuant to the first prong of Althen, whether the hepatitis B vaccine "can cause" transverse myelitis, chronic fatigue syndrome or systemic lupus erythematosus is unnecessary because even an affirmative answer to this question would not entitle petitioner to compensation. Without a finding that petitioner suffered from the condition for which she seeks compensation, petitioner cannot establish the second prong of Althen, which is "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. Because petitioner does not suffer from "the injury," there can be no "logical" sequence of steps.

> **Bladder and bowel problems.** These problems include an increased urinary urge, difficulty urinating and constipation.
>
> Other signs may include:
>
> Muscle spasms, especially in your legs
> Headache
> Fever
> Loss of appetite

Exhibit 70 (Mayo Clinic, Transverse Myelitis, http://www.mayoclinic.com (printed Feb. 18, 2008)) at 1-2.

The Mayo Clinic article also states that "researching a diagnosis of transverse myelitis also requires evidence of inflammation within the spinal cord. This may be determined with several tests:

> **Magnetic resonance imaging (MRI) scan.** An MRI scan is a test that uses a magnetic field and pulses of radio wave energy to make pictures of your body. If you have transverse myelitis, an MRI of your brain and spinal cord may show inflammation.
>
> **Lumbar puncture**. This test, also called a spinal tap, is used to collect a small amount of the fluid that surrounds your spinal cord and brain. During this test, your doctor injects a numbing medicine into your lower spine and then inserts a needle into your spinal canal to measure the fluid pressure and collect a sample.

Id. at 3-4. These criteria will be used to determine whether petitioner suffers from transverse myelitis.

2. Petitioner's condition

For the purposes of determining whether petitioner suffered from transverse myelitis, the most relevant person is Dr. Sweeney. See Capizzano, 440 F.3d at 1326 (instructing special masters to favor reports from treating doctors). Petitioner saw Dr. Sweeney, a neurologist, within four months of receiving the third dose of the hepatitis B vaccine. Dr. Sweeney conducted a neurologic examination and did not diagnose petitioner with transverse myelitis. Exhibit 13 at 33-34. Thus, when, based upon Dr. Tornatore's opinion, petitioner claims that she suffered from transverse myelitis, petitioner is seeking a finding that is inconsistent with the opinion of a treating neurologist.

Another doctor who treated petitioner after the October 28, 1997 hepatitis B vaccination was Dr. Teresa George, a rheumatologist. On February 24, 1998, Dr. George found, as part of an

examination of petitioner's neurological system, that petitioner's "[s]ensory and light touch was intact." Exhibit 40 at 103. Dr. George's finding reinforces Dr. Sweeney's conclusion that petitioner was not suffering from transverse myelitis in early 1998. See tr. 133 (Dr. Leist's testimony that a person with myelitis would have a sensory abnormality).

The idea that petitioner suffers from transverse myelitis originated in this litigation. None of petitioner's treating physicians diagnosed her with transverse myelitis. The only doctor to diagnose petitioner as suffering from transverse myelitis is Dr. Tornatore. Thus, the process by which Dr. Tornatore reached his conclusion that petitioner suffers from transverse myelitis is relevant.[12]

Initially, Dr. Tornatore reviewed petitioner's medical records. See exhibit 44 (report dated October 16, 2006). However, he could not conclude which condition afflicted petitioner based on those records alone. To provide a diagnosis, Dr. Tornatore stated that an MRI of petitioner's spine

> would be an important piece of information to better understand [petitioner's] clinical situation. If the MRI reveals a demyelinating lesion of the thoracic spine, then her treatment would change and the etiology of her flank pain and its association with the Hepatitis B vaccination would be clarified and my report would be materially different.

Exhibit 44 (emphasis added). The emphasized portion of Dr. Tornatore report implies that Dr. Tornatore was looking for a lesion. Without an MRI of petitioner's thoracic spine, Dr. Tornatore declined to render an opinion. Dr. Tornatore's interest in reviewing the results of an MRI is consistent with medical articles that discuss the need for an MRI in a patient who may have transverse myelitis. Exhibit 70 (Mayo Clinic) at 3-4.

Petitioner underwent an MRI of her thoracic spine on December 5, 2006. Exhibit 49 at 1, 4; exhibit 55. The impressions listed in the MRI report state "mild atrophy of the thoracic cord at mid thoracic levels: without neurally compressive lesion or intrinsic focal cord lesion depicted."

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[12] Dr. Tornatore commented that Dr. Sweeney's examination was "absolutely pitiful." Tr. 89. Dr. Tornatore stated that he believed that petitioner's presentation to Dr. Sweeney suggested that petitioner had a problem in her thoracic spine. Tr. 93. According to Dr. Tornatore, Dr. Sweeney should have ordered tests, such as an MRI. Tr. 63; tr. 79.

Dr. Tornatore may be correct that Dr. Sweeney should have ordered an MRI. However, it is impossible to know what would have been shown if petitioner had an MRI in 1998.

The undersigned must evaluate the record as it exists. This record includes a note from Dr. Sweeney that a "complete neuro[logical] exam was performed. It was essentially WNL [within normal limits]." Exhibit 13 at 34. Under these circumstances, the undersigned cannot speculate what the MRI would have shown.

Based on the results of the MRI, Dr. Tornatore submitted a supplemental report on January 28, 2007. Exhibit 49. In that report, Dr. Tornatore states that petitioner's thoracic spine would not atrophy "unless there is a significant pathological process present in the spinal cord. Most notably, the cord atrophy was focal suggesting a focal process, e.g., myelitis, must have been the etiology. Spinal cord atrophy is a well recognized sequelae of inflammation of the spinal cord." Therefore, Dr. Tornatore concluded that petitioner suffered from transverse myelitis. Exhibit 49; tr. 67.

Whether petitioner's MRI showed a lesion is one important factor for diagnosing transverse myelitis. In considering whether a person suffers from transverse myelitis, "[a] magnetic resonance imaging (MRI) scan is invaluable." Exhibit M (Anu Jacob et al., An Approach to the Diagnosis of Acute Transverse Myelitis, 28 No. 1 Seminars in Neurology 105 (2008)) at 1. When a person has transverse myelitis, the MRI usually shows inflammation. Exhibit 70 (Mayo Clinic, Transverse Myelitis) at 3.

Petitioner's MRI reports that she did not have a "neurally compressive lesion" and that no intrinsic focal cord lesion was depicted. Exhibit 49 at 4. This report appears not to present the information for which Dr. Tornatore was looking when Dr. Tornatore prepared his initial report, exhibit 44.

Nevertheless, Dr. Tornatore did not distinguish "lesion" from "atrophy." In his testimony, Dr. Tornatore indicated that the terms can have the same meaning. He testified:

> [The MRI] shows atrophy, which is a lesion. That's not normal. You have to understand [that by] the word lesion, we use to mean a problem in that area, [i.e. pathology] and that lesion – a tumor could be considered a lesion, a stroke could be considered a lesion, a plaque could be considered a lesion, atrophy is considered a lesion. . . . I think atrophy when you see it on an MRI is a lesion.

Tr. 95.

Dr. Tornatore's attempt to equate a lesion, for which he had been looking, with atrophy, which was actually found, is not persuasive. The meanings of these two terms differ. Several factors contradict Dr. Tornatore's opinion. First, the MRI report, itself, distinguishes "atrophy" from "lesion." Dr. Burk, who interpreted the MRI, stated that the MRI showed "[m]ild atrophy . . . without neurally compressive lesion or intrinsic focal cord lesion depicted." Exhibit 49 at 4 (emphasis added). If "atrophy" meant "a lesion," Dr. Burk would not have added the additional findings that a lesion was not present. The use of two separate terms suggests that each word conveys different information. Cf. Walton v. United States, 551 F.3d 1367, 1370 (Fed. Cir. 2009) (statutory interpretation); Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1369 (Fed. Cir. 2007) (discussing claim differentiation in patent law). Second, medical dictionaries define the two words differently. A lesion is defined as "any pathological or traumatic discontinuity of tissue or loss of function of a part" while atrophy is defined as "a wasting away; a diminution in

the size of a cell, tissue, organ, or part". Dorland's Medical Illustrated Dictionary, (30th ed. 2003) at 175. The third factor indicating that Dr. Tornatore was not persuasive was the testimony of Dr. Leist. Dr. Leist stated that "lesion" and "atrophy" are "not necessarily interchangeable terms." Tr. 123. All these reasons support a finding that petitioner did not have a lesion in her spinal cord on December 5, 2006.

Notwithstanding Dr. Tornatore's initial interest in finding a "lesion" to support an opinion that petitioner suffered a demyelinating illness, Dr. Tornatore maintained that spinal cord "atrophy" can be a sign of myelitis. Exhibit 49 at 2-3; tr. 67; tr. 94-95. Dr. Tornatore stated that the atrophy, which was seen in the December 2006 MRI, is a consequence of the inflammation that must have present in November 1997. Tr. 94.[13]

Dr. Tornatore's attempt to use atrophy, which was seen in 2006, as evidence of inflammation in 1997 is not persuasive. Inflammation is not the only cause of a focal process that can lead to atrophy in the spinal cord. Tr. 108. One potential cause of spinal cord atrophy is a deficiency in vitamin B12. Tr. 198-99. Petitioner was deficient in vitamin B12, probably because she was a vegetarian.[14] Consequently, although petitioner's 2006 MRI is not inconsistent with the assertion that she suffered inflammation in 1997, the 2006 MRI does not necessarily mean that petitioner had inflammation eight years earlier. Under this circumstance, petitioner's medical records that were created between November 1997 and April 1998, are worth reviewing in detail.

One prominent problem reported by petitioner between November 1997 and April 1998 was pain in her right flank. Exhibit 11 at 4-14, 15-17. Petitioner points to the pain in her right side as additional evidence that she experienced transverse myelitis in November 1997. Pet'r Reply Br., filed June 10, 2009, at 4. Dr. Tornatore stated that this pain is consistent with a person having transverse myelitis. Tr. 60; tr. 80-81. This argument stretches too far to be persuasive.

The doctors who saw petitioner in the hospital where she complained about flank pain did not diagnose her as having transverse myelitis because of this pain. Exhibit 2 at 16-18 (Dr. Conaway); exhibit 11 at 4-14; exhibit 40 at 110-11 (Dr. George); see also tr. 82-83 (Dr. Tornatore).

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[13] Dr. Tornatore cited two articles on brain or spinal cord atrophy and multiple sclerosis to support his diagnosis of transverse myelitis. Exhibit 50 (R. Bakshi et al., Measurement of Brain and Spinal Cord Atrophy by Magnetic Resonance Imaging as a Tool to Monitor Multiple Sclerosis, 15 J. Neuroimaging, 30S-45S (2005)); exhibit 51 (C. Tench et al., Spinal Cord Imaging in Multiple Sclerosis, 15 J. Neuroimaging, 94S-102S (2005)). Dr. Tornatore did not explain the usefulness of these articles during his testimony on direct examination. Without some guidance from Dr. Tornatore about why the articles support a diagnosis of transverse myelitis for petitioner, the undersigned finds little relevance to them.

[14] Petitioner's vitamin B12 deficiency is discussed more extensively in section IV.B.2.b below.

The type of pain that petitioner experienced in November 1997 is not the type of pain usually associated with transverse myelitis. Tr. 129; see also exhibit M (Anu Jacob et al., An Approach to the Diagnosis of Acute Transverse Myelitis, 28 No. 1 Seminars in Neurology 105, 110 (2008) at 6). The Mayo Clinic article states that the typical presentation of pain associated with transverse myelitis "often begins suddenly in the neck or back. Sharp, shooting pains may also radiate down the arms and legs." Exhibit 70 at 1. Petitioner experienced pain in her right flank, i.e., "the side of the body inferior to the ribs and superior to the ilium (pelvis)." See Dorland's at 708; but see tr. 55-56 (testimony of Dr. Tornatore stating petitioner's pain was actually "mid-thoracic"). Pain in the right side is not the type of pain typically seen in individuals with transverse myelitis. People with transverse myelitis experience pain in the neck and upper back, with pain possibly radiating down to the legs. Exhibit 70 (Mayo Clinic) at 1-2.

Petitioner ignores much information in the record that is not consistent with a diagnosis of transverse myelitis. In the months following her hepatitis B vaccinations, petitioner did not report to doctors that she was experiencing other symptoms of transverse myelitis, such as focal weaknesses and numbness. Some doctors affirmatively stated that petitioner did not have these symptoms. Exhibit 2 at 1 (Dr. Conaway's report stating that there were no focal deficits); exhibit 40 at 101 (Dr. George record stating that petitioner denied any focal weakness, numbness or paresthesias.). Consistent with the medical records, respondent argued that petitioner's symptoms after the hepatitis B vaccination did not match what is expected when someone suffers from transverse myelitis. Resp't Br. at 19-20. Yet, petitioner's reply brief largely fails to address the lack of numbness, the lack of tingling, the lack of muscles spasms, the lack of problems with her bowel, and the lack of problems with her bladder. See Pet'r Reply Br. at 4-9.[15] If petitioner truly had transverse myelitis, then she would have experienced these types of problems and reported them to her doctor. See tr. 129-138 (Dr. Leist's testimony that if petitioner had transverse myelitis, she would likely have also experienced significant sensory abnormalities, changed reflexes and issues with her bowel and bladder). The omission of these problems in medical records created around the time that petitioner was allegedly suffering from transverse myelitis supports an inference that petitioner did not have numbness, tingling, muscle spasms, problems with her bowel, or problems with her bladder. See Cucuras, 993 F.2d at 1528 (aff'g special master's decision not to find a medical problem that was not reported in medical records created contemporaneously).

During his testimony, Dr. Tornatore stated that he believed that what petitioner was experiencing was actually incomplete transverse myelitis. According to Dr. Tornatore, with incomplete transverse myelitis, there are a more limited number of symptoms. Dr. Tornatore

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[15] Petitioner suggests that respondent is "penalizing" her because her doctors in November 1997 failed to order an MRI. Pet'r Reply Br. at 5.

The undersigned does not understand respondent to be "penalizing" petitioner. Respondent seems to be drawing reasonable inferences as part of the normal process of litigating. Here, it appears that one reasonable explanation for the lack of an MRI in 1997-98 is that the petitioner's treating doctors did not consider transverse myelitis to be a possible diagnosis.

stated that because of the incomplete nature of the transverse myelitis, the flank pain she was experiencing was the "prominent" symptom, while her bowel and bladder issues were "secondary" in nature. Tr. 202-03.

Dr. Tornatore's resort to describing petitioner as having "incomplete" transverse myelitis is not persuasive. Incomplete transverse myelitis may be an appropriate diagnosis when the person has some (but not all) of the symptoms of transverse myelitis. However, petitioner seems to have none of the typical problems associated with transverse myelitis.

Consequently, petitioner has failed to establish, by a preponderance of the evidence, that she suffers from transverse myelitis. In short, her clinical presentation between November 1997 and April 1998 is not consistent with the signs and symptoms of a person with transverse myelitis. Thus, her treating doctors, including her treating neurologist, did not diagnose her with transverse myelitis. In addition, the only imaging study, the MRI ordered by Dr. Tornatore in 2006, lacks the probative force to counter the conclusions reached by petitioner's treating doctors.

Because a preponderance of the evidence does not establish that petitioner suffered from transverse myelitis, determining whether petitioner has met the three factors from Althen is not necessary. Instead, the next step is to consider whether petitioner has established, by a preponderance of the evidence, that she suffers from chronic fatigue syndrome.

B. Chronic Fatigue Syndrome

The second condition for which petitioner seeks compensation is chronic fatigue syndrome. For this aspect of her case, petitioner relies upon the opinion of Dr. Shoenfeld. However, Dr. Shoenfeld's opinion is not persuasive, because other problems are more likely to explain petitioner's chronic fatigue.

1. Criteria for Diagnosing Chronic Fatigue Syndrome

"Chronic fatigue is defined as self-reported persistent or relapsing fatigue lasting 6 or more consecutive months." Exhibit 45 (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. 223.

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 45 (Fukoda at 955) at 116. Dr. Shoenfeld agrees that these problems are part of diagnosing chronic fatigue syndrome. Exhibit 42 at 11-12.

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. Because there are no specific laboratory tests that confirm or exclude the diagnosis of chronic fatigue syndrome, to diagnose chronic fatigue syndrome properly, the doctor must exclude other medical conditions that can cause chronic fatigue. A diagnosis of chronic fatigue syndrome is based upon certain defined conditions and is accepted only after all alternative causes have been ruled out. Exhibit 45 (Fukoda at 955) at 116; tr. 348; tr. 396. For example, Fukoda lists five conditions that may explain chronic fatigue such as:

1. Any active medical condition that may explain the presence of chronic fatigue, such as untreated hypothyroidism, sleep apnea, and narcolepsy, and iatrogenic conditions such as side effects of medication.

2 Any previously diagnosed medical condition whose resolution has not been documented beyond reasonable clinical doubt and whose continued activity may explain the chronic fatiguing illness. Such conditions may include previously treated malignancies and unresolved cases of hepatitis B or C virus infection.

3. Any past or current diagnosis of a major depressive disorder with psychotic or melancholic features; bipolar affective disorders; schizophrenia of any subtype; delusional disorders of any subtype; dementias of any subtype; anorexia nervosa; or bulimia nervosa.

4. Alcohol or other substance abuse within 2 years before the onset of chronic fatigue and at any time afterward.

5. Severe obesity as defined by a body mass index [body mass index = weight in kilograms/(height in meters)^2] equal to or greater than 45.

Exhibit 45 (Fukoda at 955) at 116. Only when conditions, such as the type referenced above have been ruled out, can a diagnosis of chronic fatigue syndrome be considered.

2. Petitioner's Condition

Petitioner has failed to establish by a preponderance of the evidence that she suffers from chronic fatigue syndrome. Petitioner fulfilled the inclusive criteria for diagnosing chronic fatigue syndrome. However, doctors must also exclude other medical conditions that may explain the presence of the chronic fatigue. In petitioner's case, other plausible alternative causes for her chronic fatigue have not been excluded.

a. Inclusive Items

The primary quality of chronic fatigue syndrome is chronic fatigue. Petitioner established that she experienced more than six months of fatigue. Evidence supports a finding that petitioner

was experiencing fatigue during November 1997 and for six months thereafter. Exhibit 2 at 1, 6, 15-16, 19; exhibit 5 (continued complaints of fatigue in October 1998); exhibit 39 at 2. Respondent does not dispute that petitioner was fatigued for more than six months. Resp't Br. at 29.

Besides prolonged fatigue, the diagnosis of chronic fatigue syndrome requires at least four of the eight ancillary factors. Exhibit 45 (Fukoda at 955) at 116. Petitioner asserts, and respondent does not dispute, that she fulfills at least four criteria for chronic fatigue syndrome. Resp't Br. at 29. Although not specifically stated in her brief, it appears that respondent does not dispute that petitioner experienced (1) impaired memory or concentration (exhibit 3 at 2; exhibit 34 at 118), sore throat (exhibit 2 at 19; exhibit 30 at 35, 37), tender cervical or axillary lymph nodes (exhibit 30 at 35) and new headaches (exhibit 3 at 2; exhibit 34 at 118). Thus, the evidence demonstrates that petitioner does fulfill at least four of the eight diagnostic criteria for chronic fatigue syndrome.

b. Exclusive Items

The remaining issue in determining whether petitioner suffers from chronic fatigue syndrome is whether petitioner suffered from any condition that could explain her chronic fatigue. See Resp't Br. at 29. If another condition explains why a patient is suffering from chronic fatigue, then the diagnosis of chronic fatigue syndrome should not be made. Exhibit 47 (K. Konstantinov et al., Autoantibodies to Nuclear Envelope Antigens in Chronic Fatigue Syndrome, 98 J. Clin. Invest. 8 (1996)) at 1; tr. 348; tr. 396.

The evidence presented by respondent undermines Dr. Shoenfeld's conclusion that petitioner suffered from chronic fatigue syndrome. See Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (stating "[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief.").

Respondent's expert, Dr. Kagen, identified a number of medical conditions documented in petitioner's medical records that could be the cause of her fatigue, including (1) multiple nutritional deficiencies, particularly deficiency of vitamin B12, (2) osteoarthritis with spinal cord and nerve root compression, and (3) weight gain. Exhibit A at 8-9; tr. 361. These alternative causes are considered in the following sections.

(1) Nutritional Deficits, Including Deficit in Vitamin B12

Evidence presented in the medical records confirms that petitioner did have a persistent vitamin B12 deficiency. Exhibit 2 at 12 (lab results summary, dated 2/22/98 through 4/8/98); exhibit 13 at 21 (lab report dated 3/16/98); exhibit 16 at 167, 175, 177 (lab reports dated 9/20/98 and 4/1/99); exhibit 34 at 559, 566 (lab results dated 4/16/03 and 2/25/03).

Although these medical records are persuasive by themselves, petitioner also displayed symptoms of having a deficiency in vitamin B12. These symptoms include shortness of breath, rapid heart rate, fatigue, loss of appetite, sore mouth, tingling and numbness of hands and feet, bleeding gums, loss of deep tendon reflexes, positive Babinski's reflex, and unsteady gait. Exhibit C at 14; exhibit 34 at 201. Dr. Leist, in his report, cited areas in petitioner's medical records where she makes a number of these complaints. Id.; exhibit G at 3. Dr. Kagen also opined that petitioner likely suffered from a severe vitamin B12 deficiency because of several other factors, including petitioner's deficiency in thiamin, depression and memory loss. A deficiency in thiamin, depression and memory loss are all additional symptoms of a vitamin B12 deficiency. Tr. 388-391.

In the litigation, all but one of the experts recognized that petitioner suffered from vitamin B12 deficiency. Dr. Kagen's report and testimony indicated that there appeared to be no question that petitioner had a vitamin B12 deficiency. Exhibit A at 4; tr. 396-97; tr. 401. Dr. Leist agreed. Exhibit C at 3. Petitioner's own expert, Dr. Tornatore, also noted in his initial report that petitioner's tests revealed a low vitamin B12 level. Exhibit 44 at 2.

During his testimony, Dr. Shoenfeld stated that he saw no evidence of a vitamin B12 deficiency in petitioner's blood. Tr. 244. Dr. Shoenfeld stands alone in this statement. The evidence in medical records and laboratory tests consistently show that petitioner had a vitamin B12 deficiency. Exhibit 2 at 12; exhibit 13 at 21; exhibit 16 at 167, 175, 177; exhibit 34 at 559, 566.

Dr. Shoenfeld seemed to argue that petitioner's deficiency in vitamin B12 could not have caused her problems for two reasons. First, petitioner's deficiency was too mild to cause significant problems. Tr. 245. Second, Dr. Shoenfeld testified that because petitioner was given a vitamin B12 injection, her condition should have improved but did not. Id.

Respondent's expert, Dr. Kagen, disagreed with Dr. Shoenfeld's assessment. Dr. Kagen opined that petitioner had a significant B12 deficiency. Exhibit A at 4; tr. 387. Dr. Kagen explained that even though petitioner may have had a B12 injection to assist her, her body may not have absorbed the vitamin B12 because of her vegetarian diet. Tr. 385.[16] Dr. Kagen stated that some individuals, such as vegetarians and people with gastritis or an atrophic stomach, have problems with the intake and absorption of vitamin B12. Thus, these individuals do not show much improvement with vitamin B12 supplementation. Dr. Kagen's explanation for why supplementation with vitamin B12 did not improve petitioner's condition is persuasive.

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[16] The experts agreed that vegetarians often experience a deficiency in vitamin B12. Tr. 138-39 (Dr. Leist); tr. 241 (Dr. Shoenfeld); exhibit I (R. Obeid et al., The Impact of Vegetarianism on Some Haematological Parameters, 68 Eur. J. Haematol 275, 276 (2002)) at 276.

Likewise, Dr. Leist stated in his report that symptoms of a vitamin B12 deficiency include shortness of breath, rapid heart rate, fatigue, weakness and irritability to name a few symptoms. Exhibit C at 14; exhibit G at 3. "If a vitamin B12 repletion is not initiated, permanent neurological damage, including degeneration of nerves and spinal cord can result. Recent studies suggest that mental symptoms of depression and fatigue are detectable before anemia develops." Exhibit 34 at 201 (statement from laboratory). Consequently, petitioner's presentation, which includes depression and fatigue, is consistent with a deficiency in vitamin B12. The finding is consistent with comments made by petitioner's treating doctors, which are discussed in section 5, below.

Dr. Shoenfeld maintained that a deficiency in vitamin B12 will "not cause severe fatigue." Tr. 248. However, Dr. Shoenfeld's opinion is in conflict with the opinions of Dr. Leist and Dr. Kagen. Literature in the record supports the opinion of Dr. Leist and Dr. Kagen that a deficiency in vitamin B12 can cause fatigue. Exhibit 34 at 201 (statement from laboratory); exhibit J (S. Aaron et al., Clinical and Laboratory Features and Response to Treatment in Patients Presenting with Vitamin B12 Deficiency-Related Neurological Syndromes, 53 Issue 1 Neurology India 55, 58 (2005)). Thus, as to whether a deficiency in vitamin B12 can cause fatigue, the opinions of Dr. Leist and Dr. Kagen are persuasive. The opinion of Dr. Shoenfeld is not. See Moberly, 2010 WL 118661, at *7 (stating "the special master is entitled to require some indicia of reliability to support the assertion of the expert witness"); see also Cucuras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 537, 543 (1992) (stating "The special master had to reconcile conflicting expert testimony. As long as it is reasonable, his choice of respondent's expert opinion over petitioners' experts, and his acceptance of conclusions in relevant medical literature, is within the discretion granted to special masters in the Program."), aff'd, 993 F.2d 1525.

In light of petitioner's history of deficiencies in vitamin B12, a problem that can cause fatigue, Dr. Shoenfeld's diagnosis of chronic fatigue syndrome appears to be incorrect. The diagnosis of chronic fatigue syndrome is proper only when other explanations for the person's chronic fatigue have been excluded. Dr. Shoenfeld has not persuasively explained why petitioner's chronic fatigue could not have been a consequence of her vitamin B12 deficiency.

(2) Osteoarthritis and Disc Degeneration

Dr. Kagen also proposed that osteoarthritis and disc degeneration, which petitioner certainly had, would account for much of her joint and muscle pain. Exhibit A at 8; tr. 361-369; exhibit 35 at 5, 32-33; see also Resp't Br. at 13, 29. Petitioner did suffer from osteoarthritis and disc degeneration. Exhibit 13 at 9 (radiology report). Petitioner's expert, Dr. Tornatore, also confirmed that petitioner suffered from osteoarthritis and osteoporosis. Tr. 101.

Petitioner did relatively little to counter this argument. Petitioner's reply brief did not address this argument. Pet'r Reply Br. at 13. Dr. Shoenfeld testified that petitioner did not have osteoarthritis because she is a "young lady." Dr. Shoenfeld stated that osteoarthritis pains are seen when aging. Tr. 508; see also Pet'r Br. at 24-25. Dr. Shoenfeld's testimony is not persuasive. At the time of the hearing, petitioner was 61 years old. Tr. at 8. Dr. Shoenfeld's conclusion that a

61-year-old person cannot suffer from osteoarthritis is contradicted by medical records showing petitioner did have osteoarthritis.

Osteoarthritis and disc degeneration can cause abnormalities in the joints and bones leading to muscle and joint pains. Tr. 364-367; tr. 399-400; tr. 445; tr. 474 (Kagen). Dr. Shoenfeld also referenced joint pain associated with osteoarthritis in his testimony. Tr. 508. Thus, the evidence presented shows that the muscle and joint pains petitioner experienced, which are listed as criteria for chronic fatigue syndrome, could have been caused by petitioner's osteoarthritis and disc generation. Dr. Shoenfeld did not explain persuasively why the origins of petitioner's joint pain were not osteoarthritis and/or disc degeneration.

(3) Weight Gain

A third condition identified by Dr. Kagen as a cause for petitioner's fatigue was her gain in weight. Tr. 373; see also exhibit 45 (Fukoda) at 117. It is accurate to note that petitioner gained approximately 50 pounds in about five years. Exhibit 2 at 17; exhibit 34 at 347-348; exhibit 40 at 101.

However, the amount of weight that petitioner gained is not significant enough that it would exclude the diagnosis of chronic fatigue syndrome. From the group of people potentially suffering from chronic fatigue syndrome, Fukoda excluded people who suffered from "obesity," which is defined as having a body mass index ("BMI") equal to or greater than 45. Exhibit 45 (Fukoda) at 117. Petitioner's BMI was approximately 27. See exhibit 34 at 32 (providing Petitioner's height at 5 feet 3 ½ inches) and exhibit 2 at 16 (providing Petitioner's weight at 160 lbs). Thus, Petitioner's weight gain does not constitute a reason excluding Petitioner from chronic fatigue syndrome.

(4) Other Problems

Dr. Kagen also ruled out chronic fatigue syndrome as an appropriate diagnosis for petitioner because her presentation did not match what is typically seen in patients with chronic fatigue syndrome. Tr. 349; see also Resp't Br. at 30. For example, within two weeks of receiving the third dose of the hepatitis B vaccine, petitioner experienced severe flank pain, anemia, and bowel incontinence Exhibit 11 at 4-17. However, severe flank pain, bowel incontinence and anemia are not symptoms of chronic fatigue syndrome. Tr. 349; see also exhibit 45 (Fukoda) at 115.

Petitioner provided relatively little explanation for how petitioner's condition in November 1997 was consistent with chronic fatigue syndrome. Although respondent's brief argued this point, petitioner's reply brief did not address it. See Pet'r Reply Br. at 13-14. Similarly, Dr. Shoenfeld's report does list the symptoms for a diagnosis of chronic fatigue syndrome and states that petitioner experienced a majority of these symptoms "beginning in November of 1997." Exhibit 42 at 12-14. However, Dr. Shoenfeld's report fails to cite to the underlying record to support his statements that any of these symptoms began in November 1997.

It appears that Dr. Shoenfeld's source for these statements was the questionnaire that petitioner completed for Dr. Andrew Campbell, which has been discredited.[17] Thus, Dr. Shoenfeld's opinion to explain how petitioner's condition in November 1997 is consistent with chronic fatigue syndrome also cannot be credited.

In sum, because of plausible explanations for petitioner's fatigue, Dr. Kagen believed that the diagnosis of chronic fatigue syndrome was not appropriate. Exhibit A at 8-9. However, these other conditions did not prevent Dr. Shoenfeld from opining that petitioner suffered from chronic fatigue syndrome. Exhibit 42; exhibit 73. Before any conclusion about whether petitioner actually suffered from chronic fatigue syndrome is reached, information from the treating doctors should be considered. See 42 U.S.C.§ 300aa-13(b)(1) (In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record.)

(5) Treating Doctors

Because the opinions about whether petitioner suffers from chronic fatigue syndrome diverge, the views of treating doctors are important. See Capizzano, 440 F.3d at 1326. Petitioner identified two records in which a treating doctor indicated that Petitioner suffered from chronic fatigue syndrome.[18] Pet'r Reply Br. at 14, n.50, citing exhibit 30 at 3 [sic] and exhibit 3 at 3.

The records identified by Petitioner in her brief provide some support for the proposition that a treating doctor diagnosed her with chronic fatigue syndrome. The first record, exhibit 30, is a series of entries from Dr. Conaway from March 2002 to October 2003. These records indicate

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[17] Dr. Shoenfeld's reliance on the records of Dr. Andrew Campbell appears to be a mistake made without nefarious intent. Dr. Shoenfeld denied knowing that the Texas Medical Board was investigating Dr. Campbell. Tr. 271; see also exhibit P (final order of Texas Medical Board finding that Dr. Campbell failed to practice medicine in an acceptable manner); exhibit Q (order of the District Court for Travis County, Texas, granting Dr. Campbell a temporary injunction from enforcing the final order of the Texas Medical Board).

On the other hand, a review of petitioner's medical records reveals that Dr. Andrew Campbell's records includes symptoms that are not found in medical records of other doctors who treated petitioner. Moreover, respondent's report, filed pursuant to Vaccine Rule 4, alerted Dr. Shoenfeld that Dr. Andrew Campbell's records were not consistent with other records. Resp't Rep't, filed April 9, 2007, at 20. Consequently, Dr. Shoenfeld is expected to be more thorough in reviewing medical records in the future.

[18] There is a difference between suffering from chronic fatigue and chronic fatigue syndrome. Chronic fatigue syndrome requires chronic fatigue plus ancillary problems and the exclusion of other causes for the fatigue. Although several medical records say that Petitioner suffered from chronic fatigue or fatigue, these records do not state that Petitioner suffered from chronic fatigue syndrome.

that petitioner complained of "chronic fatigue" and was assessed as having, among other problems, "chronic fatigue syndrome." Exhibit 30 at 34-40.[19]

The basis for Dr. Conaway's diagnosis of chronic fatigue syndrome is not clear. Dr. Conaway saw petitioner approximately five times from November 1997 until April 1998. (A time which is much closer to when petitioner received the hepatitis B vaccine.) During these visits, Dr. Conaway evaluated petitioner for "chronic fatigue." Exhibit 2 at 1, 6, 8, 16. During this time, Dr. Conaway learned that petitioner was deficient in vitamin B12 because of tests performed by Dr. John Campbell at the Cleveland Clinic. Dr. Conaway stated that he was "not really sure that the mild vitamin B-12 deficiency explains these symptoms" referring to petitioner's chronic fatigue. Exhibit 2 at 16 (entry for April 23, 1998). Dr. Conaway did not diagnosis petitioner with chronic fatigue syndrome at this time and later referred her to Dr. Andrew Campbell.

When evaluating petitioner, Dr. Andrew Campbell also ordered tests that demonstrated that petitioner was deficient in vitamin B12. Exhibit 16 at 167 & 171 (report from Sept. 19, 1999); id. at 175-79 (report from April 2, 1999).[20] Deficiency symptoms of vitamin B12 include shortness of breath, fatigue, weakness, irritability, sore tongue, decrease in blood cell counts (red, white and platelets). Dr. Campbell's information sheet also states that if "Vitamin B12 repletion is not initiated, permanent neurological damage, including degeneration of nerves and spinal cord can result. Recent evidence suggests that mental symptoms of depression and fatigue are detectable before anemia develops." Id. at 171. In accord with these findings, Dr. Andrew Campbell recommended that petitioner get vitamin B12 shots. Exhibit 34 at 84 (report dated July 8, 1999).

In summary, approximately ten weeks after petitioner received the third dose of the hepatitis B vaccine on October 28, 1997, she complained about being fatigued to Dr. Conaway. Exhibit 2 at 8-9. Dr. Conaway did not diagnosis petitioner as suffering from chronic fatigue syndrome. Both Dr. John Campbell and Dr. Andrew Campbell recognized that petitioner was deficient in vitamin B12 and recommended that she take vitamin B12. Exhibit 13 at 21 & at 36; exhibit 34 at 84. Approximately four years later, Dr. Conaway diagnosed petitioner as suffering from chronic fatigue syndrome. Exhibit 30 at 34.

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[19] It appears that these records were raised for the first time in petitioner's reply brief. The undersigned could not locate any testimony about these records.

[20] While in previous sections, the accuracy of Dr. Andrew Campbell's records have been questioned, the same situation is not present with regard to tests of petitioner's vitamin levels. Dr. Campbell's records contain inaccurate information about petitioner's history. However, a laboratory conducted tests to determine whether a vitamin deficiency was present. These test results are not influenced by the medical history given by petitioner and thus are credited as being accurate.

The difficulty with Dr. Conaway's 2002 diagnosis is that Dr. Conaway provided no information about how he concluded that petitioner suffered from chronic fatigue syndrome. Exhibit 30, which is the set of records from Dr. Conaway from 2002 to 2004, does not contain any information showing that Dr. Conaway was aware of petitioner's continued deficiency in vitamin B12. See exhibit 34 at 559, 566 (lab results dated 4/16/03 and 2/25/03). Without evidence that Dr. Conaway was aware of petitioner's vitamin B12 deficiency in 2003, it is difficult to infer that Dr. Conaway considered this deficiency as a possible alternative cause for petitioner's fatigue and then rejected it. See Vanieken-Ryals, 508 F.3d at 1042 (noting that the Office of Personnel Management may consider, in evaluating statements made by treating doctors, the "failure of the professional to consider relevant factors"). Thus, Dr. Conaway's 2002 diagnosis is not persuasive evidence that petitioner suffered from chronic fatigue syndrome in 1998.

The second record identified in petitioner's reply brief is exhibit 3 at 3. In this document, which is dated October 18, 1999, Dr. Sandra Stewart-Pinkham noted that petitioner was exhibiting the symptoms of individuals with a "chronic fatigue immune dysfunction." Exhibit 3 at 3.

Dr. Stewart-Pinkham's report is too vague to be helpful. First, Dr. Stewart-Pinkham uses the term "chronic fatigue immune dysfunction," not "chronic fatigue syndrome." The difference in wording implies a different condition. Second, Dr. Stewart-Pinkham indicates that petitioner's problems may have originated in nutritional deficiencies because Dr. Stewart-Pinkham recommended that petitioner change her diet. Exhibit 3 at 2-3.[21] Thus, Dr. Stewart-Pinkham may have been concerned about a vitamin B12 deficiency, just like Dr. John Campbell and Dr. Andrew Campbell.

The report from Dr. Stewart-Pinkham in 1999 and the reports from Dr. Conaway in 2002-2004 must be placed in the context of statements from all petitioner's treating doctors. See 42 U.S.C. § 300aa-13(b)(1) (In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record.) Many other doctors noted that Petitioner had fatigue, yet these doctors did not diagnose her as suffering from chronic fatigue syndrome. E.g., exhibit 40 at 99-103 (Dr. George), exhibit 18 at 19 (Dr. Whistler).

3. Conclusion on Chronic Fatigue Syndrome

Petitioner experienced some of the symptoms attributable to chronic fatigue syndrome. However, for an accurate diagnosis of chronic fatigue syndrome, a doctor must exclude other medical conditions that may explain the presence of chronic fatigue. Ultimately, a number of alternative causes for petitioner's fatigue, including her vitamin B12 and thiamin deficiency explain why petitioner had fatigue. Most of petitioner's treating doctors did not diagnose her with

[21] Dr. Stewart-Pinkham also stated that petitioner's problems could be due to "mercury toxicity." As mentioned earlier, petitioner stated that she is not relying upon Dr. Stewart-Pinkham's report. See footnote 6.

chronic fatigue syndrome. Thus, a preponderance of the evidence indicates that petitioner did not suffer from chronic fatigue syndrome. Under these circumstances, examining whether petitioner satisfied the three factors identified in Althen is not necessary.

C. Systemic Lupus Erythematosus

During the second hearing, petitioner raised for the first time, more than 8 years after the initial petition was filed, the idea that she suffered from systemic lupus erythematosus. This is the third and final condition identified by her experts. However, as discussed below, petitioner does not fulfill the criteria for systemic lupus erythematosus.

1. Criteria for the Diagnosis of Systemic Lupus Erythematosus

Systemic lupus erythematosus is a disease affecting many systems of the body. It has manifestations in the skin, musculosketal system, and the pulmonaries of the heart, lungs, brain and the kidneys. Systemic lupus erythematosus is an inflammatory and chronic disease. The cause of it is not known. Tr. 469; exhibit 301 (Tracy Skaer et al., Medication-Induced Systemic Lupus Erythematosus, 14 No. 4 Clinical Therapeutics 496 (1992)) at 496.

In 1982, the American College of Rheumatologists issued revised criteria for the diagnosis of systemic lupus erythematosus. According to the criteria, a patient must exhibit at least four of the eleven criteria in order to be diagnosed with systemic lupus erythematosus. These eleven criteria are: (1) malar rash, (2) discoid rash, (3) photosensitivity, (4) oral ulcers, (5) arthritis, (6) serotitis, (7) renal disorder, (8) neurologic disorder, (9) hematologic disorder, (10) immunologic disorder, and (11) antinuclear antibody (ANA). Exhibit N (Eng M. Tan et al., The 1982 Revised Criteria for the Classification of System Lupus Erthematosus, 25 No. 11 Arthritis and Rheumatism 1271 (1982)) at 1274. The undersigned will use these criteria to determine whether petitioner has established, by a preponderance of evidence, that she suffers from systemic lupus erythematosus.[22]

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[22] When Dr. Shoenfeld testified on April 9, 2008, Dr. Shoenfeld referenced 11 criteria for diagnosing lupus. Tr. 224. In a supplemental report that Dr. Shoenfeld filed after this testimony, Dr. Shoenfeld also referenced the 11 criteria in the article by Eng Tan. Exhibit 86.

However, during his November 25, 2008 testimony, Dr. Shoenfeld suggested that reviewing the criteria one-by-one was an erroneous way to approach the problem. Tr. 496-501. Yet, petitioner has not offered a persuasive substitute for Eng Tan's criteria. See Moberly, 2010 WL 118661, at *7 (stating "the special master is entitled to require some inidicia of reliability to support the assertion of the expert witness"); see also Cucuras, 26 Cl. Ct. at 543 (1992) (stating "The special master had to reconcile conflicting expert testimony. As long as it is reasonable, his choice of respondent's expert opinion over petitioners' experts, and his acceptance of conclusions in relevant medical literature, is within the discretion granted to special masters in the Program."), aff'd, 993 F.2d 1525. Thus, the undersigned will use the criteria discussed by the parties and their experts.

2. Petitioner's Condition

Each of the eleven criteria is analyzed in the following paragraphs. For three conditions (discoid rash, renal disorder, and immunologic disorder), Dr. Shoenfeld stated that petitioner did not fulfill the criteria for lupus. In addition, Dr. Tornatore has ruled out another criterion, serotitis. The parties agree that petitioner had a hematologic disorder and antinuclear antibodies. Thus, of the 11 criteria, the parties dispute only five: malar rash, photosensitivity, oral ulcers, arthritis, and neurologic disorder.

1. Malar Rash

The 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus defines a "malar rash" as "fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds." Exhibit N (Eng Tan, The 1982 Revised Criteria) at 4.

Dr. Shoenfeld stated that petitioner did not have a "malar rash." Tr. 537. Dr. Kagen also stated that there was no evidence of petitioner experiencing a malar rash. Tr. 471.

Although this agreement would appear to resolve the issue, Dr. Shoenfeld asserted that looking for only a "malar rash" was too narrow. Instead, a clinician would consider other types of rashes. Tr. 504-6. Thus, to Dr. Shoenfeld, a rash on petitioner's upper lip or an oral ulceration can fulfill this criterion. Tr. 504-6; tr. 537.

The 1982 Revised Criteria locates the rash "over the malar eminences." Dr. Shoenfeld's attempt to broaden the definition is not persuasive. Thus, petitioner does not fulfill this criteria for SLE.

2. Discoid Rash

A "discoid rash" is defined as erythematous raised patches with adherent keratotic scaling and follicular plugging; atrophic scarring may occur in older lesions." Exhibit N (Eng Tan, The 1982 Revised Criteria) at 4. Dr. Kagen described a discoid rash as a "chronic, destructive scarring rash" and as a rash "that does not come and go", but rather is a permanent condition. Tr. 471.

Dr. Kagen did not see any evidence in the record of petitioner having a discoid rash. Tr. 471. Dr. Shoenfeld agreed that petitioner does not have a discoid rash. Tr. 538. Thus, petitioner does not fulfill this criterion for SLE.

3. Photosensitivity

The third criterion is "photosensitivity" which is described as a "skin rash as a result of unusual reaction to sunlight, by patient history or by physician observation." Exhibit N (Eng Tan, The 1982 Revised Criteria) at 5. Dr. Kagen testified that photosensitivity requires "the production of a characteristic rash in the presence of light or a source of ultraviolet light." Tr. 472. Dr.

Shoenfeld essentially agreed. Tr. 506 (stating "when you are exposed to sun, you develop pigment.")

The record contains conflicting information as to whether petitioner was photosensitive. The strongest evidence supporting petitioner's position is a record from April 23, 2002, prepared by Dr. Whisler. This record states that petitioner had "sensitivity to light" in 1997. Exhibit 18 at 18-19.[23] Another record is exhibit 30 at 43. Additional support comes from the medical history she gave to Dr. Andrew Campbell. Exhibit 34 at 37.

Other medical records affirmatively deny any photosensitivity. Exhibit 39 at 2; exhibit 40 at 101.

The records stating that petitioner did not have photosensitivity are probative. Notably, Dr. George evaluated petitioner in February 1998 (approximately four months after the third dose of the hepatitis B vaccine). Dr. George is a rheumatologist, who was specifically looking for evidence of lupus. Under these circumstances, it is highly likely that if petitioner had experienced photosensitivity, then she should have informed Dr. George. See Cucuras, 993 F.2d at 1528. However, Dr. George reported that petitioner did not have photosensitivity. Exhibit 40 at 101. As the record of treating doctor, Dr. George's report is entitled to careful consideration. See Capizzano, 440 F.3d at 1326 (instructing special masters to favor reports from treating doctors).

Similarly, Dr. Schlessel distinguished between rashes and "photosensitive rashes." (Dr. Schlessel is a rheumatologist. See Pet'r Reply Br. at 21; exhibit 88). Dr. Schlessel stated that "There have been no definite photosensitive rashes." Exhibit 39 at 2 (report dated Aug. 2, 2005).

The reports cited by Dr. Shoenfeld (in his reports) or petitioner (in briefs) are less persuasive. Dr. Whisler's report states that petitioner had "sensitivity to light," which appears to be a broader term than saying that she had a "skin rash" brought on by light. Like Dr. Schlessel, Dr. Whisler made note of petitioner's history of having had skin rashes, but did not describe her as having a rash brought about by light. Exhibit 18 at 18. Thus, Dr. Whisler's report does not support petitioner's claim.

Petitioner also cited to a report prepared by a nurse in Dr. Conaway's office. Pet'r Reply Br. at 12. This report indicates that petitioner was positive for "photophobia." However, "photophobia" is "abnormal visual intolerance to light." Dorland's at 1431. This condition differs from a rash.

Finally, for the reasons set forth above, the medical history given by petitioner to Dr. Campbell is discredited. Thus, on balance, the more persuasive evidence indicates that petitioner did not have photosensitivity as defined in the 1982 Revised Criteria.

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[23] Although Dr. Shoenfeld's June 10, 2008 report lists Dr. Whisler's report, neither Dr. Shoenfeld nor Dr. Kagen discussed Dr. Whisler's report during the hearing.

4. **Oral ulcers**

The fourth criterion is "oral ulcers." An oral ulcer is an "oral or nasopharyngeal ulceration, usually painless, observed by a physician." Exhibit N (Eng Tan, The 1982 Revised Criteria) at 4.

Some evidence indicates that petitioner was experiencing canker sores and at least one mild pharyngeal ulcer. Exhibit 30 at 37; tr. 472. However, petitioner denied have any oral ulcerations to another doctor. Exhibit 2 at 9. Given that there is some medical documentation of a physician observing at least one oral ulcer, petitioner fulfills this criterion for SLE.

5. **Arthritis**

"Arthritis" is described in the Revised Criteria as "nonerosive arthritis involving 2 or more peripheral joints, characterized by tenderness, swelling or effusion." Exhibit N (Eng Tan, The 1982 Revised Criteria) at 5. Much like the meaning of "malar rash," Dr. Shoenfeld and Dr. Kagen dispute the meaning of this term.

Dr. Shoenfeld contended that this criterion actually includes "arthralgia," which means pain in the joints. Tr. 508; tr. 540; see also Dorland's at 149.[24]

Dr. Shoenfeld's attempt to broaden the criterion for lupus is not persuasive. Presumably, the doctors who authored the 1982 Revised Criteria understood the difference between arthritis and arthralgia. Although Dr. Shoenfeld contended the 1982 Revised Criteria is a "shortcut," tr. 508-09, this is the criteria introduced into this record. See footnote 22 above. Consistent with the content of the 1982 Revised Criteria, Dr. Kagen distinguished arthritis from arthralgia. Tr. 473-75.

When restricted to "arthritis" as defined in the 1982 Revised Criteria, Dr. Shoenfeld conceded that petitioner did not have "arthritis." Tr. 541. Dr. Kagen also stated that petitioner did not have arthritis. Tr. 473-475. Thus, petitioner does not fulfill this criterion.

6. **Serositis**

The sixth criterion is "serositis." Serositis is defined as "(a) Pleuritis – convincing history of pleuritic pain or rub heard by a physician or evidence of pleural effusion, OR (b) Pericarditis – documented by ECF or rub or evidence of pericardial effusion." Exhibit N (Eng Tan, The 1982 Revised Criteria) at 5.

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[24] Neither Dr. Shoenfeld nor Dr. Kagen asserted that petitioner's osteoarthritis satisfied the lupus criterion. Although the record is not clear, osteoarthritis may differ from the arthritis found in systemic lupus erythematosus because osteoarthritis may be a type of erosive arthritis and the 1982 Revised Criteria specifies that the arthritis must be "nonerosive."

Petitioner presented relatively little evidence that she suffered from pleuritis. Initially, the medical records indicated that petitioner was diagnosed with pleuritis. Exhibit 2 at 17; exhibit 11 at 1. However, a later CT scan of petitioner's chest and abdomen yielded negative results. Exhibit 2 at 19. Thus, Dr. Tornatore stated that petitioner's CT scan did not support a diagnosis of pleurisy. Tr. 83. Dr. Shoenfeld only mentions that petitioner had "some lung involvement." See Pet. Br. at 25, citing tr. 499.

The determination by the treating doctors that petitioner did not have pleurisy is determinative. See exhibit 2 at 19; Capizzano, 440 F.3d at 1326. Thus, petitioner does not fulfill this criterion.

7. **Renal disorder**

The seventh criterion is a "renal disorder." Dr. Shoenfeld stated that petitioner did not have a renal disorder. Tr. 541. Petitioner does not fulfill this criterion for SLE.

8. **Neurologic Disorder**

The eighth criterion is a neurologic disorder. The Revised Criteria defines a "neurologic disorder" as "a) Seizures – in the absence of offending drugs or known metabolic derangements; e.g., uremia, ketoacidosis, or electrolyte imbalance, OR b) Psychosis – in the absence of offending drugs or known metabolic derangements, e.g., uremia, ketoacidosis, or electrolyte imbalance." Exhibit N (Eng Tan, The 1982 Revised Criteria) at 4. Once again, Dr. Shoenfeld attempted to broaden this criterion.

Dr. Shoenfeld stated that neurologic problems other than seizures or psychosis satisfy the criterion for diagnosis of systemic lupus erythematosus. Tr. 509-10; tr. 541. Dr. Shoenfeld's attempted expansion is not persuasive. The only diagnostic criteria submitted by the parties is the 1982 Revised Criteria. See order, filed April 11, 2008 (urging both parties to file literature setting forth diagnostic criteria); order, filed Nov. 25, 2008 (directing petitioner to file the chapter from Dr. Shoenfeld's book addressing the criteria for diagnosing lupus). Thus, the undersigned will rely upon the 1982 Revised Criteria.[25]

Dr. Shoenfeld agreed that petitioner did not experience seizures or psychosis. The medical records also indicate that petitioner did not experience these conditions. Exhibit 2 at 9; exhibit 7 at 14; exhibit 34 at 125. At least one of petitioner's treating physicians affirmatively stated that petitioner most likely did not have a neurologic problem. Exhibit 13 at 33-34. Therefore, petitioner does not fulfill this criterion for SLE.

[25] During his testimony, Dr. Shoenfeld asserted that other publications recognize many neurological problems as part of the diagnosis for systemic lupus erythematosus. See tr. 509-10. However, petitioner did not file any authorities to support Dr. Shoenfeld's assertion.

9. **Hematologic disorder**

The ninth criterion is evidence of a hematologic disorder. Petitioner satisfied this criterion. Tr. 479; see also Resp't Br. at 41.

10. **Immunologic disorder**

The tenth criterion is evidence of an immunologic disorder which is defined as "a) Positive LE cell preparation OR b) Anti-DNA: antibody to native DNA in abnormal titer OR c) Anti-Sm: presence of antibody to Sm nuclear antigen OR d) False positive serologic test for syphilis known to be positive for at least 6 months and confirmed by Treponema pallidum immobilization or fluorescent treponema antibody absorption test." Exhibit N (Eng Tan, The 1982 Revised Criteria) at 4.

Laboratory tests indicate that petitioner did not have anti-DNA, nor did she have Sm antibodies, for which she was tested three times. Exhibit 2 at 27; exhibit 8 at 6; exhibit 30 at 10; exhibit 40 at 103; see also tr. 481 (testimony of Dr. Kagen discussing these results). Dr. Kagen emphasized that for a patient who did not have anti-DNA antibodies, the diagnosis of lupus "would be very, very, very unlikely." Tr. 381.

Dr. Shoenfeld appeared to take inconsistent positions. In one report, Dr. Shoenfeld stated that petitioner did not have the "specific serological (anti-DNA, anti-Sem) or clinical findings for SLE [systemic lupus erythematosus] or any other defined autoimmune rheumatic disease." Exhibit 42 at 12 (report dated May 15, 2006). Despite this earlier statement, Dr. Shoenfeld later opined that other serologic tests indicated that petitioner had systemic lupus erythematosus. Tr. 116-17; exhibit 86 at 1-2.

Dr. Shoenfeld's reference to these other tests is not persuasive. The 1982 Revised Criteria identified four specific ways to satisfy this criterion. Other serologic tests, which Dr. Shoenfeld discussed, are not listed. Therefore, petitioner does not fulfill this criterion for a diagnosis of SLE.

11. **Antinuclear antibody**

The final criterion from the Revised Criteria for a diagnosis of systemic lupus erythematosus is the presence of antinuclear antibodies defined as "an abnormal titer of antinuclear antibody by immunofluorescense or an equivalent assay at any point in time and in the absence of drugs known to be associated with 'drug induced lupus' syndrome." Exhibit N at 4.

Petitioner has had an abnormal (positive) ANA results. Exhibit 2 at 14; exhibit 8 at 47; exhibit 36 at 15. Thus, respondent does not challenge that petitioner satisfies this criterion. Resp't Post Hearing Br. at 42.[26] Petitioner fulfills this criterion for a diagnosis of SLE.

Conclusion

At best, petitioner fulfills three of the eleven criteria for a diagnosis of systemic lupus erythematosus. The three criteria that petitioner satisfied are oral ulcers, hematological disorder and antinuclear antibody. Petitioner must fulfill at least four of the eleven criteria to satisfy the diagnostic criteria for SLE. Thus, petitioner does not suffer from systemic lupus erythematosus.

A finding that petitioner did not present a preponderant amount of evidence indicating that she suffers from SLE is consistent with the work of her treating doctors. From the period of 1997 to 2007, none of petitioner's treating doctors diagnosed her as suffering from SLE. Two of petitioner's treating physicians considered lupus and ruled it out. Exhibit 8 at 1 (medical records of Dr. Joseph Plouffe); exhibit 40 at 103 (report by Dr. George, a rheumatologist, from February 24, 1998).

Dr. Shoenfeld attempted to minimize the conclusions drawn by petitioner's treating doctors by stating that treating doctors often do not recognize systemic lupus erythematosus initially. Tr. 227; tr. 251. Dr. Shoenfeld is not persuasive. Even if Dr. Shoenfeld's assertion were true in general, some of petitioner's treating doctors investigated petitioner for SLE specifically. For example, Dr. George, a rheumatologist who saw petitioner approximately four months after receiving the third dose of the hepatitis B vaccine, evaluated petitioner for "possible lupus." Exhibit 40 at 99. Dr. George concluded that "I do not think that there is enough evidence for systemic lupus erythematosus or another autoimmune process at this time." Exhibit 40 at 103. Because Dr. George examined petitioner with an eye toward determining whether she had lupus, it is highly unlikely that Dr. George would have missed the condition at that time.

Dr. Shoenfeld was the first doctor to diagnose petitioner as having SLE. However, his conclusion is not persuasive for the reasons explained above.

After the hearing was complete and after petitioner filed her reply brief, petitioner filed a letter from Dr. Schlessel, which is two sentences. Dr. Schlessel states that petitioner's "laboratory tests will be consistent with a diagnosis of systemic lupus erythematosus." Exhibit 88 (dated June

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[26] Respondent notes that although petitioner satisfied this criterion, her ANA tests were not consistent with what is expected in a patient with systemic lupus erythematosus. The ANA pattern in an individual with lupus is usually homogenous rather than a speckled pattern. Tr. 358 (testimony of Dr. Kagen); tr. 377 (same); see also tr. 227 (testimony of Dr. Shoenfeld). However, petitioner's ANA results demonstrated more a speckled pattern. Exhibit 2 at 14; exhibit 8 at 47; exhibit 36 at 15.

10, 2009). Without having the laboratory tests – which petitioner could have obtained – assessing the reliability of Dr. Schlessel's statement is difficult. See Perreira, 33 F.3d at 1377 n.6 .

In light of all the information in the record, petitioner has not established that she suffers from systemic lupus erythematosus. Without a preponderance of evidence demonstrating this assertion, analyzing petitioner's claim that she fulfilled the Althen test connecting the hepatitis B vaccine to her development of system lupus erythematosus is not necessary.

D. Additional Comments on Diagnosis

In this case, petitioner claims to suffer from three different conditions. Significantly, petitioner has seen many doctors after her hepatitis B vaccinations in 1997. Yet, petitioner has not identified any treating doctor that diagnosed her as suffering from either transverse myelitis or systemic lupus erythematosus. While some medical records reference chronic fatigue syndrome, several other factors and conditions explain petitioner's fatigue other than chronic fatigue syndrome.

Petitioner necessarily relies upon opinions expressed by Dr. Tornatore and Dr. Shoenfeld, two people whom she retained for this litigation. To the extent that Dr. Tornatore (in diagnosing Petitioner as suffering from transverse myelitis) and Dr. Shoenfeld (in diagnosing her as suffering from either chronic fatigue syndrome or systemic lupus erythematosus) are attempting to correct the mistakes made by petitioner's treating doctors, both Dr. Tornatore and Dr. Shoenfeld fall well short of presenting a persuasive case. At various times, Dr. Tornatore and Dr. Shoenfeld appear to stretch well beyond what the facts about petitioner indicate.

Given that petitioner has not established that she suffers from either transverse myelitis or chronic fatigue syndrome or systemic lupus erythematosus, a question may arise as to what is (are) petitioner's illness(es)? The answer to this question is elusive. However, respondent is not required to establish an alternative cause for petitioner's problems because petitioner has not established that the hepatitis B vaccine caused her to suffer any conditions about which her experts opined. See Bazan, 539 F.3d at 1354; Broekelschen, 89 Fed. Cl. at 347; Spates v. Sec'y of Health & Human Servs., 76 Fed. Cl. 678, 685 (2007) (stating that "Petitioner is not entitled to compensation by default in the absence of an alternative explanation."). In traditional tort litigation, a defendant may challenge the differential diagnosis offered by plaintiff's experts by presenting other possible causes of plaintiff's condition. See Westberry v. Gislaved Gummi AB, 178 F.3d 257, 265-66 (4th Cir. 1999).

Respondent's experts, Dr. Leist and Dr. Kagen, presented other possible causes for petitioner's condition. Dr. Leist observed that petitioner had a deficiency in her vitamin B12 level. Dr. Leist further opined that the vitamin B12 deficiency "contributed to the complex of symptoms that she complained of in 1997." Exhibit C at 15; see also exhibit G. Dr. Leist also stated that the episodes of flank pain "were due to passage of [kidney] stones. Exhibit C at 16. Finally, Dr. Leist stated that "[petitioner] had pre-existing osteopenia and was later shown to have

significant degenerative changes in her cervical spine. These can be contributing factors to the symptom complex with which petitioner presented in 1997." Exhibit C at 17.

Dr. Kagen proposed five conditions that fit petitioner's presentation: "(1) mixed connective tissue disease - rheumatoid arthritis overlap, (2) osteoarthritis with spinal cord and nerve root compression, (3) multiple nutritional deficiency states, particularly deficiency of vitamin B12, (4) allergic reaction to toxic mold exposure, [and] (5) depression." Exhibit A at 8-9.

Petitioner's experts challenged, in their testimony, the diagnoses proposed by Dr. Leist and Dr. Kagen. However, the undersigned does not need to resolve whether any of the other possible causes offered by respondent's experts have been established by a preponderance of the evidence. Determining whether some factor, other than the vaccine, caused petitioner's condition is necessary only after petitioner has met her burden of establishing, by a preponderance of the evidence, that the hepatitis B vaccine caused her adverse reaction. See Bazan, 539 F.3d at 1354; Broekelschen, 89 Fed. Cl. at 344. Even if the conditions proposed by Dr. Leist and Dr. Kagen were not accurate, petitioner would not prevail merely because of "the absence of an alternative explanation." Spates, 76 Fed. Cl. at 685. "[A] simplistic elimination of other potential causes of the injury [does not] suffice[], without more, to meet the burden of showing actual causation." Althen, 418 F.3d at 1278.

E. Treating Physicians

The final topic is determining whether the medical records, by themselves, establish that the hepatitis B vaccination caused petitioner some harm. Although not addressed in petitioner's briefs, she could have argued that the statements of Dr. Andrew Campbell, Dr. Joseph Plouffe and Dr. Michael Conaway support a finding of logical sequence of cause and effect. Because special masters are obligated to consider "the record as a whole," 42 U.S.C. § 300aa–13(a); these physicians' statements will be considered. However, it is emphasized that petitioner has not argued in her post trial brief that these reports fulfill her burden of producing evidence showing a logical sequence of cause and effect. See Vaccine Rule 8(f).

Some statements in the medical record indicate that a treating doctor stated that the hepatitis B vaccine caused petitioner's health to deteriorate. The statements that most directly discuss "causation" come from Dr. Andrew Campbell. For example, he diagnosed petitioner as having an adverse reaction to a vaccine. Exhibit 34 at 109-110 (note from visit, dated July 31, 1998). In another record, Dr. Campbell stated that petitioner's "decline in overall health and subsequent disability status is a direct result of her Hepatitis B vaccines." Exhibit 34 at 376 (letter, dated October 12, 1998).

Dr. Andrew Campbell's statements are not reliable for two reasons. First, his opinion is based upon mistaken information. Records from his office include an assertion that petitioner suffered flu-like symptoms after the first and second hepatitis B vaccinations. Exhibit 34 at 113. However, petitioner testified that she did not react adversely to the first and second doses of the

hepatitis B vaccine. Tr. 12. Thus, Dr. Campbell's statement may be based on an untrue assumption that Ms. Campbell actually experienced adverse reactions after the first two hepatitis B vaccinations. When treating doctors rely upon inaccurate information, a finder of fact may reject their conclusions. Perreira, 33 F.3d at 1377 n.6; Burns, 3 F.3d at 417; see also Brooke Group Ltd. v. Brown & Williamson Tobacco Corp, 509 U.S. 209, 242 (1993); Vanieken-Ryals, 508 F.3d at 1042-43 (noting that the Office of Personnel Management may consider whether a treating doctor has considered "relevant factors" in reaching a diagnosis).

The second problem with Dr. Andrew Campbell's diagnosis is a concern about Dr. Campbell's medical judgment. The Texas Medical Board found that he failed to practice medicine in an acceptable manner. Exhibit P.[27] He has some notoriety for diagnosing people with reactions to vaccines. Boley v. Sec'y of Health & Human Servs., No. 05-420V, 2008 WL 4615034, at *23-24 (Fed. Cl. Spec. Mstr. Sept. 9, 2008), aff'd 86 Fed. Cl. 294 (2009); Simmons v. Sec'y of Health & Human Servs., No. 99-546V, 2006 WL 5649844, at *14-16 (Fed. Cl. Spec. Mstr. Aug. 31, 2006). In one case, his opinion that mold caused plaintiffs' immune problems was rejected as unreliable. Gaudette v. Conn Appliances, Inc., No. 09-06-44 CV, 2007 WL 2493437 (Tax. App. Beaumont, Sept. 6, 2007) (not selected for publication). These other decisions reinforce the finding that Dr. Campbell's statements that a hepatitis B vaccine caused petitioner's health problem are not persuasive.

In addition to the statements made by Dr. Andrew Campbell, statements by two other treating doctors (Dr. Plouffe and Dr. Conaway) could have been advanced to support petitioner's claim. Dr. Joseph Plouffe noted in his records that petitioner had a "possible immunolgic process of questionable etiology[.] Hep B vaccine certainly possible." Exhibit 8 at 1. Dr. Conaway, wrote in a "To Whom It May Concern" letter, which apparently was written to support petitioner's claim for disability benefits, that he was treating petitioner for "chronic fatigue and chronic chest wall pain that initially arose immediately after her third Hepatitis B vaccine . . . . It is certainly possible that she is having a chronic severe reaction to the Hepatitis B vaccine as reported by a specialist in Texas." Exhibit 2 at 6.

These statements hold little persuasive value. There is an absence of explanation as to how these physicians came to their conclusion. Both statements contain too much uncertainty. Dr. Plouffe stated that petitioner had a "possible immunologic process of questionable etiology." For the cause of this possible immunologic process, Dr. Plouffe stated that the hepatitis B vaccine was "certainly possible." Exhibit 8 at 1 (all emphases added). Dr. Conaway used the same phrase – he stated that a "chronic severe reaction to the Hepatitis B vaccine" was "certainly possible." Exhibit 2 at 6 (emphasis added.)

When these legal concepts of "preponderance of the evidence" and "relevant evidence" are applied to the statements of Dr. Plouffe and Dr. Conaway, it is clear that the doctors' statements

[27] A state court has enjoined the Texas State Board from enforcing its order while Dr. Campbell appeals. Exhibit Q.

do not constitute persuasive evidence. Expressing the idea that it is "possible" – or even "certainly possible" – that the hepatitis B vaccine caused petitioner to suffer some adverse health consequence does not help the undersigned, as trier of fact, determine whether it is more likely than not that the hepatitis B vaccine caused a health problem for petitioner. See section III.B.

Finally, one additional reason diminishes the weight of Dr. Conaway's statement. Dr. Conaway refers to the hepatitis B vaccination as being associated with petitioner's symptoms only after receiving a report from Dr. Andrew Campbell. Before Dr. Conaway received the report from Dr. Campbell, Dr. Conaway made no association between petitioner's ailments and the hepatitis B vaccination. See, e.g., exhibit 2 at 6 (letter from Dr. Conaway, dated December 1, 1998). When Dr. Conaway finally refers to the hepatitis B vaccination, Dr. Conaway states that "she is having a chronic severe reaction to the Hepatitis B vaccine as reported by a specialist in Texas." Exhibit 2 at 6. Because Dr. Andrew Campbell's opinion is a foundation for Dr. Conaway's statement and Dr. Andrew Campbell's opinion is not reliable, Dr. Conaway's statement is also not reliable.

Consequently, the statements of treating doctors do not fulfill petitioner's burden of proof. petitioner's case would not have been persuasive even if she had advanced them.

V. Conclusion

Petitioner has not established that she suffers any of the conditions for which she seeks compensation (transverse myelitis or chronic fatigue syndrome or systemic lupus erythematosus). Thus, she is not entitled to compensation. The Clerk's Office is ordered to enter judgment consistent with this decision unless a timely motion for review is filed.

IT IS SO ORDERED.

s/ Christian J. Moran
Christian J. Moran
Special Master