REDACTED OPINION

In The United States Court of Federal Claims

No. XX-XXXV
Filed: August 5, 2010
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JANE DOE 60,	*	
	*	**Motion for Review of Special Master's**
Petitioner,	*	**Decision; National Vaccine Injury Act,**
	*	**42 U.S.C. §§ 300aa-1, et seq.; Hepatitis B**
v.	*	**Vaccine; Transverse Myelitis, Chronic**
	*	**Fatigue Syndrome, Systemic Lupus**
SECRETARY OF DEPARTMENT	*	**Erythematosus; Preponderance of the**
OF HEALTH AND HUMAN	*	**Evidence**
SERVICES,	*	
	*	
Respondent.	*	
	*	

Clifford Shoemaker, Shoemaker & Associates, Vienna, Virginia, for the Petitioner.

Heather R. Pearlman, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for the Respondent. With her were **Tony West**, Acting Assistant Attorney General; **Timothy P. Garren**, Director; **Mark W. Rogers**, Acting Deputy Director; **Catharine E. Reeves**, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

O P I N I O N

HORN, J.

Petitioner filed a timely petition seeking compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1, et seq. (2006) (the Vaccine Act). Petitioner alleges that she suffered various injuries as a result of a series of Hepatitis B vaccinations received on April 1, 1997, May 6, 1997, and October 28, 1997. Petitioner focused her case, and offered expert opinions in support of, claims that she suffers from

[1] This opinion was issued under seal on August 5, 2010. The parties proposed redactions to the opinion, which were incorporated into this version. The court made additional conforming redactions for consistency.

transverse myelitis,[2] chronic fatigue syndrome,[3] and systemic lupus erythematosus (SLE)[4] as a result of her Hepatitis B vaccinations. After the case was reassigned several times, Special Master Christian Moran determined that petitioner is not entitled to compensation because she "has not established that she suffers from any of the three conditions that provide the basis for her experts' opinions."

Three hearings were held by Special Master Moran to elicit testimony, much of which came from expert witnesses. In brief, at the first hearing on November 1-2, 2007, petitioner and two experts, Dr. Carlo Tornatore and Dr. Thomas Leist, testified. petitioner's expert, Dr. Tornatore, a neurologist, stated that an MRI performed on petitioner on December 1, 2006, indicated that her thoracic spine was atrophied. Dr. Tornatore offered his opinion that the atrophy was caused by spinal cord inflammation known as transverse myelitis that he concluded resulted from an adverse reaction to the

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[2] The Special Master defined transverse myelitis as "an acute inflammatory process affecting a focal area of the spinal cord. It 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." Douglas Kerr, "Transverse Myelitis," Current Therapy in Neurologic Disease 1, 1 (R.T. Johnson et al., eds., 6th ed. 2001).

[3] The Special Master noted, "[b]ecause 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." He referred to the following study, Keiji Fukoda et al., "The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study," 121 Ann. Intern. Med. 953, 955 (1994). The Special Master used the following definitions for chronic fatigue syndrome: "Chronic fatigue is defined as self-reported persistent or relapsing fatigue lasting 6 or more consecutive months." Id. at 954. According to the Special Master, "[i]n 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, (8) post-exertion malaise." See Fukoda, 121 Ann. Intern. Med. at 955.

[4] The Special Master defined SLE as, "a disease affecting many systems of the body. It has manifestations in the skin, musculoskeletal 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." See Tracy Skaer et al., "Medication-Induced Systemic Lupus Erythematosus," 14 Clinic Therapeutics No. 4 496, 496 (1992). According to revised criteria issued by the American College of Rheumatologists in 1982, a patient must exhibit at least four of the following eleven criteria for a diagnosis of SLE: (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). Eng M. Tan et al., "The 1982 Revised Criteria for the Classification of System Lupus Erythematosus," 25 Arthritis and Rheumatism No. 11 1271, 1274 (1982).

Hepatitis B vaccine. Dr. Leist, also a neurologist, testified for the government. Dr. Leist offered his opinion that petitioner suffers from (1) a vitamin B12 deficiency, (2) an evolving, mixed collagen, vascular disorder, and (3) osteopenia, with degenerative changes in her cervical spine. Dr. Leist rejected Dr. Tornatore's hypothesis that petitioner suffers from transverse myelitis as a result of her series of Hepatitis B vaccinations.

At the second hearing, on April 9, 2008, Dr. Yehuda Shoenfeld testified for the petitioner, and Dr. Lawrence Kagen testified for the government. Previously, petitioner had submitted an expert report from Dr. Shoenfeld, an immunologist and rheumatologist, in which he had suggested that petitioner suffers from chronic fatigue syndrome, which can be caused by the Hepatitis B vaccinations. In Dr. Shoenfeld's opinion, petitioner's chronic fatigue syndrome was a "direct result" of her Hepatitis B vaccine. Dr. Shoenfeld also stated, for the first time at the hearing, and not in his expert report, that petitioner's condition, in addition to fulfilling the diagnosis of chronic fatigue syndrome, also meets the diagnostic criteria for SLE, a condition he believed was caused by the Hepatitis B vaccinations she received in 1997. Dr. Shoenfeld stated, "[i]f I would been asked just given the details, which I mentioned, will you diagnose this patient as SLE? I will say yes." Dr. Kagen, the government's rheumatologist, offered additional possible diagnoses at the hearing, which he had previously written into his expert report. His opinion was that 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. He did not comment as to whether petitioner suffers from chronic fatigue syndrome or whether the Hepatitis B vaccine could have caused the illnesses he diagnosed.

The third hearing was held on November 25, 2008. At the third hearing, Dr. Shoenfeld and Dr. Kagen testified regarding whether petitioner met the diagnostic criterion for SLE. Dr. Kagen assessed each of the eleven criteria identified by the American College of Rheumatology in the 1982 Revised Criteria for the Classification of SLE, of which a patient who meets four of the eleven criteria qualifies for an SLE diagnosis. Dr. Kagen indicated that there was no evidence he had found in the medical records that petitioner meets the criteria for SLE. Contending that the diagnostic criteria were there to "sharpen" the diagnosis, but were "not necessary," Dr. Shoenfeld repeated his belief that petitioner's symptoms are consistent with the diagnosis of SLE.

After the third hearing, both parties submitted post-trial briefs, following which Special Master Moran issued his decision denying relief. The Special Master found that petitioner had not established, by a preponderance of the evidence, that she suffers from any of the specific conditions identified by petitioner's expert witnesses who submitted expert reports or testified in connection with this litigation. According to the Special Master, petitioner's case is "complicated" because she alleges that she suffers from three conditions, and unusual, because expert witnesses at trial could not reach any consensus about what condition or conditions affect her now or affected her in the 1997 to 1998 time frame, closer to the time of her Hepatitis B vaccinations.

Not even petitioner's own treating doctors were able to diagnose her with one condition consistently, and the Special Master noted that petitioner's own witnesses proposed differing explanations for her different identified symptoms. Of the two medical expert witnesses for petitioner, Dr. Tornatore proposed transverse myelitis as a result of her Hepatitis B vaccinations, while Dr. Shoenfeld diagnosed chronic fatigue syndrome and SLE. Dr. Shoenfeld stated that chronic fatigue syndrome and SLE were both a result of petitioner's Hepatitis B vaccinations. The doctors who testified as medical experts for the respondent offered other possibilities. Dr. Leist suggested explanations including vitamin B12 deficiency, an evolving, mixed collagen, vascular disorder, osteopenia, with degenerative cervical spine changes, and depression. Dr. Leist rejected Dr. Tornatore's diagnosis of transverse myelitis as a result of the Hepatitis B vaccinations. Respondent's medical expert, Dr. Kagen, offered, yet again, a different set of theories, including a mixed connective tissue disease with rheumatoid arthritis overlap, osteoarthritis with spinal cord and nerve root compression, an allergic reaction to mold, depression and like Dr. Leist, a vitamin B12 deficiency. Dr. Kagen found no Hepatitis B connection and rejected Dr. Shoenfeld's diagnosis of SLE. The Special Master found that evidence of "'possible' – or even 'certainly possible'" causation, unsupported by other evidence, was insufficient for the trier of fact to "determine whether it is more likely than not" causation was related to the administration of the vaccine. In addition, the Special Master found that, unlike in Kelley v. Secretary of Health and Human Services, 68 Fed. Cl. 84, 100 (2005), petitioner has not argued that the three conditions are so similar that they could be considered conditions along a spectrum of diseases.

The medical records list yet additional symptoms attributed to petitioner and allege additional causations. Therefore, the Special Master also addressed whether these medical records themselves established injury to petitioner from the Hepatitis B vaccinations. The Special Master concluded that petitioner had not established more than a possibility of a connection, which was insufficient to establish that the Hepatitis B vaccinations, more likely than not, caused health problems for petitioner.

The Special Master found that petitioner had not established, by a preponderance of the evidence, that she suffered from any of the identified diseases "discussed by her experts." For this reason, the Special Master wrote, "[c]onsequently, this decision does not determine whether [petitioner] satisfied the additional elements necessary for compensation set forth in Althen [v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005)]." The Special Master explained:

> 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.

The Special Master consequently found that petitioner was not entitled to compensation under the Vaccine Act.

Petitioner filed a Motion for Review pursuant to Rule 23 of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rules. Petitioner raises three major objections to the Special Master's decision. First, petitioner contends that Special Master Moran arbitrarily and capriciously required her to prove, by a preponderance of the evidence, that she had a specific diagnosis, "transverse myelitis, chronic fatigue syndrome, or systemic lupus erythematosus (SLE)," which she alleges is an impermissibly high burden of proof, given that the Vaccine Act only requires a finding that the Hepatitis B vaccine caused "any illness, disability, injury, or condition not set forth in the Vaccine Injury Table." See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Petitioner alleges that this occurred in contravention of Kelley v. Secretary of Health and Human Services, 68 Fed. Cl. at 100, in which the court held that "[t]he Vaccine Act does not require petitioners coming under the non-Table injury provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury – regardless of the ultimate diagnosis."

Second, petitioner on review contends that by disregarding or excluding medical records and statements of treating doctors (particularly those after 1999) regarding petitioner's symptoms, the Special Master abused his discretion. Petitioner insists that the testimony from her expert witnesses, in addition to the statements of treating physicians and her medical records, establish that she does have transverse myelitis, chronic fatigue syndrome, and SLE. Third, petitioner contends that, despite a full and detailed evidentiary record and the presentation of plausible biological theories casually connecting the vaccine to her symptoms, the Special Master impermissibly refused even to address the question of whether she had met her burden under Althen to demonstrate that the Hepatitis B vaccine caused her symptoms. Therefore, petitioner requests that the Special Master's decision be set aside and a decision in her favor be entered.

Respondent replied and requests that the Special Master's decision be affirmed. Respondent contends that the Special Master's decision that petitioner does not have any of the conditions for which she alleges vaccine causation is amply supported in the record before the Special Master and should not be disturbed. Respondent argues that if a petitioner, like the petitioner, does not suffer from any of the conditions she alleges were caused by the vaccination, then an expert's opinion regarding a reliable medical theory to explain how the vaccine caused the condition is not relevant. Respondent argues that Kelley v. Secretary of Heath and Human Services is distinguishable because in that case, the petitioner's diagnosis wavered between two conditions (Guillain-Barré Syndrome and Chronic Inflammatory Demyelinating Syndrome), both demyelinating neuropathies of the peripheral nervous system, leading the court to

conclude that the two conditions were "on a spectrum, and that distinctions between them are hopelessly blurred." Kelley v. Sec'y of HHS, 68 Fed. Cl. at 102. Therefore, in Kelley, no ultimate diagnosis was required. Id. at 100. Because petitioner does not claim that any of her three alleged conditions are so similar as to be on a spectrum of diseases, nor are they, respondent argues that the plain language of the Vaccine Act requires Petitioner to establish from what injury she is suffering. Respondent cites Devonshire v. Secretary of Health and Human Services, 76 Fed. Cl. 452, 454 (2007), which states "it is axiomatic that as a prerequisite to proving causation [for Off-Table injuries], a petitioner must prove by a preponderance of the evidence the existence of the injury she claims was caused by the vaccination." Respondent also quotes from Broekelschen v. Secretary of Health and Human Services, 89 Fed. Cl. 336 (2009), appeal docketed, No. 2009-5132 (Fed. Cir. Sept. 29, 2009), "it was appropriate in this case – where virtually all of the evidence on causation was dependant on the diagnosis of petitioner's condition – for the special master to determine the proper diagnosis before applying the Althen test." Id. at 344.

According to respondent, the Special Master should be accorded discretion to review the available evidence, evaluate credibility, reconcile conflicting evidence by weighing, and come to a reasonable conclusion. The government argues that because the Special Master found that petitioner did not establish, by a preponderance of the evidence, that she suffers from transverse myelitis, chronic fatigue syndrome or SLE, the Special Master did not commit legal error by not addressing the test laid out in Althen v. Secretary of Health and Human Services, 418 F.3d at 1278. The government agrees with Special Master Moran that "without knowing what the injury is, an evaluation of the three Althen prongs cannot be performed." Therefore, the government argues that the decision by Special Master Moran was in accord with the law, and not arbitrary, capricious or an abuse of discretion. Respondent requests that the Special Master's decision be affirmed.

FINDINGS OF FACT

Petitioner was born on October 17, 1946. She received her Hepatitis B vaccinations in 1997. Petitioner's history prior to receiving the Hepatitis B vaccination, at the age of 51,[5] is considered relevant to the outcome of petitioner's claim for relief.[6]

[5] The Special Master indicated petitioner was 56 when she received her first dose of the vaccine.

[6] Unfortunately, the medical records in the case, as filed with the Special Master and the court, are assembled poorly and disorganized, for example, with respect to the inadequacy of an index; exhibits containing multiple records are amalgamated, without numbered tabs; there are overlapping exhibit numbers throughout the record, and the record does not contain consecutive page numbers from start to finish of the submitted record. Moreover, the same exhibits appear multiple times, although this may be due to their origin from the files of separate doctors. In addition, many of the copies are very difficult to read and no attempt was made by the parties to assist the court to interpret those documents, even when the documents were relevant to the case under review.

Unfortunately, as discussed below, the relevant details in the record of petitioner's medical history prior to petitioner receiving the Hepatitis B vaccinations are sparse. The record does reveal that petitioner became a vegetarian at the age of 25. She underwent a hysterectomy at the age of 31, had her appendix removed in her early 30's and had her silver dental amalgams removed at age 38. In 1993, at the age of 37, petitioner had problems with her gallbladder, and subsequently underwent surgery for its removal. At age 40, her father died and her brother committed suicide. In August 1990, her only child died under tragic and extraordinary circumstances, as a result of which petitioner took a six month leave of absence from work.

According to the record, which is not entirely clear, prior to her vaccinations, petitioner had worked for Abbott Laboratories, during which time she worked with a chemical, cyclohexane. From sometime in 1989, petitioner was employed by Ross Laboratories. Her position at Ross Laboratories involved handling boxes contaminated with bodily fluids. Petitioner was strongly encouraged by her employer to take the Hepatitis B vaccine. Initially, she refused to receive the vaccine due to concerns about possible side effects. At the continued urging of her employer, petitioner agreed to receive the first dose of the Hepatitis B vaccine on April 1, 1997, and suffered no adverse reaction. She received the second dose of the Hepatitis B vaccine on May 6, 1997, also with "no effect." On October 28, 1997, the third Hepatitis B injection was administered. Petitioner claims that after the third dose she began to feel like she had the flu.[7] By November 8, 1997, petitioner alleged that she began to experience pain in her right flank that radiated into her right chest. She sought treatment the following day, November 9, 1997, at the Mount Carmel Medical Center Emergency Room. Various tests were performed, and she was subsequently discharged the same day with a diagnosis of atypical chest pain. Petitioner returned to the Emergency Room on November 14, 1997, still complaining of right flank pain. Tests run by the Mount Carmel Medical Center again failed to detect any identifiable problems.

Petitioner indicated that she continued to experience pain on her right side and that she was weak and fatigued. On January 15, 1998, she was seen by internal medicine specialist, Dr. Michael Conaway. At her visit with Dr. Conaway, petitioner complained of severe right-sided lateral rib cage pain, fatigue, and nausea. At the same visit on January, 15, 1998, petitioner also informed Dr. Conaway that she had experienced weight gain of forty pounds in the past five years. Dr. Conaway reviewed the results of blood drawn on January 13, 1998, which indicated that petitioner had a

[7] The files from Dr. Andrew Campbell, a preventative medicine specialist consulted by petitioner in 1998, indicate that petitioner felt "flu-like" after her first vaccine. At the first hearing, however, petitioner testified that she suffered no problems after the first and second Hepatitis B shots. Therefore, for this reason and because of his general distrust of Dr. Andrew Campbell's credibility, as discussed more fully below, Special Master Moran found that a preponderance of evidence indicates that Dr. Andrew Campbell's note is "not accurate."

positive antinuclear antibody (ANA)[8] of 1:1280 with a speckled pattern. Petitioner was diagnosed with pleurisy[9] by Dr. Conaway. Dr. Conaway ordered additional tests to determine whether petitioner had SLE.

In February 1998, petitioner was evaluated for possible SLE by Dr. Teresa George, a rheumatologist. Dr. George found no abnormalities on exam. Dr. George noted that petitioner had a history of joint pain, although the joint pain had not been associated with swelling. Dr. George's notes also indicate that during the visit, petitioner denied any skin rashes, hair loss, photosensitivity or changes in memory or concentration. With the exception of a higher antinuclear antibody (ANA) rate, Dr. George found that all other laboratory tests, including other serologies for diagnosing SLE, were normal. Dr. George noted, "I suspect that she has probably had a positive ANA in the past, although I do not have a record of this." After her examination and review of petitioner's laboratory results, Dr. George concluded that petitioner's right chest pain was of "unclear etiology" and that there was not "enough evidence for systemic lupus erythematosis [sic] or another autoimmune process at this time."

In February and March 1998, petitioner followed up with Dr. Conaway at three separate visits, continuing to complain of right-sided pain, nausea, and fatigue. After having put petitioner through a workup, Dr. Conaway noted at the last visit that he was "really at a loss to explain both her pain and her fatigue at this point." Dr. Conaway referred petitioner to the Cleveland Clinic to obtain a more comprehensive diagnostic evaluation.

Still experiencing right flank pain, petitioner saw preventative medicine specialist, Dr. John Campbell,[10] at the Cleveland Clinic on March 16, 1998. Dr. John Campbell ordered blood tests, which revealed that petitioner had a vitamin B12 deficiency and an elevated level of methylmalonic acid. Dr. John Campbell requested that petitioner have additional tests and see a neurologist. A radiology report indicated that petitioner had decreased bone density, consistent with osteopenia of her lumbar spine, and

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[8] Antinuclear antibody, or ANA, is an antibody "showing an affinity for nuclear antigens including DNA and found in the serum of a high proportion of patients with systemic lupus erythematosus, rheumatoid arthritis, and certain collagen diseases, and in some of their healthy relatives, as well as about 1% of otherwise healthy people. Different antinuclear a.'s [antibodies] generate distinctive patterns on immunofluorescence staining tests. These patterns have clinical relevance and reflect which nuclear constituents (autoantigens) are generative specific antibody responses." Stedman's Medical Dictionary 103 (28th ed. 2006).

[9] Pleurisy is "[i]nflammation of the pleura." Stedman's Medical Dictionary 1512 (28th ed. 2006). The pleura is "[t]he serous membrane enveloping the lungs and lining the walls of the pulmonary cavities." Id.

[10] Petitioner was treated by two different, unrelated Dr. Campbells – preventative medicine specialist Dr. John Campbell at the Cleveland Clinic and Dr. Andrew Campbell, medical director of the Center for Immune & Toxic Disorders, in Spring, Texas.

osteoporosis in her left hip. Dr. John Campbell's notes indicate as an entry on physical evaluation form titled "impressions," "post hepatitis B – fatigue …," followed by an illegible word.[11]

Based on a consult from Dr. John Campbell, on April 9, 1998, petitioner was examined by Dr. Patrick Sweeney, a neurologist at the Cleveland Clinic, and Dr. Ian Lavery in the colorectal surgery department. Dr. Lavery did not note any problems, stating in his impressions "normal sigmoidoscopy" and "normal," followed by another illegible word. After an exam, Dr. Sweeney concluded that petitioner was unlikely to have a neurologic problem, stating "doubt neuro disease." Petitioner returned to Dr. John Campbell after her visit with Dr. Sweeney. In his impressions, Dr. John Campbell summarized findings from Dr. Sweeney and noted that petitioner suffered from "post vaccine syndrome." Dr. John Campbell recommended that petitioner take B12 vitamins and follow-up with her local physician.

On April 23, 1998, petitioner returned to be seen again by internal medicine specialist Dr. Conaway to follow-up on her fatigue and right lateral rib cage pain. Petitioner told Dr. Conaway that she was still very fatigued and could only walk for about ten minutes before becoming exhausted. Dr. Conaway assessed petitioner with chronic fatigue, expressing uncertainty as to whether the mild vitamin B12 deficiency could explain her symptoms. Dr. Conaway gave petitioner an injection of 1000 mcg of vitamin B12, deciding to await further records from Dr. John Campbell's analysis before ruling out vitamin B12 deficiency as an explanation for her symptoms. Dr. Conaway also assessed petitioner with "chronic right lateral rib cage pain," but was unable to determine a cause for the pain. At the visit, Dr. Conaway referred petitioner to Dr. Elizabeth Hurst for a psychological evaluation to investigate whether underlying depression or trauma could account for her symptoms. The record, however, does not include records of the psychological consultation with Dr. Hurst.

Petitioner returned to Dr. Conaway's office on May 1, 1998. Petitioner told Dr. Conaway that she was prompted to go to her doctor because a friend had told her about a news report suggesting that the Hepatitis B vaccine could lead to chronic fatigue by causing rheumatologic problems. Petitioner and her husband told Dr. Conaway that "her entire being changed" after the Hepatitis B vaccine, resulting in severe chronic fatigue and nausea. In his notes, Dr. Conaway indicated that he was "unsure what to make of her positive ANA." However, Dr. Conaway noted that the "fact that I have seen no objective signs of a rheumatologic condition and her sed rate[12] has always been

[11] The Special Master notes that Dr. John Campbell's notes are "somewhat difficult to read," which the undersigned confirms. Similarly, Dr. Lavery's notes, discussed below, also contain illegible entries.

[12] "Sed rate, or erythrocyte sedimentation rate (ESR), is a blood test that can reveal inflammatory activity in your body." Sed rate (erythrocyte sedimentation rate), Mayoclinic.com, July 2, 2010, http://www.mayoclinic.com/health/sed-rate/MY00343. The test "measures the distance red blood cells fall in a test tube in one hour. The distance indirectly measures the level of inflammation – the further the red blood cells have

normal combined with the fact that she has not responded in the past to NSAIDs [non-steroidal anti-inflammatory drugs] and/or steroids tend to push me away from that diagnosis."

In early July 1998, Dr. Conaway referred petitioner to see Dr. Andrew Campbell,[13] a specialist with experience evaluating chronic fatigue syndrome due to the Hepatitis B vaccine. Petitioner was evaluated by Dr. Andrew Campbell in Texas on July

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descended, the greater the inflammatory response of your immune system." Id. When blood is placed into a glass tube for the sed rate test, red blood cells settle to the bottom. Id. Where inflammatory activity has occurred in the body, certain proteins of red blood cells are altered, which causes the cells to clump together. Id. The denser clumps of cells settle more quickly to the bottom of the glass. Id.

[13] The court notes that the Texas Medical Board has initiated disciplinary action against Dr. Andrew Campbell. According to an exhibit in the record, on June 6, 2007, a final order was entered against Dr. Andrew Campbell by the Texas State Office of Administrative Hearings, subjecting him to disciplinary action for his failure to practice medicine in an acceptable professional manner consistent with the public heath and welfare. It was concluded that Dr. Andrew Campbell had failed to treat patients according to the generally accepted standard of care, prescribed or administered drugs or treatments that were non-therapeutic, and engaged in unprofessional or dishonorable conduct likely to deceive, defraud, or injure the public. Dr. Andrew Campbell appealed to the District Court of Travis County, Texas, which temporarily enjoined the Texas Medical Board from enforcing the June 6, 2007 Order, pending results of a trial on the merits of the case. Litigation regarding the suspension of Dr. Andrew Campbell's medical license and other sanctions has continued to bounce between the state district court and the Texas Medical Board, proceedings which are ongoing and apparently without final disposition. On August 7, 2009, the Texas Medical Board filed another complaint against Dr. Andrew Campbell, alleging misdiagnosing and mistreating seven more patients, relying on "junk science," taking inadequate history and physical exams, ordering inappropriate diagnostic tests, prescribing inappropriate medication, and billing insurance companies improperly. See First Amended Complaint in the Matter of the Complaint Against Andrew William Campbell, M.D., SOAH Docket No. 503-08-4400, (Texas State Office Of Administrative Hearings Aug. 7, 2009), http://www.casewat ch.org/board/med/campbell/amended complaint 2009. shtml. Based on that Amended Complaint, on November 6, 2009, the Texas Medical Board entered an Amended Final Order suspending Dr. Andrew Campbell's medical license for a period of eight months. See Amended Final Order In the Matter of the Complaint Against Andrew William Campbell, M.C., SOAH Docket No. 503-04 5717 (Texas Medical Board Nov. 6, 2009), http://marcus.tmb.state.tx.us/hostconnect/bcshostconnectqresult.asp. More recently, an Order issued by the District Court of Travis County, Texas on March 8, 2010 indicates that the Texas Medical Board has been temporarily enjoined from enforcing the November 6, 2009 Order, pending the results of a trial on the merits of the claims against Dr. Andrew Campbell. See Order, Cause No. D-1-GN-09-004392, (Travis County, Tex. Dist. Ct. Mar. 8, 2010), http://marcus.tmb.state.tx.us/ hostconnect/ bcshostconnectqresult.asp.

12, 1998. After considering a questionnaire filled out by petitioner and interviewing her, Dr. Andrew Campbell assessed petitioner with fatigue, chest pain, and polyneuropathy. On October 12, 1998, Dr. Andrew Campbell indicated that petitioner also suffered from high cholesterol.[14] Dr. Andrew Campbell prescribed vitamins, including a vitamin B complex.

A few weeks later, on July 31, 1998, petitioner followed up with Dr. Andrew Campbell. She told him that she was feeling much worse, a result of symptoms including gastrointestinal problems and feeling tired all the time with no energy. Again, Dr. Andrew Campbell diagnosed petitioner with fatigue and polyneuropathy. He added the diagnosis of an adverse reaction to a vaccine, and recommended a reassessment in 90 days. About three weeks later, petitioner requested another visit with Dr. Andrew Campbell because she continued to get worse and had started to drop things. After running a series of tests, Dr. Andrew Campbell stated in his notes that the decline in petitioner's health was a direct result of her Hepatitis B vaccination.

At a visit with Dr. Albert Beraducci of Neurologic Associates, Inc., on October 6, 1998, petitioner indicated on a patient medical questionnaire she filled out herself that her symptoms included dropping things, seeing double sometimes, right leg going numb, and occasional incontinence. No descriptions or diagnoses from her visit with Dr. Beraducci were placed in the record. On October 30, 1998, petitioner also saw Dr. Joseph Plouffe, an infectious disease specialist. According to Dr. Plouffe, petitioner's blood tests indicated that she had an ANA rate of 4+, but specific antibodies to test for SLE were negative. Dr. Plouffe concluded that petitioner had a "[p]ossible immunologic process of questionable etiology Hep B vaccine certainly possible."

Throughout 1999, petitioner continued to see Dr. Andrew Campbell, but her condition, according to the Special Master, "did not change in any meaningful way" under his care. On September 24, 1999, petitioner again had a positive ANA test. In late 1999, on the advice of Dr. Andrew Campbell, petitioner began intravenous immunoglobin treatment for chronic inflammatory demyelinating polyneuropathy and remained on the treatment through at least May 2000.

On August 26, 1999 and September 22, 1999, petitioner was seen by Dr. Sandra Stewart-Pinkham, a pediatrician who evaluated petitioner for "persistent health complaints following a series of Hepatitis B injections." Dr. Stewart-Pinkham concluded

[14] Discussing the time period from approximately July 12, 1998 to "a few weeks later" when petitioner returned to see Dr. Andrew Campbell on July 31, 1998, and citing to petitioner's exhibit 34, at 182-84, the Special Master wrote, "[petitioner's] laboratory results 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." Copies of exhibit 34, at 182-84, which are laboratory test results included in petitioner's submission of Dr. Andrew Campbell's records, though poorly copied and difficult to read, appear to be laboratory results based on a blood sample collected from petitioner in late September 1999, over one year later than indicated in the Special Master's opinion.

that petitioner's problems "are best explained by an adverse reaction to Hepatitis B vaccine which contains 25 mcg of mercury in each injection." Dr. Stewart-Pinkham noted that petitioner's problems "are identical to individuals with chronic fatigue immune dysfunction, a disease of unknown etiology." However, Dr. Stewart-Pinkham also stated that "[c]ertainly, individuals can have the same complaints without exposure to mercury."

In January 2000, an administrative judge at the Social Security Administration held that petitioner was "disabled" and, therefore, entitled to benefits. The administrative judge considered information, including reports from Dr. John Campbell, Dr. Michael Conaway, Dr. Andrew Campbell, Dr. Albert Beraducci, and Dr. Sandra Stewart-Pinkham. Dr. Gordon Snider appeared before the Social Security Administration judge as a medical expert witness, testifying that petitioner most likely suffered from mixed connective tissue disease, a disorder that has parts of SLE, myositis, and scleroderma. Petitioner was found to suffer from impairments "best described as mood disorder, with depression, osteoarthritis of left knee, sensory neuropathy secondary to hepatitis B vaccine, history of chronic fatigue syndrome with fibromyalgia, positive ANA, somatization disorder[15] and borderline intellectual functioning."

Petitioner was evaluated by a dermatologist, Dr. Adam Hessel, in September 2001 for a recurrent episodic rash. A skin biopsy was performed on March 7, 2002, after which petitioner was diagnosed with Well's Syndrome. Dr. Hessel indicated that Well's Syndrome "could be seen in association with a vaccination reaction" but that the "relationship is uncertain." Petitioner later contacted Dr. Hessel, indicating that her severe rash was likely caused by a reaction to toxic black mold found in her home.

On June 18, 2004, a CT scan of petitioner's abdomen was performed. Results indicated a tiny, unobstructive stone, found in the upper pole of the right kidney and an even smaller stone which "may" have been in the lower pole of the right kidney. The study was otherwise normal. Urologist Dr. Bruce E. Woodworth stated that, based on the results, "One wonders if the patient's episodes of right flank pain may be due to passage of tiny calculi." A radiographic examination of petitioner's cervical spine taken on October 28, 2004 showed multilevel degenerative disk disease with spondylosis and compression of the spinal cord at levels C5-6 to the left and C6-7 to the right, associated with disc protrusions and foraminal stenoses. In a November 10, 2004 Progress Note, Dr. Conaway assessed petitioner with "1. Cervical disk degeneration [and] cervical spinal stenosis" and "2. Chronic Fatigue Syndrome." He referred her to a chiropractor and an anesthesiologist for steroid injection.

[15] Somatization, or somatization disorder, is "[t]he process by which psychological needs are expressed in physical symptoms; e.g., the expression or conversion into physical symptoms of anxiety, or a wish for material gain associated with a legal action following an injury, or a related psychological need." Stedman's Medical Dictionary 1788 (28th ed. 2006).

On December 1, 2006, at the request of petitioner's expert, Dr. Carlo Tornatore, an MRI of petitioner's thoracic spine was performed. In order to evaluate petitioner for his expert witness report, Dr. Tornatore had stated that an MRI of petitioner's spine "would be an important piece of information to better understand [petitioner's] clinical situation." The impression of her condition stated in the radiology report was "mild atrophy of thoracic cord at mid thoracic levels: without neurally compressive lesion or intrinsic focal cord lesion depicted." The report also stated that the MRI was "[n]egative for dominant or neurally compressive disc herniation."

Petitioner's treating rheumatologist, Dr. Kevin Schlessel, wrote a note containing his assessment on June 10, 2009. The note read: "Please be advised that the above patient has a number of complaints. Her laboratory tests will be consistent with a diagnosis of systemic lupus erythematosus." The laboratory tests, however, were never filed by petitioner as part of the record before the Special Master and the court.

DISCUSSION

When reviewing a Special Master's decision, the assigned judge of the United States Court of Federal Claims shall:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); see also Rule 27 of the Rules of the United States Court of Federal Claims (RCFC) App. B (Vaccine Rules). The legislative history of the Vaccine Act states that, "[t]he conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 512-13, 517, reprinted in 1989 U.S.C.C.A.N. 1906, 3115, 3120.

Regarding the standard of review, in Markovich v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of HHS, 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also de Bazan v. Sec'y of HHS, 539 F.3d 1347, 1350 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2008); Althen v. Sec'y of HHS, 418 F.3d at 1277.

As described by the Federal Circuit in Althen:

> The [Vaccine] Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I).

Althen v. Sec'y of HHS, 418 F.3d at 1278; Pafford v. Sec'y of HHS, 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007).

Petitioner claims that as a result of Hepatitis B vaccinations received in 1997, she suffered various injuries, and that she is entitled to compensation for an off-Table injury, with conditions and symptoms not listed on the Vaccine Injury Table. Under the off-Table theory of recovery, a petitioner is entitled to compensation if she can demonstrate, by a preponderance of the evidence, 42 U.S.C. § 300aa-13(a)(1)(A), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine that is listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also Althen v. Sec'y of HHS, 418 F.3d at 1278; Hines ex rel. Sevier v. Sec'y of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

Since petitioner's condition does not meet the requirements of a presumptively on-Table, vaccine-related condition, to prove entitlement for an off-Table injury, petitioner must

> prove causation-in-fact. Grant [v. Sec'y of HHS], 956 F.2d [1144,] 1147-48 [(Fed. Cir. 1992)]. [The United States Court of Appeals for the Federal Circuit has] held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm."

de Bazan v. Sec'y of HHS, 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a)). A "'substantial factor' standard requires a greater showing than 'but for' causation." de Bazan v. Sec'y of HHS, 539 F.3d at 1351 (quoting Shyface v. Sec'y of HHS, 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor." de Bazan v. Sec'y of HHS, 539 F.3d at 1351.

The petitioner must prove her case by a preponderance of the evidence. See 42 U.S.C. § 300aa-13(a)(1)(A). According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple

preponderance, of 'more probable than not causation.'" Althen v. Sec'y of HHS, 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of HHS, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). Decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard," and by the vaccine system created by Congress in which "close calls regarding causation are resolved in favor of injured claimants" without the need for medical certainty. Althen v. Sec'y of HHS, 418 F.3d at 1280. The Althen court further noted that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id. (citing Knudsen ex rel. Knudsen v. Sec'y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994)). When proving eligibility for compensation for an off-Table injury under the Vaccine Act, however, petitioner may not rely on her testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See 42 U.S.C. § 300aa-13(a)(1).

The court in Althen defined a three-prong test which a petitioner must meet to establish causation in an off-Table injury case:

> To meet the preponderance standard, [petitioner] must "show a medical theory causally connecting the vaccination and the injury." Grant v. Sec'y of Health & Humans Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury [,]" the logical sequence being supported by "reputable medical or scientific explanation [,]" i.e., "evidence in the form of scientific studies or expert medical testimony [.]" Grant, 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, [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 HHS, 418 F.3d at 1278 (brackets in original); see also Moberly ex rel. Moberly v. Sec'y of HHS, 592 F.3d 1315, 1322 (Fed. Cir.), reh'g en banc denied (Fed. Cir. 2010); Pafford v. Sec'y of HHS, 451 F.3d at 1355; Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1324 (Fed. Cir. 2006).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," Althen v. Secretary of Health and Human Services, 418 F.3d at 1278, the Althen court analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that provide "objective confirmation" of medical plausibility. Althen v. Sec'y of HHS, 418 F.3d at 1278, 1279-80. In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Althen court turned to the analysis undertaken in Knudsen ex rel. Knudsen v. Secretary of Heath and Human Services, 35 F.3d at 549. See Althen v. Sec'y of HHS, 418 F.3d at 1279-80. In Knudsen ex rel. Knudsen v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen ex rel. Knudsen v. Sec'y of HHS, 35 F.3d at 549. Further,

> [t]he Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury or that the [petitioner's] injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury. See 42 U.S.C. § 300aa-13(a)(1), (b)(1).

Id. (brackets added).

The second prong of the Althen test requires the petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of HHS, 418 F.3d at 1278; see also Pafford v. Sec'y of HHS, 451 F.3d at 1355. In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen v. Sec'y of HHS, 418 F.3d at 1278 (quoting Shyface v. Sec'y of HHS, 165 F.3d at 1352). In Capizzano v. Secretary of Health and Human Services, 440 F.3d at 1326, the Federal Circuit stated, "'[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." Capizzano v. Sec'y of HHS, 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa-11(c)(1) – 13(a)(1) (2006)).

The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of evidence, "a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d at 1278. The United States Court of Appeals for the Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Secretary of Health and Human Services, when it noted that, "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." Pafford v. Sec'y of HHS, 451 F.3d at 1358. Requiring evidence of strong temporal linkage is consistent with the third requirement articulated in Althen because "[e]vidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." Id. (citing Capizzano v. Sec'y of HHS, 440 F.3d at 1326). The court further explained,

> [i]f, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury.

Pafford v. Sec'y of HHS, 451 F.3d at 1358.

According to the court in Capizzano v. Secretary of Health and Human Services, evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. Capizzano v. Sec'y of HHS, 440 F.3d at 1326 ("We see no reason why evidence used to satisfy one of the Althen III prongs cannot overlap to satisfy another prong."). If a petitioner satisfies the Althen burden and meets all three prongs of the test, the petitioner prevails, "unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." Knudsen ex rel. Knudsen v. Sec'y of HHS, 35 F.3d at 547 (brackets in original; citation omitted).

In his opinion, the Special Master found that petitioner had not proven, by a preponderance of the evidence, that she suffers from transverse myelitis, chronic fatigue syndrome, or SLE. He, therefore, concluded that he did not have to examine petitioner's claim for vaccine injury using the three-part Althen, causation-in-fact analysis. The Special Master's opinion first evaluates whether petitioner fulfills the medical diagnostic criteria for transverse myelitis, chronic fatigue syndrome or SLE, the possible diagnoses raised by petitioner. The Special Master explained that assessing whether the Hepatitis B vaccine "can cause" transverse myelitis, chronic fatigue

syndrome or SLE pursuant to the first prong of Althen would be unwarranted without a finding that petitioner actually suffers from such conditions. Therefore, because the Special Master found that "[petitioner] does not suffer from 'the injury,' there can be no 'logical' sequence of steps" establishing that the vaccine was the reason for the injury.

Petitioner argues that when the Special Master ruled that petitioner did not have any one of the three specific diagnoses alleged, he rejected her claim without analyzing or addressing whether she had met the three-prong Althen test. Petitioner argues it was incorrect for the Special Master to require petitioner to establish, by a preponderance of the evidence, that she actually suffers from transverse myelitis, chronic fatigue syndrome or SLE before analyzing her case pursuant to the Althen test, as opposed to whether petitioner could be compensated on the basis of multiple symptoms and/or injuries she alleges she suffered as a result of her vaccinations.

Special Master Moran indicated he was persuaded by the reasoning in Devonshire v. Secretary of Health and Human Services, 76 Fed. Cl. 452. In that case, the judge held that "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 HHS, 76 Fed. Cl. at 454. The Special Master relied on the "holding [in Devonshire] that a petitioner must establish, by a preponderance of the evidence, that she suffers from the condition discussed by her experts."

In Althen, when the court established the standard for determining causation under the Vaccine Act, see Althen v. Secretary of Health and Human Services, 418 F.3d at 1278, there was no dispute as to whether the petitioner, Margaret Althen, actually suffered from a central nervous system demyelinating disorder. Therefore, the Federal Circuit was not presented with a case in which the diagnosis itself was questioned, but one in which causation of the injury by the vaccine was the issue in dispute. See Althen v. Sec'y of HHS, 418 F.3d at 1282. The Special Master noted that "[petitioner's] case is complicated because she alleges that she suffers from three conditions." Her case is further complicated by the fact that there was little agreement as to the diagnosis of her condition or her symptoms among her treating physicians or among the experts. Thus, upon review, a question is raised as to whether a petitioner must first establish a specified, medically recognized diagnosis, or a consistent "collection" of potentially debilitating medical symptoms, by a preponderance of evidence, before the three-prong test under the Althen standard should be applied. The Special Master framed the issue in petitioner's case as follows:

> [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.[16]

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.… Without a binding decision from the Federal Circuit addressing whether a petition 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.

[16] Among the other possibilities identified in the record are vitamin B12 deficiency, an evolving, mixed collagen, vascular disorder, and osteopenia with degenerative changes in the cervical spine, all suggested by respondent's expert, Dr. Leist. In addition, respondent's other expert, Dr. Kagen, diagnosed a mixed connective tissue disease with rheumatoid arthritis overlap, osteoarthritis with spinal cord and nerve root compression, a nutritional deficit due to a lack of vitamin B12 in her diet, an allergic reaction to mold, and depression.

A. Dr. Tornatore's diagnosis of transverse myelitis

One of the illnesses identified by an expert for petitioner, alleged to have been caused by petitioner's Hepatitis B vaccinations, was transverse myelitis. In order to establish that petitioner suffers from transverse myelitis caused by her Hepatitis B vaccinations, petitioner relied upon the testimony and expert reports of Dr. Carlo Tornatore. One of the issues of concern with regard to Dr. Tornatore's diagnosis of transverse myelitis in October 2006 was that diagnostic and treating neurologists closer to the time the vaccines were administered, namely Dr. Sweeney and Dr. George, did not diagnose transverse myelitis. Petitioner's expert witness, neurologist Dr. Tornatore, was the sole physician to diagnose her with transverse myelitis, a diagnosis that did not occur until nearly a decade after her vaccinations. Moreover, upon his initial review, Dr. Tornatore felt petitioner's medical records were inadequate for him to make a diagnosis, and requested an MRI of her thoracic spine. It was Dr. Tornatore's belief that a thoracic spine problem was indicated by petitioner's presentation, and that Dr. Patrick Sweeney, who had performed a neurological exam on petitioner in 1998, should have ordered an MRI of her thoracic spine. According to Dr. Tornatore, the neurological exam performed by Dr. Sweeney in 1998 was "absolutely pitiful."[17] The MRI of petitioner's thoracic spine, ordered by Dr. Tornatore in 2006, showed "mild atrophy of the thoracic cord at mid thoracic levels: without neurally compressive lesion or intrinsic focal cord lesion depicted." Therefore, on January 28, 2007, Dr. Tornatore submitted a supplemental expert report, incorporating the 2006 MRI results. In his supplemental report, Dr. Tornatore stated: the "thoracic spinal cord does not atrophy unless there is a significant pathological process present in the spinal cord. Here the cord atrophy was focal, suggesting a focal process, e.g. myelitis, must have been the etiology." Dr. Tornatore also noted that "[s]pinal cord atrophy is a well recognized sequelae of inflammation of the spinal cord."

Dr. Tornatore proposed a medical theory causally connecting the Hepatitis B vaccination to his diagnosis of transverse myelitis. According to Dr. Tornatore's testimony, the first two rounds of petitioner's Hepatitis B vaccine "primed" her immune system, and the third booster generated a "brisk immune response, but that immune response then spill[ed] over." According to Dr. Tornatore, at that point, instead of responding only to the Hepatitis B antigen, petitioner's immune response was directed against other antigens, including those in nerves in the spinal cord, particularly the myelins, causing spinal cord inflammation. Eventually, that immune response caused shrinkage and atrophy of the spinal cord, seen on the MRI, resulting in his diagnosis of transverse myelitis nine years later. The Special Master in petitioner's case found that

[17] According to Special Master Moran, while Dr. Tornatore may be correct that Dr. Sweeney should have ordered the MRI, it is impossible to know what an MRI in 1998 would have shown. Therefore, the Special Master wrote, "[t]he 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].' Under these circumstances, the undersigned cannot speculate what the MRI would have shown." (brackets in Special Master's Opinion).

Dr. Tornatore had not explained the usefulness of the two medical journal articles on brain or spinal cord atrophy and multiple sclerosis submitted by petitioner during his testimony on direct examination. The Special Master suggested that little relevance would be imparted to them. Dr. Tornatore, however, indicated that these journal articles were offered for "important points." Dr. Tornatore explained that, although these journal articles followed patients with multiple sclerosis (MS), rather than with transverse myelitis, the journal articles showed that inflammatory diseases of the nervous system, such as multiple sclerosis (MS) and transverse myelitis, do lead to shrinkage of the brain and spinal cord, which was observed on petitioner's thoracic spinal cord MRI.

Dr. Tornatore also described the following sequence of events, leading to his diagnosis of transverse myelitis:

> 1) On October 28, 1997 [petitioner] received the third dose of her hepatitis B vaccination.
>
> 2) Eleven days after the third vaccination (11/9/97), [petitioner] presented to the Emergency Room at Mount Carmel Medical Center with a one day history of nausea and right flank discomfort that radiated into her right chest. This represents the initial episode of focal myelitis of the thoracic spinal cord.
>
> 3) Flank pain continues for many months culminating in a visit to the Neurology service at the Mayo Clinic on April 9, 1998.
>
> 4) Somatosensory evoked responses of the lower extremities (done 3/6/02) were delayed, while evoked responses of the upper extremities were normal, consistent with a lesion in the thoracic spinal cord.
>
> 5) MRI of the thoracic spinal cord (12/06) demonstrated thoracic cord atrophy consistent with the diagnosis of myelitis 9 years prior. (internal citations omitted).

Dr. Tornatore offered his opinion that explaining the sudden onset of flank and chest pain experienced by petitioner eleven days after the third dose of her Hepatitis B vaccine with the diagnosis of transverse myelitis, apparently missed by her treating physicians for almost a decade, "makes perfect sense." He observed that, because on the MRI, petitioner had no tumors, no spinal cord compression, and very focal spinal atrophy, a diagnosis of transverse myelitis best explained the MRI results. Dr. Tornatore further suggested that a diagnosis of transverse myelitis also would offer an explanation of petitioner's positive ANA, which indicates an autoimmune process, such as myelitis, and causes inflammation of the spinal cord, leading to the spinal cord atrophy noted in the MRI results. According to Dr. Tornatore, once activated by the vaccine, petitioner's ongoing inflammatory disorder led to the fatigue and cognitive issues she experienced between 1997 and the time of his testimony.

Dr. Tornatore further suggested that petitioner's visit to the Emergency Room for flank pain radiating into her chest in November 1997, eleven days after the final dose of the vaccination, was the first episode of her focal myelitis of the thoracic spinal cord. The right flank pain, which according to Dr. Tornatore is "pretty high" and "really mid-thoracic," was a clear symptom that started after the vaccine and the turning point in her medical record. On November 1, 2007, when Dr. Tornatore had the opportunity to examine petitioner's thoracic spine, he noted an "area of numbness on the right in the thoracic area that comes around in a circumferential pattern, and it extends up and down probably about three and a half inches, so over about four or five different dermatomes, roughly from about T-4 down to roughly about T-8 or T-9." This is the region of atrophy noted on the MRI, and according to Dr. Tornatore, this also was the "area exactly where [petitioner] was telling us she was having this pain for so long." Dr. Tornatore, therefore, proposed that temporally, petitioner's initial myelitis occurred eleven days following the vaccine, and numbness consistent with thoracic spinal cord atrophy seen on MRI[18] was still evidenced when he examined her on November 1, 2007, and was consistent with his diagnosis of incomplete transverse myelitis.

The time span from administration of the third dose of the Hepatitis B vaccine in 1997 to the diagnosis of transverse myelitis by Dr. Tornatore in 2007, based on an MRI performed nine years after administration of the vaccine, presents a substantial weakness to overcome in supporting a claim for causation under the Vaccine Act. Respondent's expert, Dr. Thomas Leist, indicated that the "MRI essentially just tells you that something would have occurred. It does not put a timeline on when this has occurred." Dr. Leist testified that he believed petitioner's contemporaneous medical records did not indicate "focal neurological deficits in line with a significant myelitis" because he did not see "weakness, significant sensory abnormalities," or "contemporaneous issues with bowel and bladder." As an alternative explanation, Dr. Leist proposed that petitioner's initial symptom of right flank pain could have been caused by the passage of kidney stones, as postulated by petitioner's treating urologist, Dr. Woodworth. Therefore, Dr. Leist concluded that myelitis was not indicated at the time of petitioner's initial hospital visit for flank pain. He continued that, without contemporaneous records supporting symptoms for transverse myelitis or test results confirming the diagnosis of transverse myelitis in her thoracic spinal cord in 1997-98, even assuming, arguendo, that Dr. Tornatore is correct that the MRI shows spinal cord atrophy consistent with transverse myelitis, the nine years between the alleged injury and the ultimate diagnosis makes establishing a timeline of when the injury occurred not possible. Dr. Leist suggested that any number of other causes for right flank pain, spinal inflammation, and atrophy, such as kidney stones, cervical disc disease, and stenosis, could have occurred in that time span.

[18] Respondent's expert, Dr. Leist, disagreed with Dr. Tornatore's interpretation of the MRI results and wrote that the finding in the MRI report of "mild atrophy of the thoracic cord between T4 and T9" should be "viewed with caution." In his expert report, Dr. Leist suggested that: (1) where a cord lesion leads to atrophy, the spinal cord just below the lesion should be smaller and "not just a segment in the middle;" and (2) atrophy of the spinal cord is "difficult to appreciate and quantitate on routine MRIs unless it is marked."

The court notes that Dr. Tornatore has been recognized as an expert in past vaccine cases. The United States Court of Appeals for the Federal Circuit has observed, "[a]s the Court of Federal Claims correctly recognized, Tornatore has 'excellent medical credentials.' He is director of the residency program in the neurology department at Georgetown University, has done research at the National Institutes of Health on the toxic effect of bacterial and viral products on cells, and is an expert in the pathogenesis of brain injury." Andreu ex rel. Andreu v. Sec'y of HHS, 569 F.3d 1367, 1377 n.4 (Fed. Cir. 2009) (quoting Andreu ex rel. Andreu v. Sec'y of HHS, No. 98-817V, 2007 WL 2706159, at *4-*5 (Fed. Cl. Spec. Mstr. Aug. 29, 2007)). Based on the record before him, Special Master Moran, however, reasonably rejected Dr. Tornatore's expert opinion that petitioner suffers from transverse myelitis. Regarding Dr. Tornatore's opinions, the Special Master concluded that, "[petitioner] ignores much information in the record that is not consistent with a diagnosis of transverse myelitis." The Special Master found that the most relevant person for assessing whether petitioner suffers from transverse myelitis was Dr. Sweeney, the neurologist who saw petitioner within four months of receiving the vaccine. Although Dr. Sweeney did not order an MRI, he did conduct a neurologic examination, and did not diagnose petitioner with transverse myelitis.

On February 28, 1998, petitioner also was seen by neurologist Dr. Teresa George to determine if she had SLE, discussed more fully below. Dr. George did not find that petitioner suffered from transverse myelitis. Dr. George noted, however, that petitioner's "[s]ensory and light touch was intact." Based upon her exam, Dr. George concluded that petitioner's right chest pain was of "unclear etiology" and that there was not "enough evidence for systemic lupus erythematosis [sic] or another autoimmune process at this time." The Special Master found that Dr. George's finding strengthens the conclusion that petitioner was not suffering from transverse myelitis in 1998, because petitioner would have presented with a sensory abnormality if she had transverse myelitis. Special Master Moran found, therefore, that Dr. Tornatore's diagnosis of transverse myelitis is not consistent with the findings of Dr. Sweeney and Dr. George, petitioner's contemporaneously treating neurologists.

Petitioner argues that she is being "penalized for the fact that her doctors at the time she first presented with flank pain did not order the proper tests that now, in retrospect, might make her diagnosis more clear." The Special Master rejected petitioner's claim and concluded that a reasonable inference for the lack of an MRI in 1997-98 is that "[petitioner's] treating doctors did not consider transverse myelitis to be a possible diagnosis." As the Special Master also pointed out, it is impossible to speculate what an MRI would have shown had one been ordered within a short time after petitioner's vaccinations. Moreover, the Special Master stated that "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."

Special Master Moran also examined other medical records and medical literature presented by the parties to support his conclusion that petitioner's "clinical

presentation between November 1997 and April 1998 is not consistent with the signs and symptoms of a person with transverse myelitis." The Special Master found that the type of pain documented in petitioner's contemporaneous medical records is inconsistent with the pain that is typically associated with transverse myelitis. According to the Special Master, petitioner repeatedly presented with pain in her right flank that radiated into her chest. The Special Master defined the right flank as "the side of the body inferior to the ribs and superior to the ilium (pelvis)" (quoting Dorland's Medical Illustrated Dictionary 708 (30th ed. 2003)). The Special Master found that petitioner's pain was inconsistent with pain in the neck and upper back, which possibly radiates down to the legs. Quoting an article emanating from the Mayo Clinic submitted by petitioner about symptoms associated with transverse myelitis, at the outset of his assessment of transverse myelitis, Special Master Moran noted that, with pain associated with transverse myelitis, "[s]harp, shooting sensations may also radiate down your legs or arms or around your abdomen." Mayo Clinic, "Transverse Myelitis," Feb. 18, 2008, http://www.mayoclinic.com. In this regard, respondent's expert, Dr. Leist, when asked whether right flank pain is usually indicative of a neurologic problem, testified that "transverse myelitis is normally not associated. It can be transiently associated with increased pain, but it's normally not directly associated with a longer term pain syndrome afterwards."

The Special Master found that the omission in petitioner's contemporaneous medical records of symptoms of tingling, muscle spasms, problems with bowel and bladder, sensory abnormalities, and changed reflexes does not support finding that she suffered from these symptoms following her vaccination and, therefore, that petitioner did not develop transverse myelitis in 1997, following the administration of her vaccination. Dr. Michael Conaway, who examined petitioner in 1998, did not report focal weakness and numbness, as is evidenced in his report, which states "[n]eurologically, there are no focal deficits." Dr. George's report also stated that petitioner denied any focal weakness, numbness or paresthesias. Dr. Leist testified that petitioner's main symptoms of right flank pain and nausea, "in the absence of, for example, dysesthesia, meaning funny feelings in the lower extremity, weakness or an essentially focal neurological complaints [sic]," would not lead him to think that petitioner had a neurologic process going on at the time of her vaccination. The Special Master found, therefore, that "[b]ecause 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."

B. Dr. Shoenfeld's diagnosis of chronic fatigue syndrome

Petitioner also urged, at hearings and in briefings before the Special Master, that she is entitled to compensation on the basis of chronic fatigue syndrome, allegedly caused by her Hepatitis B vaccinations. In this regard, petitioner relies primarily on the report and medical opinion of Dr. Yehuda Shoenfeld.[19] In his initial expert report, Dr.

[19] The Special Master discredited the medical testimony of Dr. Shoenfeld, in part as a result of Dr. Shoenfeld's reliance on the medical records of Dr. Andrew Campbell. The Special Master found,

Shoenfeld offered the opinion that petitioner suffers from chronic fatigue syndrome "which developed following a series of 3 hepatitis B vaccines." Dr. Shoenfeld stated that, once one accepts the proposition that an infection can cause an autoimmune disease, it is assumed that vaccines also can lead to autoimmunity in some susceptible (genetic) subjects. This is because vaccines include infecting agents that are attenuated, killed, modified or recombinant, which can cause an autoimmune reaction. Dr. Shoenfeld substantiated his diagnosis of chronic fatigue syndrome on the finding that petitioner

> had chronic symptomatology without apparent cause (except of the HBV [Hepatitis B vaccine]), without relief upon rest, with a significance [sic] disturbance in daily roles leading to her unemployment. She had at least 4 out of 8 signs/symptoms for more than 6 months: memory defects, lymph mode [sic] sensitivity, muscle pains, sore throat joints pains [sic], headaches, non refreshing sleep, malaise following efforts. (internal citations omitted).

Unlike the diagnosis of transverse myelitis, petitioner's medical records contain a diagnosis of chronic fatigue syndrome by treating physicians prior to Dr. Shoenfeld's expert report on her condition prepared in connection with this litigation. In his assessment on April 23, 1998, Dr. Michael Conaway wrote, "(1) Chronic fatigue.[20] I'm not really sure the mild vitamin B-12 deficiency explains these symptoms," and later, in early 2004, Dr. Conaway diagnosed petitioner with chronic fatigue syndrome. In a letter dated October 4, 2007, Dr. Conaway stated that petitioner "suffers from chronic fatigue syndrome as a result" of receiving a series of Hepatitis B vaccines. The Special Master noted, however, that "approximately ten weeks after petitioner received the third dose of the hepatitis B vaccine on October 28, 1997, she complained about being fatigued to

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> 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. Thus, Dr. Shoenfeld's opinion to explain how [petitioner's] condition in November 1997 is consistent with chronic fatigue syndrome also cannot be credited. (footnote omitted).

The Special Master indicated, however, that Dr. Shoenfeld's use of Dr. Andrew Campbell's records was "a mistake made without nefarious intent," because "Dr. Shoenfeld denied knowing that the Texas Medical Board was investigating Dr. [Andrew] Campbell." However, the Special Master also found that "Dr. Shoenfeld is expected to be more thorough in reviewing medical records in the future."

[20] As the Special Master noted, "chronic fatigue" and "chronic fatigue syndrome" are two different diagnoses. The major difference, as explained by the Special Master, is that "[c]hronic fatigue syndrome requires chronic fatigue plus ancillary problems and the exclusion of other causes for the fatigue."

Dr. Conaway…. Approximately four years later, Dr. Conaway diagnosed petitioner as suffering from chronic fatigue syndrome." The Special Master indicated that he was unconvinced by the assertion that fatigue that began approximately ten weeks after the vaccinations and resulted in a diagnosis of chronic fatigue syndrome four years later was caused by the Hepatitis B vaccinations. On October 18, 1999, Dr. Sandra Stewart-Pinkham found "[h]er complaints are identical to individuals with chronic fatigue immune dysfunction, a disease of unknown etiology." On June 31, 2001, Dr. Stewart-Pinkham stated, "I conclude that the chronic fatigue syndrome was precipitated by vaccination with the Hepatitis B vaccine."

A study submitted by petitioner, and relied upon by the Special Master in his assessment of the diagnosis of chronic fatigue syndrome, states that, in addition to chronic fatigue, a person fulfills the diagnostic criteria for chronic fatigue syndrome by having four or more of eight different problems for more than six months. See Keiji Fukoda et al., "The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study," 121 Ann. Intern. Med. 953, 954-55 (1994). The eight problems are: (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, (8) post-exertion malaise. Id. at 955. The Special Master acknowledged that petitioner evidenced four out of the eight ancillary symptoms defined in the Fukoda study, including over six months of fatigue, in addition to (1) impaired memory or concentration, (2) sore throat, (3) tender cervical or axillary lymph nodes, and (4) new headaches. The Special Master observed, however, that "[petitioner] provided relatively little explanation for how [petitioner's] condition in November 1997 was consistent with chronic fatigue syndrome." The Special Master noted that respondent's experts advanced other possible causes for the chronic fatigue, and that because chronic fatigue syndrome is a diagnosis of exclusion, petitioner must persuasively disprove alternate causes for the symptoms leading to a diagnosis of chronic fatigue syndrome, including her positive ANA and her vitamin B12 deficiency, before attributing her chronic fatigue to the Hepatitis B vaccinations.[21] According to the Special Master, respondent presented evidence that petitioner also suffers from other conditions that could explain her chronic fatigue, which, the Special Master found, undermines the diagnosis of chronic fatigue syndrome.

In his expert report, Dr. Lawrence Kagen suggested that petitioner's fatigue could be caused by (1) multiple nutritional deficiencies, in particular vitamin B12 deficiency or (2) osteoarthritis with spinal cord and nerve root compression. Dr. Kagen also offered the opinion that petitioner does not suffer from chronic fatigue syndrome because she did not match the typical diagnostic criteria for chronic fatigue syndrome at the time her

[21] According to the Special Master, chronic fatigue syndrome is described as a diagnosis of exclusion because it should not be made if another condition explains why the patient is suffering from chronic fatigue, citing Dr. Kagen's testimony and a medical journal article submitted by petitioner, K. Konstantinov et al., "Autoantibodies to Nuclear Envelope Antigens in Chronic Fatigue Syndrome," 98 J. Clin. Invest. No. 8 1888, 1888 (1996).

symptoms began to appear. In particular, according to Dr. Kagen, the severe flank pain, bowel incontinence, and anemia, experienced within two weeks after her third Hepatitis B vaccine, are not symptoms typically associated with chronic fatigue syndrome.

The medical records submitted by petitioner confirm that she had a persistent vitamin B12 deficiency from at least February 1998 through February 2003.[22] In fact, three of the four experts agree that petitioner had a persistent and documented vitamin B12 deficiency. Dr. Kagen's report specified that petitioner had a vitamin B12 deficiency in 1998 and 1999. Dr. Tornatore indicated in his first report on October 16, 2006 that petitioner had a low vitamin B12 level, found in conjunction with an elevated level of methyl malonic acid, confirming the physiologic significance of the low vitamin B12. According to the expert neurologist report submitted by Dr. Leist, symptoms of vitamin B12 deficiency 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. In documenting petitioner's vitamin B12 deficiency, Dr. Leist noted that several of these symptoms were described in patient information sheets throughout petitioner's medical records. Dr. Leist stated that petitioner had "clinically significant" vitamin B12 deficiency "consequentially related to her diet" which "pre-existed and contributed to the complex of symptoms that she complained of in 1997." He also indicated that "the B12 deficiency continued to contribute to the symptom complex during much of the follow-up between 1997 and 2005."

The Special Master noted that Dr. Shoenfeld was the only expert to assert that he saw no evidence of a vitamin B12 deficiency, despite the reports of treating physicians and laboratory results in the record, which suggested that petitioner had a vitamin B12 deficiency. Dr. Shoenfeld argued that petitioner's problems could not have been caused by a vitamin B12 deficiency for two reasons: (1) the deficiency was too mild to cause severe problems; and (2) petitioner's condition should have improved when she was given a vitamin B12 injection, but it did not. Petitioner also asserted, albeit incorrectly, that the "Special Master did not even consider the possibility that maybe her fatigue is not a result of her vitamin B12 deficient [sic] as her fatigue was so severe."[23] The Special Master indicated that "Dr. Kagen also opined that [petitioner]

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[22] The experts, including petitioner's Dr. Shoenfeld and respondent's Dr. Leist, offered that petitioner's vitamin B12 deficiency might be explained by her vegetarian diet. Respondent also submitted an article, R. Obeid et al., "The Impact of Vegetarianism on Some Hematological Parameters," 68 Eur. J. Haematol 275, 276 (2002), on which Dr. Leist relied in support of his conclusion.

[23] Before this court, petitioner now argues the vitamin B12 deficiency went away after April 2003. Petitioner suggests that vitamin B12 deficiency could not have caused the symptoms observed by other experts because those symptoms should have gone away when the deficiency went away and they did not. Petitioner goes on to suggest that "this is why Dr. Conaway with confidence can state in his letter of 2007 she has chronic fatigue syndrome." This argument is not persuasive and does not appear to have been raised before the Special Master.

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." After discussing Dr. Kagen's explanation that petitioner's body may have been unable to absorb vitamin B12 due to her vegetarian diet because of gastritis or an atrophic stomach, the Special Master determined that "Dr. Kagen's explanation … is persuasive." After suggesting that petitioner's presentation, including her depression and fatigue, is consistent with the symptoms of vitamin B12 deficiency addressed by respondent's other expert, Dr. Leist, the Special Master found that "the opinions of Dr. Leist and Dr. Kagen are persuasive. The opinion of Dr. Shoenfeld is not."

C. Dr. Shoenfeld's diagnosis of systemic lupus erythematosus (SLE)

The third and final diagnosis petitioner attempted to demonstrate was that she suffers from SLE as a result of her Hepatitis B vaccines. Only Dr. Shoenfeld diagnosed petitioner with SLE. Moreover, petitioner raised this diagnosis for the first time at the second hearing before the Special Master, over nine years after petitioner's initial petition was filed. Following a third hearing before the Special Master, which he scheduled to specifically address the diagnosis of SLE, petitioner submitted a note from her treating rheumatologist, Dr. Kevin Schlessel, dated June 10, 2009. The note read, "[p]lease be advised that the above patient has a number of complaints. Her laboratory tests will be consistent with a diagnosis of systemic lupus erythematosus." However, no records from Dr. Schlessel discussing the basis for the suggestion of SLE, or any allegedly consistent lab reports were ever filed in the record before the Special Master and the court.

Petitioner relied primarily on the expert testimony of Dr. Shoenfeld, the same individual who also had testified as an expert that petitioner's diagnosable condition was chronic fatigue syndrome, to establish a diagnosis of SLE. Dr. Shoenfeld indicated SLE is an autoimmune disease which can be caused by a vaccine similar to the way in which an infection can cause an autoimmune disease. Dr. Shoenfeld identified several theories to explain this biological process. First, he discussed "molecular mimicry." Dr. Shoenfeld described molecular mimicry as "[i]dentity in sequence of the structure of the compound of the infecting agent and the organ which is involved in the disease." According to Dr. Shoenfeld, molecular mimicry occurs between the surface antigen of hepatitis and the myelin structure or the neurological compounds. The other theory identified by Dr. Shoenfeld was "polyclonal activation." Also according to Dr. Shoenfeld, in this biological process, certain infections "turn on" the immune system, producing "a lot of immunoglobulins" and "autoantibodies." The "adjuvant," the base of every vaccine in which the immune ingredient of the virus is incorporated into the recombinant material, "continuously and perpetually stimulates the immune system to produce immunoglobulin," leading eventually to autoimmune disease. Dr. Shoenfeld suggested that these are two mechanisms that explain how a vaccine can cause SLE, which "play in concert to induce the autoimmune disease." Petitioner also alleges that the 1982 criteria issued by the American College of Rheumatologists for diagnosis of SLE, on which the Special Master relied to reject petitioner's claim of SLE, were created in the

scientific literature in order to perform pure studies, such that if a patient meets four of the eleven criteria, there is a 96 percent certainty that the patient has SLE. Because the standard under the Vaccine Act is proof by a preponderance of evidence, 42 U.S.C. § 300aa-13(a)(1)(A), petitioner contends that she is not required to prove that she fulfills the diagnostic criteria with 96 percent certainty. Therefore, petitioner urges that SLE can be diagnosed by a clinician without four of the eleven criteria, and the diagnosis of SLE for petitioner is the "most obvious" explanation for her symptomatology. The Special Master, however, concluded that petitioner does not suffer from SLE.

Dr. Shoenfeld testified that petitioner "encountered the vaccine and then progressively developed all of these [sic] myriad of manifestations, but not only manifestations, blood tests." To Dr. Shoenfeld, this was evidence of a "cause-and-effect relationship." Dr. Shoenfeld also testified that SLE "may incubate for 10 years or so." Petitioner argues that she has SLE because she "has been diagnosed with SLE by her treating rheumatologist based on laboratory results." However, those laboratory results were not submitted to the Special Master, nor were the records of Dr. Schlessel, which might explain his diagnosis of SLE. Further, unlike the diagnosis of transverse myelitis, which was not considered by contemporaneously treating neurologists, petitioner was evaluated for SLE at the time her symptoms initially appeared. In January 1998, Dr. Conaway wrote that lab tests performed on petitioner were negative and "do not support a Dx. [diagnosis] of lupus but do not entirely rule it out." After a consultation to workup a possible SLE diagnosis about a month later, in February 1998, rheumatologist Dr. Teresa George wrote that petitioner's "other serologies are all negative for supporting a diagnosis of systemic lupus. At this point, she essentially has a right chest pain, which is of unclear etiology, arthralgias and fatigue with a positive ANA. I do not think that there is enough evidence for systemic lupus erythematosis [sic] or another autoimmune process at this time." Dr. Kagen agreed that petitioner is "on the way to developing [an autoimmune disease]." He stated that "[i]t's taken about eight years [to develop the autoimmune disease], but she has a number of antibodies that are characteristic of patients with … mixed connective tissue disease. She really doesn't have anything else but just the antibody profile." The Special Master's assessment of Dr. Shoenfeld, the other experts who testified on SLE, and the statements of petitioner's treating physicians in the record, led him to conclude that "[a]t best, [petitioner] fulfills three of the eleven criteria for a diagnosis of systemic lupus erythematosus," although she "must fulfill at least four of the eleven criteria to satisfy the diagnostic criteria for SLE."

D. Injuries independently identified in petitioner's medical records

In her initial Petition for Vaccine Compensation filed July 28, 1999, petitioner stated she "received hepatitis B vaccination(s) (a vaccine set forth in the Vaccine Injury Table) in the United States and experienced an adverse reaction to this (these) [sic] inoculation." Petitioner subsequently submitted her contemporaneous medical records and filed additional exhibits with the court. She then filed an Amended Petition for Vaccine Compensation on June 22, 2004. In the Amended Petition, which was still very general in nature, after providing a somewhat more comprehensive summary of her medical history, petitioner alleged injuries sustained from the time of the administration

of the vaccines through the date of the Amended Petition. The petition states, "[a]fter receiving her Hepatitis B vaccinations, [petitioner] has sought medical treatment more frequently for her ailments, in that from the time of the vaccinations she has had to go to see a doctor at least once a month." The Amended Petition also alleges, again in general terms, "[p]etitioner's losses are compensable under the National Childhood Vaccine Act of 1986, as amended, inasmuch as [petitioner's] injuries were in fact caused by the vaccine."

In her Motion for Review of the Special Master's decision, petitioner alleges that the Special Master was arbitrary and capricious in his determination that petitioner had to prove, by a preponderance of the evidence, that she has one of the three specific, identified diseases, transverse myelitis, chronic fatigue syndrome or SLE. Petitioner argues that her "experts used these diagnoses to characterize her various injuries – not to define causation." As noted, petitioner argues that the Vaccine Act and Federal Circuit case law require a petitioner to prove only a vaccine injury, not a specific diagnosis.

As noted above, the Special Master held three hearings during which petitioner's experts testified that petitioner suffers from traverse myelitis, chronic fatigue syndrome, and SLE as a result of the Hepatitis B vaccinations. Based on the evidence presented by petitioner, after the hearings, in a November 25, 2008 Order, the Special Master ordered the parties to file briefs organized as follows, "[f]or each of the three conditions discussed by [petitioner's] experts (transverse myelitis, chronic fatigue syndrome, and systemic lupus erythematosus), the parties shall address each of the factors identified in Althen in separate sections." The Special Master later found, "[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."

The government acknowledged at the oral argument before this court upon review that the Vaccine Act does not necessarily require that the petitioner prove a specific diagnosis, and allows for recovery if a petitioner or petitioner's expert can establish a set of medical symptoms, even without diagnosis of a specific, named disease, such as transverse myelitis, chronic fatigue syndrome or SLE. See also Kelley v. Sec'y of HHS, 68 Fed. Cl. at 100 ("The Vaccine Act does not require petitioners coming under the non-Table injury provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury – regardless of the ultimate diagnosis."); Jane Doe/68 v. Secretary of Health and Human Services, Case No. redacted in original, 2010 WL 2300592, at *35 (Fed. Cl. Spec. Mstr. June 4, 2010). In the Doe case, petitioner claimed that the Hepatitis B vaccination was a substantial factor in causing her to suffer from a "fatiguing condition when combined with chronic inflammation due to decades of urinary tract and allergic conditions, and chronic leakage from silicone capsules." Id. Agreeing that the vaccine was "a substantial factor in causing her fatiguing condition," the Special Master awarded recovery and found the petitioner had proven causation for an injury (chronic fatigue), even though the

petitioner could not establish that she suffered from the named diagnosis of chronic fatigue syndrome or fibromyalgia. Id. at *34-*35.

The government argues, however, that, in the instant case, there never was any testimony by petitioner's experts on this alternate theory of recovery. Instead, according to the respondent, petitioner's "experts tailored their testimony and spoke only to how to [sic] [petitioner's] symptoms went to these three conditions that were at issue." The government argued that for the Special Master to have considered this fourth, additional theory of recovery, discussion about any of petitioner's particular symptoms and how these symptoms were caused by the vaccine would have had to occur at the hearings before the Special Master.[24]

In a supplemental brief submitted to this court by petitioner on June 28, 2010, petitioner renewed these arguments, arguing that "her experts used her diagnoses (transverse myelitis, chronic fatigue syndrome (CFS), and/or systemic lupus erythematosus (SLE)) to characterize her various injuries – not to define causation." The petitioner elaborated that the three conditions alleged are made up of a series of symptoms, each of which, when viewed individually, can be part of any number of neurological, autoimmune, rheumatologic, vascular or endocrinologic conditions. Petitioner claims that even if the court was not satisfied that petitioner suffers from the specific diagnoses of transverse myelitis, chronic fatigue syndrome or SLE, the literature, testimony, and citations to the medical record related to specific diagnoses alleged by petitioner do not lose their relevance. This is because these known diseases are diagnosed when viewing the number and the expression of a multitude of different symptoms, which then add up to a certain diagnosis. Petitioner argues that because her experts categorized her symptoms using these three diagnoses and the Vaccine Program does not require a specific diagnosis, she should be able to recover on the basis of injuries received after her vaccinations and evidenced in the record.

The Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rules, Rule 8(f)(1) provide that "[a]ny fact or argument not raised specifically in

[24] The court notes that, in addition to the medical symptoms identified by the medical experts, petitioner's health records, as submitted to the court, also identify a number of additional alleged or identified injuries. For example, petitioner's medical records indicate that she suffers from osteoarthritis and disc degeneration. Although he was not convinced that it accounted for petitioner's nervous system problems, Dr. Tornatore agreed that petitioner suffers from osteoarthritis and osteoporosis. Dr. Shoenfeld, however, stated that osteoarthritis pains are seen when aging and that petitioner could not have osteoarthritis because she is a young lady. Beyond his assertion that petitioner could not have osteoarthritis due to her age, Dr. Shoenfeld did not explain why petitioner's joint pains could not have been caused by osteoarthritis and disc degeneration. Respondent's expert, Dr. Kagen, proposed that petitioner's osteoarthritis and disc degeneration could account for much of her joint and muscular pain. As the Special Master noted, petitioner did "relatively little to counter this argument," essentially ignoring the argument in her reply brief.

the record before the special master will be considered waived and cannot be raised by either party in proceedings on review of a special master's decision." See also, e.g., Jay v. Sec'y of HHS, 998 F.2d 979, 983 n.4 (Fed. Cir.), reh'g en banc denied (Fed. Cir. 1993) (deeming theory of recovery asserted by petitioners in their petition, which was not pursued or defended at case in chief or on motions, was abandoned and waived); Nussman v. Sec'y of HHS, 83 Fed. Cl. 111, 124 (2008) (finding new argument that petitioner had proven causation based on statements in the Special Master's decision was waived when the specific argument had not been asserted before the Special Master). Therefore, assuming that petitioner could recover on the basis of symptomatology, without a named diagnosis, the viability of this fourth legal argument, that petitioner should be able to recover for injuries alleged to have been caused by her vaccinations without establishing a medically known diagnosis, is subject to the threshold question of whether it was initially raised in the record before Special Master Moran.

While not aggressively pursued by petitioner before the Special Master, the theory that petitioner should be able to recover on the basis of symptoms that do not add up to a medically identified condition falls within the general statements in petitioner's still much too general Amended Petition. The organization of petitioner's briefs around the three conditions offered by her experts was the result of the expert medical testimony offered on petitioner's behalf. The Special Master's Order of November 25, 2008 followed the three theories identified in the petitioner's experts' testimony. Nonetheless, in his opinion, the Special Master addressed a fourth theory of recovery, that a cluster of injuries, without diagnosis of a particular, identified medical disease, could result in recovery under the Vaccine Act, given establishment of causation.

Although the Special Master stated that "[petitioner] has not argued that she seeks compensation for a condition other than transverse myelitis, chronic fatigue syndrome, or systemic lupus erythematosus," consistent with his obligation to examine "the record as a whole," he devoted the final, albeit brief, section of his opinion to determining if the medical records submitted by petitioner independently establish harm caused by the Hepatitis B vaccine. See 42 U.S.C. § 300aa-13(a)(1). According to the Special Master, he undertook the inquiry to determine if the medical symptoms in the record independently establish harm caused by the Hepatitis B vaccinations, despite the fact 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.''

The Special Master discussed documents in petitioner's medical record in which physicians, who had not been presented as experts by petitioner, had speculated that her symptoms could have resulted from her Hepatitis B vaccine. These included the impressions of Dr. Andrew Campbell, Dr. Conaway, and Dr. Plouffe. The Special Master found that Dr. Andrew Campbell's statements were not reliable because they were based upon mistaken information and because actions taken against him by the Texas Medical Board raised concerns about his medical judgment, thereby casting doubt upon

his diagnosis.[25] The statements of Dr. Plouffe and Dr. Conaway were found by the Special Master to "hold little persuasive value. There is an absence of explanation as to how these physicians came to their conclusion[s]. Both statements contain too much uncertainty." The Special Master also pointed out that before Dr. Conaway received Dr. Andrew Campbell's report, he had not associated the Hepatitis B vaccinations with petitioner's ailments. The Special Master stated, regarding the statements of petitioner's treating physicians, that, "[e]xpressing 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]."

Petitioner argues that the Special Master erred by not applying the test identified in Althen v. Secretary of Health and Human Services to her case. The Althen test is generally used by a Special Master to determine whether a petitioner's injury was caused by a vaccine. In a case such as petitioner's, if expert testimony, statements of treating physicians, and contemporaneous medical records do not establish a consensus view as to the disease, or even the injuries from which a petitioner suffers, and document major disagreements and discrepancies regarding the disease and injures, then the court agrees that the Special Master is entitled to require proof of the diagnosed condition or injuries suffered by the petitioner before turning to consideration of the Althen factors. Broekelschen v. Sec'y of HHS, 89 Fed. Cl. at 344 ("Thus, Kelley is distinguishable from the case at hand, and it was appropriate in this case – where virtually all of the evidence on causation was dependent on the diagnosis of petitioner's condition – for the special master to determine the proper diagnosis before applying the Althen test."). See also Shaw v. Sec'y of HHS, 91 Fed. Cl. 715, 720 (2010) ("In some cases, however, the diagnosis of the alleged injury is quite significant because it bears directly on the plausibility of the claimant's theory. When, as here, it is necessary for a special master to determine from what condition a claimant suffers, it is not error to do so."); Devonshire v. Sec'y of HHS, 76 Fed. Cl. at 454 ("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 vaccine."). Without a clear determination of the disease or injuries from which petitioner suffers, the Special Master was entitled to reject petitioner's claims for compensation, even without an Althen test analysis.

Petitioner's own experts proposed differing theories as to her condition. Dr. Tornatore proposed transverse myelitis caused by the Hepatitis B vaccine, whereas Dr. Shoenfeld offered chronic fatigue syndrome caused by the Hepatitis B vaccine, and later added a diagnosis of SLE, he also stated was caused by her Hepatitis B

[25] The Special Master also noted that Dr. Andrew Campbell "has some notoriety for diagnosing people with reactions to vaccines." (citing, e.g., Boley v. Sec'y of HHS, No. 05-420V, 2008 WL 4615034, at *23-*24 (Fed. Cl. Spec. Mstr. Sept. 9, 2009), aff'd, 86 Fed. Cl. 294 (2009); Simmons v. Sec'y of HHS, No. 99-546V, 2006 WL 5649844, at *14-*16 (Fed. Cl. Spec. Mstr. Aug. 31, 2006)).

vaccinations. Respondent's experts proposed a number of other conditions from which petitioner suffered, any of which could have caused the symptoms that manifested in the years following the administration of her Hepatitis B vaccinations, but which were, in their view, causally unrelated to the vaccination. Dr. Leist disagreed with Dr. Tornatore's diagnosis of transverse myelitis, and suggested instead that petitioner's symptoms could be explained by her vitamin B12 deficiency, an evolving, mixed collagen, vascular disorder, and osteopenia, with degenerative cervical spine changes, all of which were causally unrelated to her Hepatitis B vaccine. Respondent's other expert, Dr. Kagen, stated his opinion that petitioner did not suffer from SLE as a result of her vaccine, but rather, that she suffers from a mixed connective tissue disorder, osteoarthritis, nerve root compression, nutritional deficits including a vitamin B12 deficiency, an allergic reaction to toxic mold, and depression, conditions he stated are unrelated to the Hepatitis B vaccine. As the Special Master noted, there was a similar lack of consensus as to petitioner's diagnosis among her contemporaneously treating physicians. None of petitioner's treating physicians, as documented in the medical records submitted to the court, provided an explanation that rises to the level of preponderant evidence, demonstrating that the Hepatitis B vaccinations caused her to suffer compensable injuries under the Vaccine Act.

The court also notes that petitioner's experts, Dr. Tornatore and Dr. Shoenfeld, both argued that the pre-1997 medical records filed by petitioner established that petitioner had been in good health and that none of the symptoms she experienced after the Hepatitis B vaccine were pre-existing. Dr. Tornatore testified, "I would disagree with you. I would say somebody noted that she was in good health previously, and we do have medical records from before." Dr. Shoenfeld stated, "[h]er medical history prior to the time of this vaccine does not reveal any evidence of a natural progression of her disease process. In fact, the symptoms appeared acutely after the series of Hepatitis B vaccines." Dr. Tornatore apparently relied on a personal medical history form that petitioner filled out herself for her employer, Ross Laboratories, on October 19, 1989, on which petitioner checked off a box stating "Good health now," and a physical exam performed that same day which found "normal exam."

Based on the record before the Special Master and the court, however, information about petitioner's health prior to the Hepatitis B vaccinations is extremely limited. None of the medical records filed with the court definitively establish whether or not petitioner had experienced flank pain, had positive ANA test results or had a vitamin B12 deficiency prior receiving the Hepatitis B vaccinations, despite Dr. George's notation of her impression that, "I suspect that she has probably had a positive ANA in the past, although I do not have a record of this, per the laboratory studies that are available for my viewing." Dr. Kagen testified that it is possible that petitioner's high ANA preceded the vaccinations. He noted, "Well, there are two things that are recorded in the record. One is that the ANA positivity was present for quite a long time, years, and the other things [sic] that's recorded in the record is that it was intermittently positive, so I think it's conceivable that it preceded the vaccination, but we just don't have the information about it." Moreover, the record also contains doctors' notes, such as those from Dr. Woodworth, suggesting possible alternate causes for petitioner's right flank

pain as possibly caused by kidney stones. In petitioner's case, despite numerous ailments identified by a myriad of doctors, the Special Master, after examining the medical records, concluded that the petitioner had offered insufficient credible evidence to establish anything other than a "'possible' – or even 'certainly possible'" disease or nexus to the Hepatitis B vaccinations. The Special Master's conclusion was justified that petitioner had not submitted a record on which entitlement to compensation under the Vaccine Act has been demonstrated.

CONCLUSION

Upon review of the record before this court in petitioner's case, including expert reports, medical records, hearing transcripts, other exhibits filed by petitioner's and respondent's counsel, and the decision issued by Special Master Moran, this court finds that petitioner's case was fatally compromised by the fact that there was no agreement among her expert witnesses, her contemporaneously treating physicians or in the underlying medical records submitted to the court, as to the injury, symptomatology or medical diagnosis from which petitioner suffered in the time span following the administration of her Hepatitis B vaccinations. Although respondent and this court acknowledged that in a case under the Vaccine Act, a petitioner can be compensated for symptoms and injuries not linked to a specific, established disease if a nexus to the vaccine can be validated, petitioner also is not entitled to compensation under such a theory.

Although the Special Master did not reach the Althen analysis, Special Master Moran was not arbitrary or capricious in his decision to deny compensation to petitioner under the Vaccine Act. In his opinion, the Special Master laid out an assessment of whether petitioner had proven each diagnosis for which she alleged entitlement to compensation – transverse myelitis, chronic fatigue syndrome, and SLE. In addition, based on an independent review of the medical records submitted to him, the Special Master considered whether petitioner could recover under a medical theory of a non-labeled, medical syndrome or symptomatology giving rise to an autoimmune disease of an unknown name, caused by her Hepatitis B vaccinations in 1997. Moreover, regardless of whether the Special Master analyzed the Althen factors, the record of divergent diagnoses and symptoms before this court cannot support analysis under Althen v. Secretary of Health and Human Services. Accordingly, the decision of the Special Master in the case of petitioner is affirmed.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge