In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. [redacted] V
Originally issued: December 15, 2009
Reissued redacted: January 4, 2010
To be Published

JANE DOE/52,	*	
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Petitioner,	*	
	*	
v.	*	Entitlement; hepatitis B vaccine;
	*	hepatitis, chronic fatigue syndrome,
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	fibromyalgia, and polyneuropathy
	*	
Respondent.	*	

Ronald C. Homer, Boston, MA, for petitioner.
Lisa W. Watts, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition on her own behalf on August 4, 1999 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that a hepatitis B vaccination, which she received on March 28, 1994, caused her an unspecified injury.

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. Petitioner moved to redact the decision on December 18, 2009, and the undersigned has granted petitioner's motion.

On August 4, 1999, this case was assigned to chief special master Gary J. Golkiewicz.

On August 4, 1999, petitioner moved to suspend proceedings for 120 days to substantiate her claim and obtain documents. On September 10, 1999, respondent filed no objection to petitioner's motion subject to petitioner's filing an affidavit within 60 days. On October 6, 1999, the chief special master granted petitioner's motion. On February 3, 2000, petitioner filed a statement that her documentation had been filed and was complete. On April 11, 2000, respondent filed a Rule 4(b) Report, stating that petitioner seeks compensation for chronic fatigue syndrome, fibromyalgia, and neuropathy that hepatitis B vaccine allegedly caused. Respondent requested petitioner file all medical records pertaining to any claim she made for Social Security Disability benefits, referring to P. Ex. 5, p. 14, where Dr. Carroll M. Leevy refers to a claim. Petitioner filed records from a workers' compensation claim on April 24, 2000. P. Ex. 17.

On April 27, 2000, the chief special master issued an order staying the proceedings.

On May 2, 2000, petitioner filed a status report with the expectation of filing a future motion for summary judgment.

On May 7, 2003, the chief special master assigned this case to former special master (now Judge) Margaret M. Sweeney as part of the hepatitis B vaccine-demyelinating diseases Omnibus Proceeding.

From October 13-15, 2005, former special master Sweeney held a trial in the Omnibus proceedings. In December 2005, former special master Sweeney left the Office of Special Masters to become a judge on the United States Court of Federal Claims.

On January 11, 2006, this case was reassigned to the undersigned together with the 65 cases comprising the Omnibus proceeding, dealing with transverse myelitis (TM), Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), and multiple sclerosis (MS).

In the four Omnibus decisions the undersigned issued[2] in the paradigm cases concerning hepatitis B vaccine and demyelinating diseases, the undersigned held that hepatitis B vaccine can and did cause GBS, CIDP, TM, or MS. Since that time, the undersigned has been working through the other 61 cases. Some have resulted in dismissals, others in settlement, with the majority leading to hearings and decisions, most of which resulted in petitioners proving entitlement.

On January 9, 2008 petitioner filed an amended petition in the instant action, alleging that hepatitis B vaccine caused her chronic fatigue syndrome and fibromyalgia.

A hearing was held on April 2, 2009. Testifying for petitioner was Dr. Susan M. Levine, a treating immunologist. Testifying for respondent was Dr. Lawrence Kagen, a rheumatologist.

Petitioner filed her posthearing brief on June 3, 2009.

Respondent filed her posthearing brief on July 6, 2009.

Petitioner filed her reply to respondent's posthearing brief on July 20, 2009.

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[2] Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (hepatitis B vaccine caused TM; onset was12 or 13 days after first vaccination with recovery; onset of TM was one week after second vaccination); Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006) (hepatitis B vaccine caused GBS and CIDP; onset was 21 days after second vaccination); Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006) (hepatitis B vaccine caused MS; onset was one month after second vaccination); Peugh v. Secretary of HHS, No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007) (hepatitis B vaccine caused GBS and death; onset of GBS was eight days after fourth vaccination).

FACTS

Petitioner was born on May 8, 1964.

Her family doctor, Dr. Kengarajan R. Wignarajan, saw her between 1981 and 1990 for complaints ranging from upper respiratory symptoms to non-specific rashes. Med. recs. at Ex. 47, p. 1.

On March 28, 1994, petitioner received her first and only hepatitis B vaccination. Within three days, she had flu-like symptoms, including malaise, low back pain, sore throat, lymph node swelling, diffuse musculoskeletal pain, and extreme exhaustion. *Id.*; Ex. 27. Dr. Wignarajan connected her symptoms to her vaccination and advised her not to receive a second hepatitis B vaccination. Ex. 47, p. 2. Her hair began to fall out. Ex. 1, p. 2. On May 2, 1994, petitioner had elevated liver function studies and she was diagnosed with non-specific hepatitis. *Id.* On May 20, 1994, she complained of numbness of both feet. *Id.* She saw Dr. Carroll M. Leevy, a hepatologist, who diagnosed her on September 4, 1995 with chronic viral hepatitis. By April 1996, petitioner was bedridden *Id.* Petitioner saw Dr. Susan Levine on October 2, 1996 who diagnosed her with chronic fatigue syndrome. *Id.* On February 2, 1997, petitioner had enlarged lymph nodes and, on April 1, 1997, she demonstrated orthostatic intolerance on a tilt test. Ex. 47, p. 3.

On February 13, 1998, an administrative law judge reversed a prior Social Security Administration Decision denying petitioner was disabled, finding that petitioner had been disabled since April 16, 1996, having chronic fatigue syndrome. Ex. 18. She had a long history of abdominal pain and illness that caused her weakness and fatigue. In 1994 and 1995, she repeatedly saw Dr. Kengarajan R. Wignarajan for complaints of abdominal pain and sore throat.

He referred her to Dr. Carroll M. Leevy who biopsied petitioner's liver. Dr. Leevy concluded that petitioner's history of chronic hepatitis was possibly secondary to Epstein-Barr viral infection and referred petitioner to Dr. Susan M. Levine. Dr. Levine diagnosed petitioner with chronic fatigue syndrome. P. Ex. 18, pp. 6-7.

In May 1998, petitioner had a brain MRI done, showing a left cerebellar venous angioma.[3] Dr. Cafferty's impression was severe paresthesias and dysesthesias. Petitioner's reflexes were totally intact which went against a diagnosis of significant motor sensory neuropathy. Her EMG findings were normal. Med. recs. at Ex. 6, p. 67.

On January 27, 1999, Dr. Norman Latov, a neurologist, wrote in a record that petitioner had EMG and nerve conduction studies in October 1998[4] revealing the presence of an axonal neuropathy. Med. recs. at Ex. 6, p. 69. Spinal tap was normal with normal protein. Dr. Latov opined that petitioner might have a small fiber sensory neuropathy which can be associated with fibromyalgia or chronic fatigue syndrome. Med. recs. at Ex. 6, p. 70.

On March 5, 1999, Dr. Latov diagnosed petitioner with large and small fiber sensory neuropathy, probably chronic inflammatory sensory polyneuritis. Med. recs. at Ex. 7, p. 71. Her EMG and nerve conduction tests on February 11, 1999 were normal. Med. recs. at Ex. 12, pp. 17-20. Petitioner underwent Somatosensory Evoked Potentials (SSEP) on February 24, 1999 to

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[3] An angioma is "a tumor whose cells tend to form blood vessels ... or lymph vessels...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 84.

[4] Dr. Richard Lechtenberg, on October 21, 1998, writes that conduction velocities of motor signals in the arms were good, but petitioner had no sensory response in the arms or legs. Petitioner did not have a radiculopathy, but there was substantial evidence of a primarily axonal, mixed sensory and motor polyneuropathy affecting the arms and legs. Med. recs. at Ex. 10, p. 2.

rule out demyelinating disease. The results were normal for her brain, arms, and legs. Med. recs. at Ex. 12, pp. 24, 26, 28.

On March 12, 1999, Dr. Latov states in a letter that petitioner is probably suffering from the sensory form of chronic inflammatory demyelinating polyneuritis. Med. recs. at Ex. 23, p. 3.

On September 7, 2000, Dr. Levine wrote that petitioner's symptoms are due to hepatitis B vaccine based on her review of the literature and her discussion with Dr. Latov. Ex. 32, p. 28.

On September 22, 2000, Dr. Latov wrote that hepatitis B vaccine caused petitioner's neuropathy. Ex. 23, p. 10; Ex. 32, p. 34.

On August 2, 2002, Dr. Latov records in his notes that petitioner has post-vaccinal neuropathy. Med. recs. at Ex. 26, p. 1.

On September 25, 2008, Dr. Russell L. Chin, a neurologist, wrote a summary of petitioner's condition as history of hepatitis B virus vaccine in March 1994 followed by diffuse myalgias, arthralgias, sore throat, generalized weakness, and fatigue. She was bedridden for four months. She reported increased liver function tests and underwent a liver biopsy. She developed some altered sensation in her hands and feet and quit work due to problems with cognition and concentration. In 1996, she was diagnosed with chronic fatigue syndrome and fibromyalgia. By March 1998, the mild numbness she had in her hands after vaccination spread and she developed burning, lancinating pains in her arms and legs, and occasional facial numbness. She first saw Dr. Norman Latov on January 27, 1999, and reported her entire body felt like it was on fire. It was painful to wear shoes or walk. Her hands felt weak. Currently, she reported increased fatigue and thinks her fibromyalgia symptoms increased over the last year. She reported numbness in her arms, legs, hands, and feet. Med. recs. at Ex. 62, p. 1. EMG

and nerve conduction studies done on October 21, 1998 of her left arm and leg showed an axonal mixed sensorimotor polyneuropathy. Tilt table testing on April 1, 1997 showed abnormal response. Med. recs. at Ex. 62, p. 2. Dr. Chin concluded petitioner had small fiber neuropathy or ganglioneuritis as well as fibromyalgia and chronic fatigue symptoms. Med. recs. at Ex. 62, p. 3.

Other Submitted Material

On May 6, 2008, petitioner filed includes Ex. 47B, "Immunologic Aspects of Chronic Fatigue Syndrome. Report on a Research Symposium Convened by The CFIDS Association of America and Co-Sponsored by the US Centers for Disease Control and Prevention and the National Institutes of Health" by T.R. Gerrity, et al., 11 Neuroimmunomodulation 351-57 (2004). One of the co-authors is Dr. Susan Levine, petitioner's treating immunologist and expert witness. The authors state that the etiology and pathophysiology of CFS are unknown, "yet studies have suggested an involvement of the immune system." *Id.* at 351. The authors did not arrive at a firm conclusion over whether immune abnormalities are causative of or resulting from CFS and encourage a multidisciplinary approach to CFS. *Id.* They discuss in 30% of CFS patients, there is persistent activity of Epstein-Barr virus and/or Human Herpes Virus-6. *Id.* at 353.

On March 23, 2009, respondent filed Ex. F, "Report of the Working Group on the Possible Relationship between Hepatitis B Vaccination and the Chronic Fatigue Syndrome" by Dr. G. Delage, et al., 3 Can Med Assoc 314-16 (1993). The working group reviewed 30 cases of self-reported CFS alleged to be secondary to hepatitis B vaccination and concluded there was no cause and effect relationship. *Id.* at 314. The great majority reported onset of chronic fatigue

after the first dose of vaccine. *Id.* at 315. Looking at a sample size of 700 students who had received hepatitis B vaccine, the study group found that none had CFS. *Id.* The study group concluded that hepatitis B vaccinees did not have CFS in a greater number than the general population. *Id.*

On March 26, 2009, petitioner filed Ex. 70, "Chronic Fatigue Syndrome: Clinical Condition Associated with Immune Activation" by A.L. Landay, et al., 338 Lancet 707-12 (1991). The authors suggest after examining the presence or reduction of immune cell populations that immune activation is associated with many cases of CFS. A similar conclusion of immune activation and CFS is reached in Ex. 71, "Cytokines and Chronic Fatigue Syndrome" by R. Patarca, Annals NY Acad of Sci 185-200 (no year), and in Ex. 75, "Markers of Inflammation and Immune Activation in Chronic Fatigue and Chronic Fatigue Syndrome" by D. Buchwald, et al., 24 J Rheumatology 372-76 (1997).

TESTIMONY

Petitioner testified that a few days after hepatitis B vaccination March 28, 1994, she got a pain in her right side and severe flu-like symptoms, headache, and dizziness. She had light numbness and tingling in her hands and feet as well. Tr. at 111. The most pain she had was the liver pain. Tr. at 112. She associated the numbness in her hands and feet with lack of circulation from not getting out of bed. *Id.* In 1998, she had electric shocks in her arms and legs. *Id.* The heaviness in her arms and legs got worse. Tr. at 113. She felt as if she had the flu every day and all her muscles hurt. She was dizzy and light-headed. Tr. at 115.

Dr. Susan Levine testified for petitioner. Tr. at 4. She is an immunologist mainly dealing with chronic fatigue syndrome and fibromyalgia. Tr. at 5. She is board-certified in

internal medicine and in infectious diseases. *Id.* She has authored or co-authored publications dealing with chronic fatigue syndrome and co-authored a manual for doctors to help doctors diagnose chronic fatigue syndrome. Tr. at 6. She is the co-president of the NJ Chronic Fatigue Association. *Id.*

Although chronic fatigue syndrome has been around for more than a century, it was formally introduced to the medical community in 1988 when a case definition was published in the Annals of Internal Medicine. Tr. at 7. Dr. Levine has participated in several workshops in the late 1990's sponsored by the Centers for Disease Control. One of those findings is that autonomic dysfunction is part of chronic fatigue syndrome. *Id.*

Chronic fatigue syndrome is a symptom complex in which someone must have four out of 11 symptom criteria for at least six months. Tr. at 8. It involves overwhelming exhaustion that rest does not improve. *Id.* Other symptoms are sore throat, lymph node swelling, cognitive dysfunction, short-term memory loss, difficulty with attention span, headache, low-grade fever, and rapid heart rate. Tr. at 9. To diagnose chronic fatigue syndrome, the doctor must rule out thyroid disease, lupus, Lyme disease, and other common disorders in addition to endogenous affective disorders like depression or anxiety disorder. *Id.*

Fibromyalgia is a similar disorder. *Id.* Seventy percent of patients with chronic fatigue disorder also have fibromyalgia. *Id.* Fibromyalgia is characterized more by muscle pain and sleep disturbances and has 18 out of 18 trigger points where, if pressed, pain is elicited, and on REM, there is a stage three sleep abnormality documented on a sleep study. *Id.*

Chronic fatigue disorder commonly has neurologic symptoms. Tr. at 10. There are also immunologic findings in chronic fatigue disorder. Tr. at 10-11. Certain infectious agents have

been associated with chronic fatigue syndrome. Tr. at 11. The common immune dysfunctions seen in chronic fatigue syndrome patients are low end natural killer cell function. *Id.* There are two branches of the immune system: the B-cells and the T-cells. Tr. at 12. The T-cells can be further divided into cytotoxic T-cells and suppressor T-cells. *Id.* The B-cells normally produce antibody. People with low end natural killer cell activity are not able to fight viruses as well as someone with normal natural killer cell function. *Id.* Chronic fatigue patients have abnormal numbers of CD57 type T-cells which produce proinflammatory cytokines including gamma interferon and interleukin -4, which are responsible for some of the allergic phenomena in these patients. This causes muscle pain, weakness, and low-grade fevers. There is no mechanism to turn off this abnormal T-cell activated immune system. *Id.*

Natural killer cells are the body's main defense against viruses. Patients with low end natural killer cell activity are not able to fight viruses as well as someone with a normal natural killer cell function. *Id.* Patients have too little antibody response from B-cells to protect them against infection, particularly IgG-1 and IgG-3 subclasses. Tr. at 13, 14. They can produce autoantibodies as well. Tr. at 14.

The activation of the cytotoxic T-cells producing cytokines can cause a constant malaise. *Id.* Patients have flu-like symptoms. *Id.* When someone has decreased natural killer cells, the body's primary immune defense system is impaired. Tr. at 15. Too few suppressor cells means we cannot turn off the production of excess cytokines. *Id.* Chronic fatigue syndrome involves a chronic activation of the immune system. Tr. at 16.

Some of the patients with chronic fatigue syndrome were complaining of headaches, weird paresthesias, numbness of the fingers, visual symptoms, and memory loss. Tr. at 18. In

one of the CDC workshops, some started doing MRIs of the brain on some of these patients and found some evidence of white matter lesions in their brains which could have been due to demyelination, i.e., the neuron sheaths were not intact, accounting for some of the symptoms like ataxia, a problem in balance, and some of the neurological findings. Tr. at 18-19.

There was the hypothesis that several viruses, for instance, Epstein-Barr virus and Human Herpes Virus-6, may be potential causes of chronic fatigue syndrome. On autopsy, they found evidence of Human Herpes Virus-6 in the neurons of these patients and also those with MS, which could cause demyelinization of the brain. Tr. at 19.

The autonomic nervous system is part of our central nervous system and controls blood pressure and pulse. In patients with autonomic dysfunction, there is a dysregulation of the blood pressure response. In a subgroup of chronic fatigue syndrome patients, if they rise too quickly from a chair, they get dizzy and flushed, and have palpitations. Tr. at 20. The tilt-table test objectively measures this response. *Id.*

Also involved in the autonomic nervous system is temperature dysregulation. Tr. at 21. Dr. Levine has a lot of chronic fatigue syndrome patients with cold hands and hot flashes. Tr. at 21-22. Sometimes, CFS extends to psychological problems like anxiety for no reason. Tr. at 22. Chronic fatigue syndrome is a heterogeneous disorder. *Id.* The cardiovascular findings tie in with the heart rate variability. Some of these patients may have a chronic viral myocarditis involving Human Herpes Virus-6. Tr. at 23.

Chronic fatigue syndrome affects mostly women at a ratio of four women to one man which is also common to lupus and connective tissue diseases. Tr. at 24. This suggests a hormonal influence. *Id.* Many of these patients have polycystic ovary disease and insulin

resistance. *Id.* Patients with chronic fatigue syndrome have low cortisol levels, thought to be a problem with hypothalamic secretion of corticotropic adrenal-releasing factor. Tr. at 25.

Initially, Epstein-Barr virus was thought to be the cause of chronic fatigue syndrome. Tr. at 27. Later, different triggering agents were considered to lead to the same pathophysiologic response. *Id.* There is a genetic component to chronic fatigue syndrome. Tr. at 29. When an individual with these dysfunctional genes is exposed to a potential triggering agent, he or she is more likely to get chronic fatigue syndrome than someone with normal genes. *Id.* One of the theories underlying fibromyalgia is too little serotonin in the spinal fluid and too few endorphins. Tr. at 32.

Over the years, Dr. Levine has treated about 2,000 chronic fatigue syndrome and fibromyalgia patients. Tr. at 33. They constitute 80 to 90 percent of her practice. *Id.* She is petitioner's treating doctor. *Id.* She confirmed petitioner's diagnosis of chronic fatigue syndrome. Tr. at 34. Petitioner had extreme exhaustion, muscle pain, headaches, and some neurological complaints. *Id.* Petitioner had evidence in her blood work of elevated antibody to Early Antigen of Epstein-Barr, suggesting reactivation of an old Epstein-Barr virus infection. Tr. at 36. It is a type of virus that can lie dormant and then reactivate. *Id.* Petitioner had a positive IgG for Human Herpes Virus-6, which indicates a history of HHV-6, but no recent acute phase of HHV-6 because she had a negative IgM which measures recent infection. *Id.*

The thinking is that chronic fatigue syndrome is more likely caused by a reactivation of a pre-existing latent virus to which the patient had been exposed as a child. Tr. at 37. Dr. Levine thinks that hepatitis B vaccine caused the reactivation of petitioner's latent Epstein-Barr virus. Tr. at 38, 39. Dr. Levine holds this opinion because of the timing and her reading of articles

linking this type of vaccine to various immune responses. Tr. at 39, 40. Within just a few days of her hepatitis B vaccination, petitioner developed a fatiguing illness sounding just like chronic fatigue syndrome. *Id.* She also bases her opinion on her knowledge of immunology and of the immune response. Tr. at 40.

Within two to three days of her vaccination, petitioner had numbness in her hands and feet, dizziness, and headaches. Tr. at 41. Dr. Levine thinks petitioner had a type of acute inflammatory response after her vaccination. Tr. at 42. This is perfectly in line with a reactivation of Epstein-Barr at the time. *Id.* Petitioner had a liver biopsy which was normal. If she had hepatitis, that would have been discovered. Tr. at 43. Her persistent mild elevated liver functions were part of her proinflammatory response. *Id.*

Hepatitis B vaccine can produce any of four immune responses. There is an early response Type 1, IgG, immediate response, which petitioner did not have, which resembles an allergic response resulting in itchiness, lip swelling, or difficulty breathing. *Id.* Secondly, there is the proinflammatory response, which petitioner exhibited, with elevated levels of cytokines (cell-mediated). Tr. at 43-44. Thirdly, is a more delayed response, which petitioner may have also, dealing with immune complex formation, and involving her brain and possibly the liver. Tr. at 44. Fourthly, there is the complement cascade, which petitioner did not have. *Id.*

Petitioner's sequelae of her Epstein-Barr reactivation causing chronic fatigue syndrome was fibromyalgia, which Dr. Levine considers more a kind of small fiber neuropathy because of the complaint of pain, although in petitioner, it is more of a burning sensation and numbness. Tr. at 46. Both HHV-6 and Epstein-Barr are neuropathic viruses, meaning they attack the nervous

system. *Id.* Petitioner does not have demyelinization. Tr. at 47. Dr. Latov, a prominent neurologist at Columbia, found petitioner had peripheral neuropathy. Tr. at 49.

Dr. Levine also believes that hepatitis B vaccine reactivated petitioner's Human Herpes Virus-6. Tr. at 52. But Dr. Levine does not have proof of this because she did not measure Early Antigen of HHV-6 in petitioner. However she thinks it is plausible that HHV-6 was reactivated because reactivations of HHV-6 and Epstein-Barr virus are often seen together. Tr. at 54. They may work as co-viruses. *Id.* Epstein-Barr may facilitate the expression at the gene level of the replication proteins for HHV-6. *Id.*

Petitioner had an abnormal blood pressure and pulse response to the tilt-table test, but it was not positional orthostatic tachycardia syndrome (POTS). Tr. at 56-57. Petitioner does not have a typical autoimmune serological profile. Tr. at 58. Dr. Levine does not assume she had an autoimmune response to hepatitis B vaccine; she just had an abnormal immune response. *Id.* This is the same as an immune-mediated disease. *Id.* Dr. Levine stated that if petitioner had not received hepatitis B vaccine, she would not have had chronic fatigue syndrome, fibromyalgia, and small fiber neuropathy. Tr. at 60. Dr. Latov believes petitioner has autonomic nervous system dysfunction. Tr. at 61.

On cross-examination, Dr. Levine admitted that petitioner's Epstein-Barr virus Early Antigen (EBV-EA) antibody in 1996 was equivocal. Tr. at 69. It is not positive. *Id.* In 1997, petitioner's EBV-EA antibody was positive. *Id.* Dr. Levine explained that the Epstein-Barr virus and other viral titers fluctuate and it depends on the activity of the immune system at the moment the blood is drawn what the results will be. Tr. at 70. She stated that she documented the Epstein-Barr reactivation, but that does not exclude a co-reactivation of HHV-6 as well

because that is implicated as an infectious cause of chronic fatigue syndrome. *Id.* But the reactivation that is documented is for Epstein-Barr virus. *Id.*

Dr. Levine did not recall if we have any information on petitioner's Epstein-Barr titers in 1994. *Id.* Her opinion is that the vaccine acted as a triggering agent to reactivate this virus and possibly other viruses and accounts for petitioner's symptoms. Tr. at 71. Dr. Levine would expect that most 32-year-olds would have antibodies to Epstein-Barr virus. *Id.* A person that age would also have antibodies to Human Herpes Virus-6. *Id.* Dr. Levine is no longer board-certified in allergy and immunology because she did not take the recertification examination. *Id.*

Dr. Levine began treating petitioner on October 2, 1996. *Id.* Her notes do not indicate that petitioner received a hepatitis B vaccination. Tr. at 75. At the time, Dr. Levine was not thinking about what caused petitioner's chronic fatigue syndrome. Tr. at 76. Dr. Levine thought petitioner's immune dysfunction was caused by a virus initially. Tr. at 78. Dr. Latov's opinion made her think more about petitioner's immunological symptoms. Tr. at 79. Dr. Levine thinks that petitioner had an inflammatory reaction to hepatitis B vaccine rather than a form of hepatitis. Tr. at 81. She stated that hepatitis B vaccine caused a reactivation of petitioner's Epstein-Barr virus which resulted in Epstein-Barr-related hepatitis which is commonly seen with acute mononucleosis. Tr. at 82.

Dr. Levine did not think that petitioner had flu-like symptoms after her 1994 hepatitis B vaccination because of an ongoing infectious process. Tr. at 84. She thought that there was clear triggering from the vaccine. *Id.* People are exposed to Epstein-Barr virus and HHV-6 (and other viruses) in their teens, and the viruses remain dormant until the system is disrupted by an insult such as a vaccination. Tr. at 85. There could be a number of stressors, including a

superimposed viral infection, that would reactivate the viruses. *Id.* Other stressors can be sinus surgery, anesthesia, giving birth, and car accidents. Tr. at 86. These can be environmental triggers that set off this immune dysregulation in certain genetically predisposed people. *Id.* She thinks an environmental trigger would be more of a personal injury than exposure to someone else who is sick. *Id.*

In Dr. Levine's reliance on medical literature to support her opinion in this case, she means case reports of different types of arthritis or neurological illness, including demyelinating disease, in recipients of hepatitis B vaccine. Tr. at 87. She thinks some of mechanisms described in these case reports can account for petitioner's illness as well. *Id.* There have been a couple of case controlled studies on hepatitis B vaccine and chronic fatigue syndrome that she has reviewed. *Id.* One Canadian study did not find an association. Tr. at 87-88. But the reviewers of that study stated the sample size was too small and the cohort was not studied long enough to determine if they developed the symptoms beyond the study period. Tr. at 88.

Petitioner received hepatitis B vaccine March 28, 1994 and, one month later, was diagnosed with non-specific hepatitis. Tr. at 89. Over the next two years, she had intermittently abnormal liver function studies. *Id.* Dr. Levine thinks that petitioner's hepatitis was just one of her problems. Petitioner was also complaining of fatigue, neurological symptoms, and cognitive symptoms. *Id.* Dr. Levine stated that petitioner had chronic fatigue all along and the elevated liver function test was just part of the syndrome. Tr. at 90. Liver dysfunction is not something doctors typically see but it was part of petitioner's chronic fatigue syndrome. *Id.* Dr. Leevy associated petitioner's chronic fatigue and her liver dysfunction. Tr. at 108.

Chronic fatigue syndrome is a diagnosis of exclusion but that does not mean that a patient cannot also have co-morbid disorders simultaneously. Tr. at 92. There are no specific diagnostic markers for chronic fatigue syndrome. Tr. at 93. There are no specific autoantibodies associated with chronic fatigue syndrome. *Id.* The etiology of chronic fatigue syndrome is unknown but there have been over 1,000 peer-reviewed research papers by respected researchers with increasing evidence that chronic fatigue patients have various virus systemic abnormalities. Tr. at 94. There is an increasing body of information that demonstrates, particularly with the Gulf War veterans, that vaccines can lead to chronic fatiguing illness resembling chronic fatigue syndrome. *Id.* Some of the non-deployed veterans experienced fatiguing illness. Tr. at 95.

Dr. Levine thinks it probable that there is a genetic predisposition for chronic fatigue syndrome. Tr. at 99. Petitioner may have lacked the proper proteins to suppress a dysregulated immune response after receiving hepatitis B vaccine. *Id.* The laboratory data support that petitioner had a reactivation of a prior Epstein-Barr virus infection triggered by the vaccine. Tr. at 101. Dr. Levine has had patients who were either previously well or in remission from chronic fatigue who got the disease or relapsed after receiving flu vaccine. Tr. at 103.

Dr. Lawrence Kagen testified for respondent. Tr. at 118. He is board-certified in internal medicine and rheumatology. Tr. at 119. He retired from private practice in 2006, but still practices in clinics and teaches students, fellows, and residents at the Hospital for Special Surgery and at New York Presbyterian Hospital. *Id.* Out of 2,000-3,000 patients when he was engaged in private practice, several hundred were chronic fatigue patients. Tr. at 120. He was Director of Occupational Health Services at the Hospital for Special Surgery in NY from 1993 to 2006 and his group gave thousands of people hepatitis B vaccine without any side effects or

adverse reactions. Tr. at 120-21. Dr. Kagen is editing a book on musculoskeletal disease called "Inflammatory Myopathy" and has written a couple of chapters for it. Tr. at 122. Dr. Kagen's primary professional interest has been in muscles, whether inflammatory muscle diseases or the process of myoglobin in muscles. Tr. at 124. Chronic fatigue syndrome is not a muscle disease. *Id.* He has never written an article on chronic fatigue syndrome. Tr. at 125.

Dr. Kagen said that chronic fatigue syndrome has no known cause. Tr. at 129. He agrees that petitioner has chronic fatigue syndrome. Tr. at 131. She also has chronic hepatitis, neuropathy, and abnormalities of the spine. *Id.* Petitioner has received many medicines which have side effects that include fatigue and insomnia. Tr. at 133. Epstein-Barr virus causes mononucleosis and hepatitis. Tr. at 134. Dr. Leevy thought petitioner had Epstein-Barr virus hepatitis. *Id.* Hepatitis can have many causes, among them viral infections, including Epstein-Barr virus. *Id.* Dr. Leevy treated petitioner with Ganciclovir, but she did not have a good response to it, and Dr. Leevy thought maybe another virus was the cause of the hepatitis. Tr. at 134-35. A second hepatologist, Dr. Bach from Mt. Sinai Hospital, thought petitioner might have drug-induced liver injury (DILI) because she had been on a number of medications and her liver function tests were fluctuating. Tr. at 135. Dr. Kagen thinks petitioner had both viral hepatitis and drug-induced liver injury. Tr. at 136.

Dr. Kagen said there is no evidence that petitioner's Epstein-Barr virus was reactivated. *Id.* We do not really know about reactivation. Tr. at 137. In 1996 in NY, petitioner had Epstein-Barr virus Early Antigen with a value of 122. The abnormal value is 140 so 122 is an equivocal value. Tr. at 138. In 1997 in NJ, petitioner had an Early Antigen value of 125 when normal was up to 110 and there was no equivocal range. Tr. at 141. In light of the 1997 reading,

Dr. Kagen thought it was very close. He thought the 1997 reading of 125 was still equivocal (and the lab report says "equivocal" not "positive"). Tr. at 142. It is not normal to be equivocal, but it is not absolutely abnormal. Tr. at 143.

Dr. Kagen thinks a latent (old) Epstein-Barr virus can caused hepatitis. Tr. at 144. It can reside in the liver and be stimulated in the liver to produce abnormalities by a concurrent febrile illness or a medication. *Id.* He cited an article on serological evidence of reactivated Epstein-Barr virus infection to state that this probably is unrelated to clinical manifestations. Tr. at 144-45. The original Epstein-Barr virus infection may have injured petitioner's liver. But when she had a liver biopsy, it did not show Epstein-Barr hepatitis. It was a normal liver biopsy. Tr. at 149. Dr. Kagen's conclusion is that Epstein-Barr virus may have injured petitioner's liver but left it looking okay but not reacting okay since liver function tests varied. Tr. at 150.

Dr. Levine answered the undersigned's question about the significance of the normal liver biopsy by stating that it consists of just a small part of a huge organ and the biopsy may have not been of the right part of the liver to show Epstein-Barr virus. *Id.*

Dr. Kagen stated that if petitioner had had reactivation of her Epstein-Barr virus in 1994, one would expect a rise in titer and then a fall, but in 1997, her titer results were almost the same. Tr. at 153. There are no early titers. Tr. at 154. Dr. Kagen thought it difficult to tell the cause of petitioner's April 1994 hepatitis one month after vaccination but he guessed the cause was Epstein-Barr virus. *Id.* He thought that hepatitis B vaccine was not the cause of petitioner's hepatitis because she had enlargement of her liver which subsequently went down. To his knowledge, hepatitis B vaccine has never been known to produce liver enlargement. Tr. at 155.

The classic case of hepatitis due to a virus includes a phase where the liver is swollen and then resolves over time. *Id.*

Dr. Kagen then said he did not think petitioner had either chronic fatigue syndrome or fibromyalgia. Tr. at 156. There is a lot else to explain her symptoms. Tr. at 157. Chronic fatigue syndrome is heterogeneous. Tr. at 158.

In answer to the undersigned's question, Dr. Levine stated that petitioner's disk herniation would not account for the degree of debility that she has. Tr. at 160.

Dr. Kagen said that, after petitioner's March 28, 1994 hepatitis B vaccination, she had widespread, disabling symptoms: weakness (heaviness of arms and legs), numbness, flu-like symptoms, exhaustion, thorax pain, abdominal pain, pain in multiple areas of her body. Tr. at 162. Patients with hepatitis have fatigue and muscle pain, but hepatitis does not explain all the symptoms she had. *Id.* Petitioner had chronic polyneuropathy. Tr. at 163. It was present very early on, but based on the doctor's records, the polyneuropathy took a few years to be diagnosed. Tr. at 165. Dr. Kagen attributes petitioner's polyneuropathy to Epstein-Barr virus, which is neurotropic. *Id.* Petitioner had a low titer to Human Herpes Virus-6 on IgG. Tr. at 167. Dr. Kagen agrees petitioner has mild polyneuropathy due to Epstein-Barr virus which may have damaged her nerves at the time she had it and from which she still suffers. Tr. at 169. He does not think the polyneuropathy is directly related to petitioner's hepatitis. *Id.*

Dr. Kagen said that petitioner's cervical disk disease causes pain and sometimes numbness and tingling in the upper extremities and in the low spine in the lower extremities. Tr. at 171. That does not negate petitioner's diagnosis of polyneuropathy, but adds to her symptoms. Tr. at 172. Petitioner had an abnormal electroencephalogram which raised the

question of her having a seizure disorder. *Id.* Petitioner has so many problems in her life that one disease cannot explain it all. Tr. at 173. Dr. Kagen thinks the Epstein-Barr virus underlies this, causing lymphatic dysfunction, leading to polyneuropathy. Tr. at 173-74. Her spinal abnormalities, EEG abnormality, and mitral valve prolapse are independent of the Epstein-Barr virus. Tr. at 174.

Dr. Kagen stated that when petitioner took hepatitis B vaccine, she had a pre-existing liver disorder due to Epstein-Barr virus. Tr. at 176. Her liver function tests results fluctuate. *Id.* Petitioner had a big liver that resolved, but the abnormal enzymes continued for years. *Id.* The only liver function test reports in the record date after the vaccination. Tr. at 178. There is nothing in the brief pre-vaccination records to indicate petitioner had hepatitis. Tr. at 181.

When Dr. Latov, the neurologist, examined petitioner, he did not know she had previously had Epstein-Barr virus and mononucleosis. Tr. at 200. Dr. Kagen said that Epstein-Barr virus can involve the central nervous system, the liver, and the spleen. Tr. at 201. It can also involve the peripheral nervous system. Tr. at 202. Dr. Kagen agrees that petitioner has an autonomic neuropathy. Tr. at 203. Dr. Latov attributed petitioner's neuropathy to her hepatitis B vaccination. Tr. at 204.

Dr. Kagen stated that the Epstein-Barr virus petitioner had in her teens caused damage and dysfunction to petitioner's liver and nervous system which are responsible for some of the symptoms which she has had chronically. Tr. at 208-09. He stated there is no evidence that petitioner had an immune dysfunction. Tr. at 211. She developed antibody to Epstein-Barr Virus, Human Herpes Virus-6, and hepatitis B vaccine. *Id.* Dr. Kagen did not know if petitioner had reactivation of her Epstein-Barr virus. Tr. at 214. Since petitioner had Epstein-Barr virus 13

years before she received hepatitis B vaccine, Dr. Kagen would not expect a marked reaction to Early Antigens. Tr. at 215-16. The degree of symptoms does not necessarily correlate with what is happening in the liver. Tr. at 217. Dr. Kagen said he did not know what an appropriate time period would be for an immune-mediated reaction to hepatitis B vaccination. *Id.*

Dr. Levine took the stand again. Tr. at 226. Petitioner's record in 1983 states she had an absence spell and a minor seizure and she was dizzy. This was before the 1994 hepatitis B vaccination. *Id.* Dr. Levine stated that, as Dr. Kagen mentioned, Epstein-Barr virus and Human Herpes Virus-6 can cause these types of problems and petitioner may have had a minor reactivation of her Epstein-Barr virus at the time, causing this absent spell or seizure disorder, but just a minor reactivation. This does not exclude the vaccine's causing a more permanent reactivation later on. Tr. at 227.

Dr. Levine also stated that at the time petitioner received hepatitis B vaccine, she had a negative mononucleosis spot, suggesting that at the time of vaccination, she did not have acute mono. Tr. at 229. This is more evidence of a reactivation of a prior infection as opposed to an acute new infection. *Id.* Dr. Levine would find it unusual for petitioner to have an Early Antigen 13 years after her mononucleosis. Tr. at 229-30.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence "(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.

Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> 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[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen . . . ."

Close calls are to be resolved in favor of petitioner. Capizzano, 1440 F.3d at 1327; Althen, 418 F.3d at 1280. *See generally*, Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

Petitioner must show not only that but for the vaccine, she would not have had the chronic fatigue syndrome, fibromyalgia, and polyneuropathy, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (Althen, 418 F.3d at 1278; Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

> Furthermore, 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. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.
>
> The 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.

35 F.3d at 549.

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Id.* at 1148.

The Federal Circuit stated in Althen, 418 F.3d at 1280, 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."

The Federal Circuit in Capizzano emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." 440 F.3d at 1326. See also Andreu v. Secretary of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009).

As the Federal Circuit stated in Knudsen, 35 F.3d at 548, "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." The undersigned's task is to determine medical probability

based on the evidence before the undersigned in this particular case. Althen, 418 F.3d at1281 ("judging the merits of individual claims on a case-by-case basis").

As for epidemiological support for causation, the Federal Circuit in Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994) ruled for petitioners even when epidemiological evidence directly opposed causation from DPT vaccine. The case concerned the cause of a baby's encephalopathy after a vaccination. Respondent provided evidence that more encephalopathies are caused by viruses than by vaccines, convincing the special master to rule against petitioners. But the Federal Circuit thought the epidemiologic evidence should not bar petitioners from prevailing. Even though epidemiological evidence supported respondent's view that viruses were more likely to cause encephalopathy than vaccinations, the Federal Circuit held that that fact alone was not an impediment to recovery of damages. In Knudsen, the Federal Circuit stated:

> The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

35 F.3d at 550.

The dispute in this case is not as significant as it might appear. Both experts, Dr. Levine for petitioner and Dr. Kagen for respondent, give a causal role to Epstein-Barr virus (EBV), which petitioner had in her teens when she had mononucleosis. Her exposure to EBV was 13 years before she received hepatitis B vaccine. Dr. Levine testified that hepatitis B vaccine reactivated petitioner's latent EBV, causing petitioner's subsequent viral hepatitis, chronic fatigue syndrome, fibromyalgia, and neuropathy, whereas Dr. Kagen ascribes sole causation of

petitioner's problems (other than her spinal problems and mitral valve prolapse) to her EBV alone, without unequivocal evidence of reactivation and without any influence from hepatitis B vaccine. In other words, petitioner alleges that there are two substantial factors here: hepatitis B vaccine and EBV, whereas respondent defends that there is only one substantial factor: EBV.

Dr. Kagen's analysis does not explain, however, why there was a cascade of symptoms within one month of hepatitis B vaccination without a reactivation of the EBV. Between her mononucleosis and hepatitis B vaccination, petitioner never had all the symptoms that afflicted her after vaccination: viral hepatitis, pronounced fatigue, aches, pains, hair loss, and peripheral neuropathy.

Moreover, the undersigned is cognizant that there are two treating physicians, Dr. Levine and petitioner's neurologist Dr. Latov, who attributed her hepatitis, chronic fatigue syndrome, fibromyalgia, and neuropathy to the hepatitis B vaccination. The Federal Circuit in Capizzano and Andreu emphasized the special masters' seriously considering the opinions of treating doctors. In the instant action, one of petitioner's treating doctors, Dr. Levine, also testified as her expert. There is a consistency here between what the treating doctors believed caused petitioner's chronic fatigue disorder, hepatitis, fibromyalgia, and polyneuropathy and the expert testimony presented at hearing.

Another factor weighing in favor of crediting Dr. Levine's testimony over that of Dr. Kagen is that the overwhelming majority of her patient caseload is devoted to chronic fatigue syndrome. She is knowledgeable about chronic fatigue syndrome as few others are in this field. She is an officer in professional societies devoted to chronic fatigue and has participated in workshops, sponsored by the Centers for Disease Control, in evaluating chronic fatigue.

On the other hand, respondent's expert Dr. Kagen, a rheumatologist, specializes in muscle diseases. Chronic fatigue syndrome is not a muscle disease. Most of his patients have not had chronic fatigue syndrome. To Dr. Levine's thousands of patients with chronic fatigue syndrome, Dr. Kagen had hundreds. He initially testified that petitioner had chronic fatigue syndrome and later in his testimony, changed his mind. The scale of persuasion weighs decidedly toward Dr. Levine based on her expertise in the very illness at issue, her clinical experience, her writings, and her exposure to leading medical opinion on the subject. Plus, she is a treating physician.

Dr. Levine testified that there is a biologically plausible theory connecting hepatitis B vaccine with reactivation of petitioner's Epstein-Barr virus that led to her hepatitis and other illnesses (chronic fatigue syndrome, fibromyalgia, and polyneuropathy). That satisfies the first prong of Althen. The Epstein-Barr virus has been associated both with hepatitis (which petitioner had), chronic fatigue syndrome, and polyneuropathy (since the virus is neurotropic). Petitioner first experienced Epstein-Barr virus when she had mononucleosis as a teenager.

Dr. Levine testified that there was a logical sequence of cause and effect in the instant action because Epstein-Barr virus is well-known to be connected to the development of chronic fatigue syndrome, as well as hepatitis and polyneuropathy. That satisfies the second prong of Althen.

Dr. Levine testified that the onset of two to three days of flu-like symptoms after vaccination was medically appropriate for an aberrant immune response. The symptomatology that initially was diagnosed as hepatitis continued unabated and included pain, chronic fatigue

syndrome, hair loss, autonomic instability, fibromyalgia, and polyneuropathy. That satisfies the third prong in Althen.

The instant action reminds the undersigned of another of her hepatitis B vaccine cases, Dunbar v. Sec'y of HHS, No. 98-627, 2007 WL 2844826 (Fed. Cl. Spec. Mstr. 2007). After hepatitis B vaccinations, Mr. Dunbar had increased fatigue, joint pain, malaise, hair loss, short-term memory loss, decreased strength, mild encephalopathy, neuropathy, postural orthostatic tachycardia syndrome, and autoimmune hepatitis (elevated liver enzymes). Although petitioner's experts did not believe Mr. Dunbar had chronic fatigue syndrome, respondent's expert did until the hearing when he retreated from that view. Citing Kelley v. Sec'y of HHS, 68 Fed. Cl. 84, 100 (Fed. Cl 2005) (whether petitioner had chronic inflammatory demyelinating polyneuropathy or Guillain-Barré syndrome was irrelevant to his proving entitlement), the undersigned stated: "That petitioner's condition may be difficult to diagnose does not prevent his being able to prove causation in fact as long as he fulfills the criteria described in Althen." 2007 WL 2844826, at *25. The undersigned ruled for petitioner in Dunbar based both on petitioner's experts' testimony and the opinions of the treating physicians that petitioner had a reaction to both hepatitis B vaccinations with permanent failure to regain his health. The undersigned notes that none of Mr. Dunbar's experts testified that hepatitis B vaccine reactivated any latent Epstein-Barr virus. Their opinions even without a viral reactivation theory were biologically plausible to persuade the undersigned. The undersigned issued a damages decision on October 2, 2009 in Dunbar. The decision was not appealed.

In the instant action, petitioner asserts that hepatitis B vaccine caused her chronic fatigue syndrome and she has, interestingly, many of the same disease systems that affected petitioner in

Dunbar: weakness, nausea, pain, cognitive difficulties, hair loss, hepatitis, fatigue, autonomic instability. Her treating doctors, one of whom was her expert witness, all stated in the medical records and/or testimony that she had an adverse reaction to her hepatitis B vaccination. Dr. Levine has given a biologically plausible medical theory for how hepatitis B vaccine can cause chronic fatigue syndrome. She has also given a logical sequence of cause and effect in this case by noting the reactivation of Epstein-Barr virus which respondent's expert agreed is linked with hepatitis as well as polyneuropathy. There is no question that the timing of two or three days is medically appropriate for causation in fact.

Medical literature which the parties filed suggests there is immune activation in chronic fatigue syndrome. The fact that there are no epidemiologic studies causally relating hepatitis B vaccination to chronic fatigue syndrome is not legally significant to the Federal Circuit, and thus not to the undersigned (Knudsen, Althen, Capizzano).

Petitioner has proven a prima facie case that hepatitis B vaccine caused her chronic fatigue syndrome, hepatitis, fibromyalgia, and polyneuropathy. Without the vaccination, she would not have these illnesses.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and will convene a telephonic status conference soon to discuss how to proceed in resolving the issue of damages.

IT IS SO ORDERED.

December 15, 2009
DATE

s/Laura D. Millman
Laura D. Millman
Special Master