In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 99-307V
October 30, 2009
To be Published

PATRICIA RODRIGUEZ,	*	
	*	
Petitioner,	*	
v.	*	Entitlement; Hepatitis B vaccination; one- or three-month onset vs. two-year onset; relapsing/remitting MS
	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner.
Lisa A. Watts and Chrysovalantis Kefalas, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

Petitioner filed a petition on May 14, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccinations administered on September 17, 1993, November 4, 1993, and May 31, 1994 caused her unspecified injury. Two years after her third hepatitis B vaccination, petitioner was diagnosed with relapsing/remitting multiple sclerosis (MS). The petition is silent as to the onset of petitioner's MS.

On May 14, 1999, the case was assigned to special master Richard B. Abell.

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[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.

On June 9, 1999, petitioner moved to stay the proceedings because petitioner's counsel stated it would "take some time" to file medical records and affidavits.

On June 17, 1999, special master Abell granted petitioner's motion.

On August 3, 1999, chief special master Gary Golkiewicz reassigned this case to himself along with 73 other cases.

On August 13, 1999, the chief special master issued an order in this and 80 other cases that all missing documentation (medical records, affidavits, expert reports) had to be filed by November 5, 1999 unless petitioners could not comply in which case they had to file a status report by November 5, 1999 describing their efforts and each 30 days thereafter.

On December 9, 1999, petitioner moved to designate a different case as a master file so that all exhibits petitioner's counsel filed in that case would apply to 135 additional cases petitioner's counsel was handling, including the instant action. Petitioner's counsel never filed the records that the chief special master required in his August 13, 1999 order in this case and never filed the requisite status report in lieu of the documentation.

On January 5, 2000, respondent responded to petitioner's motion to designate a master file in another case stating it should be denied. There were pending 282 claims alleging that hepatitis B vaccine had injured vaccinees, 137 of which were being handled by petitioner's counsel in the instant action. These cases dealt with more than one injury and petitioner's counsel had not specified what materials would be common to all 137 cases.

On February 14, 2000, the chief special master denied petitioner's counsel's motion to designate another case as a master file after having held a status conference with counsel during which he learned petitioner's counsel wanted to file discovery motions in this master file. The

chief special master stated that discovery motions were premature when petitioners had not filed the required documentation needed to assess their cases.

On February 15, 2000, petitioner filed a status report in this case, stating she was trying to gather all her records and that petitioner's counsel was trying to get Congress to amend the Vaccine Act to lighten the burden of proof. Petitioner's counsel stated he would file status reports every 90 days.

On May 16, 2000, petitioner filed a status report, stating she was trying to obtain her records and petitioner's counsel was obtaining a high speed network printer.

On August 21, 2000, petitioner filed a status report, stating she was trying to obtain her records.

On December 12, 2000, petitioner filed a status report, stating she was trying to obtain her records.

On January 4, 2001, petitioner filed another status report as well as a CD containing medical records designated as exhibits 1-10. .

On March 15, 2001, petitioner filed another status report, stating her counsel was hiring another attorney.

On April 5, 2001, the chief special master assigned this and 81 other cases in the hepatitis B group of cases to the undersigned.

On July 31, 2001, petitioner moved for authority to subpoena medical records.

On August 8, 2001, the undersigned granted petitioner's motion to subpoena medical records.

On December 5, 2002, the chief special master issued an order reassigning this case and 20 other hepatitis B vaccine-demyelinating disease cases to him.

On May 7, 2003, the chief special master issued an order reassigning this case and 36 other hepatitis B vaccine-demyelinating disease cases to former special master (now Judge) Margaret M. Sweeney.

On May 20, 2003, former special master Sweeney issued an order in this case and 36 other hepatitis B vaccine-demyelinating disease cases, all of whom petitioner's counsel in the instant action represented. The lead case in what was to become an Omnibus proceeding was another case in which former special master Sweeney ordered petitioners' counsel to provide a status report and three expert reports by June 9, 2003.

On October 10, 2003, petitioner filed medical records as exhibits 11-16

On October 31, 2003, petitioner filed medical records as exhibits 17-19.

On January 6, 2004, former special master Sweeney issued an order concerning the Omnibus hepatitis B vaccine-demyelinating diseases proceeding and the designation of four cases (not the instant action) to represent four demyelinating diseases at issue: transverse myelitis (TM), Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating disease (CIDP), and multiple sclerosis (MS). There were 65 cases encompassed within the Omnibus proceedings.

The Omnibus proceeding was held before former special master Sweeney from October 13-15, 2004. At the end of 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, the chief special master reassigned all 65 hepatitis B vaccine-demyelinating disease cases that comprised the Omnibus proceeding to the undersigned. Included in those cases was the instant action.

The first responsibility of the undersigned was to rule in the four paradigm cases upon which the testimony and exhibits focused at the Omnibus proceeding. The undersigned held that hepatitis B vaccine can cause demyelinating diseases (including MS, the disease at issue in the instant action) if the onset was between three days and one month based on the Omnibus testimony of petitioners' expert Dr. Vera Byers and respondent's expert Dr. Roland Martin. Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525, at *12, *15 (Fed. Cl. Feb. 24, 2006).[2]

In the instant action, on June 22, 2006, the undersigned issued an Order to Show Cause to petitioner why this case should not be dismissed because the medical records indicated a two-year gap between her third hepatitis B vaccination and the onset of her MS.

On July 31, 2006, petitioner responded that petitioner's onset of numbness and tingling in her toes was August 20, 1994 when she saw Dr. Fernandez-Maitin. (Actually, as petitioner's counsel realized at the hearing, August 20, 1994 was the date of petitioner's last menstrual period which was noted in the medical record dated September 7, 1994, which was three months

[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).

and one week after the third hepatitis B vaccination.) Attached to petitioner's response was the Hernán paper discussed in other material submitted in this case (below).

On August 3, 2006, the undersigned issued a scheduling order for a hearing concerning onset which was set for November 14, 2006.

On October 26, 2006, petitioner filed her affidavit and the affidavit of her husband. P. Exs. 20 and 21. Petitioner stated in her affidavit that tingling in her feet and lightheadedness caused her to set up an appointment in August 1994 with her doctor. Ex. 20, p. 1. From that point on, her symptoms occurred intermittently and were attributed to stress. She stated she still has episodes of tingling and lightheadedness. *Id.*

Petitioner's husband was silent in his affidavit of 2006 as to the onset of petitioner's tingling in her feet and lightheadedness. Ex. 21.

On November 3, 2006, in light of the affidavits filed one week earlier, the undersigned questioned whether an onset hearing was warranted but would need a neurologist's expert report to determine the significance vel non of petitioner's tingling and numbness in her toes as reported on September 7, 1994 to Dr. Fernandez-Maitin.

On November 9, 2006, the undersigned cancelled the onset hearing and ordered petitioner to file an expert report by January 8, 2007.

On January 9, 2007, petitioner's counsel orally moved for an extension of time of 45 days to file an expert report which the undersigned granted. The new deadline was February 21, 2007.

After a status conference on February 22, 2007 during which petitioner's counsel requested more time for an expert report, the undersigned issued an Order dated February 23, 2007 giving petitioner until April 23, 2007 to file an expert report.

On April 24, 2007, petitioner filed Dr. Carlo Tornatore's expert report (exhibit 22). Dr. Tornatore assumed that the onset of petitioner's first neurologic complaints of tingling in her toes began on August 20, 1994 (which was actually the date of petitioner's last menstrual period as reflected in the medical record dated September 7, 1994). He states that sensory symptoms of the lower extremities are very common in MS and are frequently transitory. Ex. 22, p. 1. Two years later, in 1996, petitioner developed similar symptoms of numbness of the feet leading to a diagnosis of MS. *Id.* To link the 1994 toe tingling and numbness to petitioner's third hepatitis B vaccination three months earlier on May 31, 1994, Dr. Tornatore states that petitioner's "initial immune activation could indeed [have] occurred shortly following the hepatitis vaccination yet gone unrecognized...." Ex. 22, p. 2. He ascribed this unrecognized earlier onset to "silent areas" in the brain "that can be injured and yet not result in any clinical manifestations, overt or otherwise [sic]." *Id.*

On May 3, 2007, the undersigned issued an order for respondent to file an expert report by June 18, 2007.

On June 14, 2007, respondent filed an expert report from Dr. Thomas P. Leist (exhibit A) together with an article entitled "Recommended Diagnostic Criteria for Multiple Sclerosis" by W. Ian McDonald (Ex. C) discussed below as the McDonald criteria. Dr. Leist attributed petitioner's toe tingling and numbness reported on September 7, 1994 to Dr. Fernandez-Maitin to her obesity (petitioner weighed 221 pounds) and accentuated lumbar lordosis and lumbar disk

disease. Ex. A, p. 7. "Lumbar disk disease can explain occurrence of abnormal sensation in a radicular pattern. Obesity and postural changes can accentuate such symptoms." *Id.* As an explanation for why Dr. Leist did not consider petitioner's toe tingling and numbness reported on September 7, 1994 to be the onset of her MS, Dr. Leist stated: "A demyelinating event is often associated with gradual worsening over days to weeks." *Id.* Petitioner did not have any worsening of her toe tingling and numbness over days to weeks after reporting the symptom on September 7, 1994. Citing the McDonald criteria for diagnosing MS, Dr. Leist said that petitioner did not have an objective examination on September 7, 1994 to determine if she did have MS. The McDonald criteria state that historical accounts of symptoms may lead to a suspicion of MS but "cannot be sufficient on their own" to diagnose MS. *Id.* Petitioner did not keep a follow-up appointment set for September 12, 1994, leading Dr. Leist to conclude that her symptoms did not worsen and may have improved, suggesting that the cause of her toe numbness was due to a radicular, rather than a demyelinating, process. *Id.*

Fifteen months later, petitioner phoned Dr. Fernandez-Maitin to report insomnia, stress, anxiety, and lightheadedness, but she did not come in for a medical visit. *Id.* Dr. Leist states these symptoms are not specific and can reflect a psychological state rather than a neurological problem. *Id.* On April 21, 1996, 23 months after her third hepatitis B vaccination, petitioner complained in an emergency room of chest tightness. Work-up was negative for myocardial infarction. She did not keep a follow-up appointment set for April 24, 1996. Petitioner reported stress, chest discomfort, heartburn, and perioral numbness. Dr. Leist states these symptoms were non-specific and not indicative of neurologic injury. Ex. A, p. 8. Some of her symptoms were due to gastric reflux disease which can occur in obesity. Her heartburn responded to antacids.

Symmetrical perioral numbness can be associated with psychological states and is less likely a neurologic symptom because it would require lesions on both the right and left sides of the brainstem which later brain MRIs did not show. *Id.* Petitioner had ample reason for stress because she had given birth in 1992 to a girl with spina bifida who developed epilepsy. *Id.* Petitioner presented with ascending numbness on August 27, 1996, about 27 months after her third hepatitis B vaccination. Ex. A, p. 9. She had a cold prior to onset of her symptoms. An MRI done on September 16, 1996 showed enhancing lesions. A cerebrospinal fluid examination done on September 20, 1996 showed 17 white blood cells. Enhancing lesions and an increased white cell count show acute inflammatory activity. *Id.* This was petitioner's first demyelinating event. Petitioner went to an ophthalmologist on November 13, 1996 complaining of visual blurring without a significant change in her visual acuity. Ex. A, p. 9. She had recurrence of lower extremity numbness in August 1997 and one brief episode of left arm numbness on August 18, 1999. Ex. 1, p. 10. Dr. Leist's opinion is that petitioner had the onset of acute myelopathy after an upper respiratory tract infection about 27 months after her third hepatitis B vaccination. *Id.* She did not have "detectable, objective neurologic abnormalities prior to August 1996...." *Id.* Her toe numbness and tingling reported on September 7, 1994 are explainable by other causes than demyelination. Ex. A, p. 11. Her vaccinations had nothing to do with her MS. *Id.*

On October 11, 2007, petitioner filed medical records (exhibits 23-24).

On December 3, 2007, petitioner filed a supplemental report from Dr. Tornatore (exhibit 25).

On March 3, 2008, respondent filed a supplemental expert report from Dr. Leist after MRI films had been provided to him (exhibit D).

A hearing was held on August 19, 2008. Testifying for petitioner were petitioner and Dr. Carlo Tornatore. Testifying for respondent was Dr. Thomas P. Leist. For the first time, petitioner changed the alleged onset of her symptoms, without any notice to the undersigned in the form of a supplemental affidavit. Petitioner testified that she had spoken to her husband the night before the hearing and he told her the onset of the tingling in her feet was the weekend of Father's Day in June 1994 when they were at the beach. This would make onset one month after the third hepatitis B vaccination, instead of three months later if onset were in August 1994, or three months and one week after vaccination if onset were around the time of her visit to Dr. Fernandez-Maitin on September 7, 1994, or two years later if onset were in1996.

Recently, in Pecorella v. Secretary of HHS, No. 04-1781V, 2008 WL 4447607 (Fed. Cl. Spec. Mstr. Sept. 17, 2008), the undersigned ruled that an appropriate onset between hepatitis B vaccine and a demyelinating disease could be up to two months because in Pecorella, respondent elected not to defend when there was a two-month onset of TM after hepatitis B vaccination.

Respondent in the instant action requested after the hearing the opportunity to file a post-hearing brief, which the undersigned granted although petitioner had not requested the same opportunity. Respondent filed her post-hearing brief on November 3, 2008.

Petitioner then requested orally on November 5, 2008 the opportunity to respond to respondent's post-hearing brief, which the undersigned granted.

On December 3, 2008, petitioner filed her post-hearing brief.

By going through the records and testimony, the undersigned realized that it would be important to take the testimony of petitioner's husband since, according to petitioner at the hearing, only by speaking to him the night before the hearing did she recollect with his

assistance that the onset of the numbness and tingling in her feet was during Father's Day weekend at the beach in June 1994 rather than at some point around her September 7, 1994 visit with Dr. Fernandez-Maitin. Petitioner's husband did not attend the hearing and was not a witness then.

Accordingly, in order to give petitioner the fullest opportunity to make her case, the undersigned took petitioner's husband's testimony on June 24, 2009.

FACTS

Petitioner was born on December 6, 1961.

On September 17, 1993, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 1, p. 1.

On November 4, 1993, petitioner received her second hepatitis B vaccination. Med. recs. at Ex. 1, p. 1.

On March 24, 1994, petitioner first saw Dr. Ania Fernandez-Maitin. Med. recs. at Ex. 5, p. 20. Petitioner had upper respiratory problems and a cough. Dr. Fernandez-Maitin prescribed Keflex. *Id.*

On the next day, March 25, 1994, petitioner saw Dr. Fernandez-Maitin again. She complained that her upper respiratory illness, which she had had for a week, had gotten worse and she was wheezing. *Id.* Petitioner was smoking three cigarettes a day. Med. recs. at Ex. 5, p. 19. Dr. Fernandez-Maitin diagnosed petitioner with rhinitis, bronchitis, and upper respiratory illness. She prescribed Keflex. Med. recs. at Ex. 5, p. 18.

Three days later, on March 28, 1994, petitioner saw Dr. Fernandez-Maitin again. *Id.* She had a bad cholesterol ratio of 5.6 with an HDL of 29. Dr. Fernandez-Maitin ordered her to undergo certain tests including a complete blood count. *Id.*

On April 1, 1994, Dr. Fernandez-Maitin noted that she attempted to inform petitioner about her test results, but was unsuccessful. Med. recs. at Ex. 5, p. 17.

On April 5, 1994, Dr. Fernandez-Maitin noted she attempted to inform petitioner about her test results, but was unsuccessful. *Id.*

On April 6, 1994, Dr. Fernandez-Maitin noted she attempted to inform petitioner about her test results, but received no answer. She sent a letter informing her of her attempts to reach her to inform her of the test results. *Id.*

On April 8, 1994, petitioner was informed of the test results and a low cholesterol diet was mailed to her. *Id.*

On May 31, 1994, petitioner received her third hepatitis B vaccination. Med. recs. at Ex. 1, p. 1.

Three months and one week after petitioner's third hepatitis B vaccination, on September 7, 1994, petitioner saw Dr. Fernandez-Maitin, complaining of a tingling feeling in her toes. Petitioner stated that, on the day before, i.e., September 6, 1994, she felt lightheaded. Med. recs. at Ex. 5, p. 17. After the episode, she ate a banana and an apple. Then she rested and woke up feeling better. *Id.* Petitioner used a rebreather paper without improvement. *Id.* On physical examination, petitioner's toes had normal sensation, but petitioner felt like they were numb. Dr. Fernandez-Maitin decided to screen petitioner for hypoglycemia and diagnosed her with episodes of dizziness and numbness. Med. recs. at Ex. 5, p. 16. The doctor prescribed a CBC

(complete blood count), a SMAC (automated chemistry serum), and a GTT (glucose tolerance test). *Id.*

On September 13, 1994, petitioner's CBC and SMAC tests were normal. Med. recs. at Ex. 5, p. 15. The results of her five-hour glucose tolerance test were pending. *Id.*

Eleven months later, on August 10, 1995, petitioner telephoned her doctor to complain about anxiety, stress, lack of sleep, and lightheadedness. Med. recs. at Ex. 5, p. 14. She was told to relax and was given reassurance. She was advised to try to sleep and to call the doctor if her symptoms got worse. *Id.*

Eight and one-half months later, on April 21, 1996, petitioner went to Baptist Hospital of Miami, complaining of chest tightness when going to bed that night. It was thought to be related to anxiety and was now resolved. Med. recs. at Ex. 17, p. 27. She has had anxiety and stress. *Id.* She was on Xanax and complained of significant stress. *Id.* She was advised to stop smoking and to lose weight. Med. recs. at Ex. 17, p. 45. Dr. Alvaro Gomez wrote a consultation report dated April 21, 1996. Med. recs. at Ex. 17, p. 50. He states that she was kept in the Chest Pain Center because of chest pains the prior night. Her previous medical history was totally unremarkable. The pain went away on its own. *Id.* She had no focal neurological deficits. Med. recs. at Ex. 17, p. 51. His impression was atypical chest pains without evidence of ischemia or infarction. She had a history of smoking and obesity. *Id.*

On May 7, 1996, nearly two years after her third hepatitis B vaccination, petitioner saw Dr. Fernandez-Maitin, complaining of numbness in her cheek and tongue, stressed nervousness, weakness for 10 days, and heartburn. Med. recs. at Ex. 5, p. 13. The numbness was in the perioral/tongue area. She had chest discomfort. Food seemed to get stuck in her mid-epiglottal

area. *Id.* She used Pepcid AC to help the heartburn and Reglan. She had a knot in her mid-stomach. *Id.* On physical examination, she had rhonchi in her chest. *Id.* She was diagnosed with anxiety, hyperventilation, and diminished breath sounds. Med. recs. at Ex. 5, p. 12.

On the next day, May 8, 1996, petitioner saw Dr. Fernandez-Maitin for a complete physical examination. *Id.*

On the next day, May 9, 1996, it is unclear if petitioner saw Dr. Fernandez-Maitin or the doctor was merely recording her findings. Petitioner had an HDL of 28. Dr. Fernandez-Maitin recommended a low cholesterol/low fat diet. She needed to rule out a urinary tract infection. Med. recs. at Ex. 5, p. 10.

On May 10, 1996, Dr. Fernandez-Maitin attempted to call petitioner about the lab results and left a message with a coworker. *Id.*

On May 14, 1996, petitioner was informed about the results and would call to repeat her urine test. *Id.*

On May 28, 1996, petitioner complained to Dr. Barry Eichenbaum, her eye doctor, of a visual problem. Med. recs. at Ex. 4, p. 1; Ex. 11, p. 2. The doctor wrote "REE LEE 2yrs." This could mean that petitioner had a right eye examination (REE) and a left eye examination (LEE) two years before this appointment. Petitioner complained of a decrease in day and night visual acuity without a prescription. She wore glasses as a child. She refused dilation of her pupils. Both of her parents had diabetes mellitus. *Id.* She noted a subjective increase during heat of her complaints about visual acuity. Med. recs. at Ex. 4, p. 2; Ex. 11, p. 3.

On June 7, 1996, petitioner's urine test was positive and she was prescribed Cipro. Med. recs. at Ex. 5, pp. 9, 10. Petitioner was to recheck her urine in two weeks. Med. recs. at Ex. 5, p. 9.

On June 25, 1996, petitioner went to Dr. Fernandez-Maitin's office, complaining that there was renovation being done at work and she felt sick and nauseated, had severe headaches, was tired and weak, and would like to be tested for iron poisoning. *Id.* Dr. Fernandez-Maitin said it was okay to test her blood level. *Id.*

Three days later, on June 28, 1996, petitioner's lead level was negative. *Id.* Petitioner was informed. *Id.*

On July 1, 1996, petitioner had a mammogram which was normal. *Id.*

On July 3, 1996, petitioner underwent a myocardial stress test on a treadmill, exercising nine minutes and achieving 88 percent of the maximum predicted heart rate. Med. recs. at Ex. 17, p. 63. She had a normal myocardial perfusion scan. Med. recs. at Ex. 17, p. 64.

On August 1, 1996, petitioner was informed that her stress test was negative. *Id.*

On August 27, 1996, petitioner saw Dr. Fernandez-Maitin, complaining of lower back pain with numbness in her left leg. *Id.* She had lost 16 pounds. Med. recs. at Ex. 5, p. 8. She had numbness in her left leg and right foot with lumbosacral sprain. Dr. Fernandez-Maitin prescribed Naprosyn and said if she did not improve, she should have an x-ray. *Id.*

Three days later, on August 30, 1996, petitioner called and complained she was not getting better. The numbness was worse. Dr. Fernandez-Maitin advised her to go to the emergency room. *Id.*

On August 31, 1996, petitioner went to Healthsouth Doctor's Hospital Emergency Department. Med. recs. at Ex. 24, p. 15. She stated she had no significant past medical history and complained of low back pain radiating down her left thigh and the back of her left leg over the prior few days. *Id.* The Naprosyn her private medical doctor put her on was not working. The pain increased with movement. She had no prior medical history. The clinical impression was back pain secondary to strain. *Id.* The nursing notes show that petitioner complained of numbness in both feet. Med. recs. at Ex. 24, p. 18.

On September 3, 1996, petitioner went to Baptist Hospital of Miami with upper body weakness. She waited seven hours in the emergency room and then left. She then went to Doctor Hospital, and they gave her a shot but she was not better. Dr. Fernandez-Maitin referred her to Dr. Enrique J. Carrazana. Med. recs. at Ex. 5, p. 7.

On September 10, 1996, petitioner saw Dr. Enrique J. Carrazana, a neurologist, stating she had an escalating feeling of numbness throughout her body. Petitioner began to experience numbness in her feet two weeks previously. The numbness climbed rapidly into her torso, associated with a feeling of minor low back discomfort. Later, she felt a similar numbness in her hands and a vague feeling of incoordination/lack of balance and shaking, which she described poorly. She may have had a viral infection or a cold a week prior to the onset of her symptoms. Petitioner did not recall an event of a similar nature in the past except in May 1996 when she had some episodes of chest pain which may have been related to stress at work. She recalled slight numbness of her face on several occasions. Her past medical history was unremarkable. Dr. Carrazana thought petitioner's clinical presentation of sensory complaints and truncal ataxia in

the possible setting of exposure to a minor viral illness might indicate encephalomyelitis. Med. recs. at Ex. 2, pp. 36, 37; Ex. 17, pp. 96, 97.

On September 16, 1996, petitioner had a brain MRI with contrast which showed multiple small white matter lesions consistent with demyelinating disease. Contrast enhancement of two small lesions was consistent with active lesions. Med. recs. at Ex. 17, p. 98.

On September 16, 1996, petitioner was in Healthsouth Doctor's Hospital Emergency Department, complaining of numbness in both legs and weakness. Med. recs. at Ex. 24, p. 23. She denied any medical history. *Id.* Over the prior few days, she had development weakness in her arms as well as her legs. Med. recs. at Ex. 24, p. 28. Her only medical history was that she fell while she was on a treadmill in April at Baptist Hospital. *Id.* On physical examination, she had some slight weakness in her lower and upper extremities. Med. recs. at Ex. 24, p. 29. She still had strength of 4 out of 5 in all her extremities. *Id.*

From September 19-24, 1996, petitioner was at Baptist Hospital. Med. recs. at Ex. 17, p. 89. Dr. Victor Faradji wrote in the discharge summary that petitioner was admitted with progressive numbness of her lower extremities and difficulty with ambulation secondary to decreased balance. She had truncal ataxia with difficulty in tandem gait and decreased vibration on sensory testing of her lower extremities. Her deep tendon reflexes were increased throughout. A brain MRI revealed multiple small white matter lesions bilaterally. She received intravenous Solu-Medrol for five days and improved considerably with near resolution of the sensation of numbness with it remaining only in her toes. Med. recs. at Ex. 17, p. 89. Her only medication on release from the hospital with the diagnosis of multiple sclerosis was multivitamins and a B complex vitamin daily. Med. recs. at Ex. 17, p. 90.

On October 17, 1996, petitioner saw Dr. Howard L. Zwibel, a neurologist associated with Dr. Carrazana, who diagnosed petitioner with relapsing/remitting MS. Dr. Zwibel states petitioner had onset of lower extremity symptoms at the end of August 1996 with sensory and motor complaints. This was preceded by a minor upper respiratory infection. Prior to this, she had no known history of neurologic dysfunction although she had a possible transient blurring in one eye earlier in 1996. Dr. Zwibel wrote that, clearly, petitioner had not had any other episodes of neurologic dysfunction. Her past history was negative for serious medical or neurologic illness. Her vision was 20/40 in each eye. Med. recs. at Ex 2, p. 12.

Petitioner's paternal first cousin has MS. Med. recs. at Ex. 7, p. 3.

On November 13, 1996, petitioner complained to her eye doctor that she had blurry vision for one week. Med. recs. at Ex. 6, p. 10.

On November 20, 1996, petitioner's ophthalmologist Dr. Harry A. Hamburger diagnosed her with resolving right optic neuritis secondary to MS. Med. recs. at Ex. 6, p. 2.

On December 12, 1996, petitioner had MRIs done on her cervical and thoracic spines. Both were normal. Med. recs. at Ex. 17, pp. 163, 164.

On December 13, 1996, petitioner had an MRI done on her lumbar spine. Med. recs. at Ex. 17, p. 164. She had mild dehydration and loss of height in the L3-4 disc without evidence of a compressive lesion. *Id.*

On May 27, 1997, petitioner saw Dr. Jim C. Hirschman and informed him that Dr. Hoff told her the optic neuritis corrected itself. Med. recs. at Ex. 8, p. 5.

On November 19, 1997, petitioner saw Dr. Allan Herskowitz, a neurologist. Med. recs. at Ex. 7, p. 3. Petitioner had apparently been in good health until September 1996 when she

developed a sudden onset of numbness from her waist down without any sphincter problems or weakness. She was admitted to Baptist Hospital for five days and put on high dose IV steroids and all her symptoms remitted. *Id.* She then saw Dr. Zwibel who did a spinal tap and a brain MRI, both of which were abnormal and consistent with demyelinating disease. Her dorsal and cervical spine MRIs were normal. *Id.* Petitioner did well and, in May 1997, was put on Copaxone. In August 1997, she had a recurrence where her whole left leg went numb. She was given a Medrol pack and her symptoms improved, but she stated her left leg did not feel quite normal although she functioned well. She also took Amantadine for fatigue. Otherwise, her health was excellent. She smoked one pack every three to four days. *Id.* Petitioner's visual acuity was intact. Med. recs. at Ex. 7, p. 4. Petitioner had normal strength and tone in her muscles. She appeared to be in remission. *Id.*

On August 26, 1998, petitioner returned to Dr. Eichenbaum, the same eye doctor she saw on May 28, 1996. Med. recs. at Ex. 11, p. 4. He notes checkup, LEE 5/96, diagnosed with MS in the beginning of September 1996 and has been seeing MD for optic neuritis. *Id.*

On July 13, 2002, petitioner saw Dr. Eichenbaum, who notes that petitioner had LEE four years ago there, and LEE one year ago. Med. recs. at Ex. 11, p. 5.

On June 1, 2007, petitioner had a brain MRI with and without contrast. Two tiny enhancing lesions were in the white matter on the left, which were new since the prior MRI of 2002. Med. recs. at Ex. 24, p. 8.

On September 14, 2007, Dr. Eichenbaum wrote a letter stating that he saw petitioner for routine eye examinations on May 28, 1996, August 26, 1998, July 13, 2002, September 19, 2003, November 1, 2004, and October 17, 2006. Med. recs. at Ex. 23, p. 1.

Other submitted material

Attached to petitioner's response to the undersigned's Order to Show Cause is an article entitled "Recombinant hepatitis B vaccine and the risk of multiple sclerosis, A prospective study" by M.A. Hernán et al., 63 *Neurology* 838-42 (2004). The authors conducted a nested case-control study of individuals who had MS and who had three years of medical records prior to the date of their onset of MS. Their conclusion was that recombinant hepatitis B vaccine could cause MS up to three years later, but that there was no increased risk of MS following tetanus and influenza vaccinations. There were 10 controls who did not have MS for each MS patient in the study. *Id.* at 839. The authors state that the proportion of cases that received at least one hepatitis B vaccination during three years before the onset of MS symptoms was 6.7% compared to 2.4% of the controls who received hepatitis B vaccination within three years. The authors calculated an odds ratio for MS for vaccination versus no vaccination of 3.1 with a confidence interval ranging from 1.5 to 6.3. *Id.* The risk was greater but not significantly when the last vaccination occurred within the second or third years before MS onset compared with the first year before onset. *Id.* at 840. The authors stress that 93% of the MS cases in their study had not been vaccinated. *Id.*

Petitioner filed as Exhibit 25 an article entitled "Original Contributions. Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977" by L.B. Schonberger, et al., 110 *Amer J Epidemiology* 2:105-23 (1979). Dr. Shonberger and his co-authors did an epidemiological analysis of cases of Guillain-Barré syndrome (GBS) arising in swine flu vaccinees compared to the rate of GBS among baseline non-vaccinees using reports to the Centers for Disease Control (CDC). Seventy-one percent of

GBS vaccinees became ill within four weeks of vaccination, including 52% in the second and third weeks after vaccination. *Id.* at 110. Moreover, only 32.8% of those vaccinees whose GBS began within four weeks of vaccination also had a history of recent acute illness, compared with 61.8% of non-vaccinees within four weeks of onset of GBS. *Id.* at 120. Although the authors in their discussion section discuss events within six weeks of vaccination, their figures 6 and 7 on page 113 indicate an increased incidence of GBS over baseline continuing to 10 weeks or two and one-half months after swine flu vaccination.

As Ex. C, attached to respondent's expert Dr. Leist's report, is an article entitled "Recommended Diagnostic Criteria for Multiple Sclerosis: Guidelines from the International Panel on the Diagnosis of Multiple Sclerosis," by W.I. McDonald, et al., 50 *Ann Neurol*:121-27 (2001). The authors represent the International Panel on MS Diagnosis and present revised diagnostic criteria for MS. *Id.* at 121. Their focus was "on the objective demonstration of dissemination of lesions in both time and space." *Id.* They begin the article by stating, "Because no single clinical feature or diagnostic test is sufficient for the diagnosis of multiple sclerosis (MS), diagnostic criteria have included a combination of both clinical and paraclinical studies." *Id.* The last formal review of criteria for MS diagnosis was in 1982.

The International Panel on the Diagnosis of MS convened in London in July 2000 under the auspices of the US National MS Society and the International Federation of MS Societies to create diagnostic criteria that practicing physicians could use, and to integrate MRI findings into the overall diagnostic scheme. *Id.* The 16 coauthors of the article (the Panel) came from England, France, the United States, Austria, Canada, Holland, and Sweden from notable institutions such as the Royal College of Physicians, Cambridge University, Mt. Sinai School of

Medicine, the National Institute of Neurological Disorders and Stroke, the National Multiple Sclerosis Society, and the Mayo Clinic. *Id.*

The Panel concluded that obtaining "**objective evidence** of dissemination in time and space of lesions typical of MS is **essential** in making a secure diagnosis, as is the exclusion of other, better explanations for the clinical features." [emphasis added.] *Id.* at 122. They stated, "Clinical evidence depends primarily on objectively determined clinical signs. **Historical accounts of symptoms may lead to a suspicion of the disease but cannot be sufficient on their own for a diagnosis of MS**" [emphasis added.] *Id.*

The Panel stated that an attack of the kind of attack which is seen in MS should for general diagnostic purposes last for at least 24 hours. *Id.* "This assumes that there is expert clinical assessment that the event is not a **pseudoattack**, such as **might be caused by a change in core body temperature or infection**. Whereas suspicion of an attack may be provided by subjective historical reports from the patient, **objective clinical findings of a lesion are required to make a diagnosis of MS. Single paroxysmal episodes (eg, a tonic spasm) do not constitute a relapse, but multiple episodes occurring over not less than 24 hours do**." [emphasis added.] *Id.*

The authors note that additional, stringent criteria are needed to diagnose MS when the presentation of clinical evidence becomes weaker. *Id.* at 123. To diagnose MS, the authors state that there must be dissemination of lesions both in space and time. *Id.* at 125. They give as an example a patient presenting with an isolated syndrome suggestive of MS (which they term monosymptomatic presentation). "A diagnosis of MS then requires 1) evidence of dissemination in space through detection of lesions using MRI ... or, lacking such solid evidence, at least two

brain lesions plus positive CSF [cerebrospinal fluid], *and* 2) evidence of dissemination in time demonstrated as for the patient presenting with one attack and clinical evidence of two lesions...." *Id.* "In this situation as well, if MRI tests are not performed, the occurrence of a second clinical attack **implicating a different site** will fulfill criteria for dissemination in time and space." [emphasis added.] *Id.*

The Panel stresses that "symptoms alone are not enough" to diagnose MS and that "objective clinical evidence of attacks or progression" is required to make the diagnosis. *Id.* The Panel concludes, "The International Panel on MS Diagnostic Criteria built upon diagnostic recommendations for MS that have served the community well for decades." *Id.* at 126.

TESTIMONY

Petitioner testified first. Tr. at 4. She first went to her primary care physician Dr. Fernandez-Maitin on March 25, 1994 for respiratory problems and did not see her again until September 7, 1994. Tr. at 30, 31, 32.

The first problem she remembers after her third hepatitis B vaccination on May 31, 1994 was on vacation in June 1994 to Fort Myers Beach. Tr. at 9. She noticed a tingling in her feet and a little numbness, but she attributed that to walking on the sand without shoes. *Id.* The numbness was in her toes mostly with a little in her feet on the bottom. Tr. at 10. It did not last long. *Id.* Every once in a while, she would notice numbness and tingling. *Id.* The initial tingling and numbness lasted a couple of hours. After that, it would come and go but nothing that caused her any real concern. Tr. at 11. It did not matter if she were barefoot or wearing shoes. *Id.* It only bothered her when she was awake. *Id.* In July and August 1994, only the frequency changed but it did not concern her. *Id.*

Petitioner admitted on cross-examination that she had not given an onset of tingling and numbness in her feet beginning in June 2004 in her affidavit signed October 26, 2006 (Ex. 20), explaining this omission by saying that only when she discussed her forthcoming testimony with her husband while reviewing her medical records when she was in Washington, DC, for the hearing did this onset in June 1994 occur to her. Tr. at 38.

Petitioner testified:

> Okay. Now, truthfully it's reviewing all my records that brought me to call my husband while I was here [in Washington, DC], and we were discussing what was happening at the time, going over everything that had happened.
> We remembered being at the beach, and that was the first time that I felt the tingling in my toes, but we didn't pay attention to that because it didn't stay. It came. It went. It wasn't put in the affidavit until I went to review my records, review with my husband what I was going to be here doing today.

Id.

Petitioner testified on direct that she became concerned when she noticed dizzy spells and lightheadedness which began in September 1994 when she finally made an appointment with her doctor. Tr. at 11. When she saw Dr. Fernandez-Maitin on September 7, 1994, she said she had had lightheadedness/dizziness whose onset was the day before the medical visit. Tr. at 36, 37. She also complained of a tingling feeling in her toes and numbness. Tr. at 11. The doctor wrote to check her for hypoglycemia and attributed her dizziness and numbness to stress. Tr. at 12, 13. The doctor told her to breathe into a brown paper bag. Tr. at 13.

Afterwards, the lightheadedness and dizziness came and went. Tr. at 14. She continued to have tingling and numbness in her feet. *Id.* It would come and go. Tr. at 15. Sometimes, it would last hours or a day or so. *Id.* Work did not seem to make a difference. *Id.*

On August 10, 1995, she complained of anxiety and stress and that she could not sleep the prior night. She also complained of lightheadedness. Tr. at 16-17. This was the first time she had any sleep problem. Tr. at 17. She did not seek treatment from any provider for these symptoms. Tr. at 58.

On April 21, 1996, she went to the emergency room at Baptist Hospital for chest pain. *Id.* She thought she was having a heart attack. Tr. at 18. Her heart was fine. *Id.* Subsequently, on May 7, 1996, she had face numbness and heartburn. Tr. at 20. The doctor told her it was stress. *Id.* On May 28, 1996, petitioner saw an eye doctor for blurred vision. Tr. at 21. Heat made it worse. *Id.* She was prescribed reading glasses. Tr. at 22.

On June 25, 1996, she went to the doctor feeling sick, nauseated, tired, weak, and headachy. She wanted to be tested for iron poisoning because her office was being renovated. Tr. at 22. She was having lightheadedness. *Id.* On August 30, 1996, there is a note saying that petitioner's numbness got worse. Tr. at 23. She went to the emergency room at Doctor's Hospital. *Id.*

She saw a neurologist Dr. Carrazana in the beginning or middle of September 1996. Tr. at 24. An MRI confirmed that she had MS. Tr. at 25. Over the years, she has had a number of relapses, usually starting with tingling in the toes, numbness in the feet and sometimes in the hands. Tr. at 26. Her first visit with Dr. Carrazana was on September 12, 1996. Tr. at 62. She told him that prior to her developing her symptoms, she had a cold. Tr. at 62-63. She does not know if she told him specifically that she was having numbness in her feet intermittently for the prior two years, but she said she told him that she had had these issues before and was informed they were stress-related. Tr. at 64.

Petitioner then saw Dr. Zwibel on October 17, 1996. Tr. at 65. She does not recall telling him when her numbness and tingling began. Tr. at 66. None of the neurologists she has seen since September 1996 told her that her hepatitis B vaccinations in 1993 and 1994 caused her MS. Tr. at 67-68.

Dr. Carlo Tornatore testified next for petitioner. Tr. at 69. He is a neurologist in charge of the MS Center at Georgetown. Tr. at 70. He met petitioner the day before and did a neurologic examination. Tr. at 71. He agrees that petitioner has MS. *Id.* He believes that hepatitis B vaccine can cause MS because the immune system may not only recognize proteins that look like hepatitis but also attack proteins found in the nervous system, particularly, the myelin. Tr. at 72. Dr. Tornatore believes that hepatitis B vaccine caused petitioner's MS. Tr. at 73. He preferred, in analyzing this case, to start from more recent records and work backward. *Id.* When petitioner was clearly recognized as having MS, she had numbness from the waist down, including her feet. Tr. at 74. Seven months earlier, she had another episode of numbness and discomfort in both upper extremities lasting three days. Tr. at 74-75. These symptoms of numbness and tingling were part of her MS. Tr. at 75. Petitioner also had optic neuritis as part of her MS. *Id.*

Dr. Tornatore then went back to before petitioner was diagnosed with MS. Tr. at 76. Petitioner was diagnosed as having stress, but Dr. Tornatore thinks she was misdiagnosed and really had MS. *Id.* Tingling in the toes in June 1994 "may have been an early symptom of MS. " Tr. at 77. Between August 31, 1996 until her hospital admission on September 19, 1996, petitioner had ascending numbness and then weakness in the context of back pain. Tr. at 78-79. He thinks her numbness in her feet and back pain in 1994 was in retrospect related to MS. Tr. at

79. The symptom of numbness in her feet when she was clearly diagnosed with MS in 1996 is the same symptom she had in September 1994, a little more than three months after her third hepatitis B vaccination. *Id.* Petitioner also recalled having the same symptom two to three weeks after the vaccination. *Id.* She received the third vaccination in May 1994, went to the beach in June, noticed some numbness in her toes but did not pay too much attention, and, in September 1994, sought medical attention for lightheadedness and numbness. Two years later, she had full-blown numbness in both feet which was recognized as MS. Tr. at 79-80.

On May 28, 1996, four months before she was diagnosed with MS in September 1996, petitioner had worsening vision and complained her visual acuity had decreased for two years. Tr. at 82-83. Her vision changed with heat, which is a classic sign of demyelination of the optic nerves called Uhthoff's phenomena. Tr. at 83. When the core body temperature gets warm, the demyelinated nerves will not conduct electricity as well, and you get transient symptoms until you cool down. Tr. at 84. It is not clear from the medical records when this particular symptom began, but the visual symptoms appear to have been occurring for about two years. *Id.* That would make onset in May of 1994, the time of the vaccination. Tr. at 85.

The undersigned asked what LEE in the May 28, 1996 ophthalomologic record represented. *Id.* Dr. Tornatore said left eye. And there was a reference to the right eye (REE), but Dr. Tornatore had no idea what the second E represented in LEE. *Id.* Dr. Tornatore referred petitioner's symptoms in 1996 to two years earlier after the vaccination: numbness and tingling of the feet which by medical records occurred a little more than three months (September 1994) after the vaccination but, according to petitioner's testimony, occurred earlier in June 1994 or about a month after the vaccination. Tr. at 88.

The undersigned asked Dr. Tornatore which onset of MS he picked: mid-June 1994 or September 1994. Tr. at 89. He said it was immaterial because "in that range three months really even for me is pushing, but it's in that right timeframe." *Id.* He thought either a month or the end of three months was a reasonable timeframe. Tr. at 89-90. Based on petitioner's testimony, Dr. Tornatore said he would pick an onset of mid-June 1994. Tr. at 90. He thought minor and occasional symptoms going on for two years and then significant problems was an appropriate picture for MS. *Id.* Patients whose symptoms are mainly sensory as they were in petitioner's case with facial and toe numbness kind of slip through the cracks. Tr. at 91.

The undersigned asked Dr. Tornatore if lightheadedness were a symptom of MS. *Id.* He replied that it was a difficult symptom because it is nonspecific. *Id.* It could be attributable to vertigo or presyncope or just being unsteady. Tr. at 92. It is a very difficult symptom and could be part of MS. *Id.* Petitioner also complained of fatigue on a number of occasions which is a prominent symptom of MS. *Id.* With reference to a three-month onset, Dr. Tornatore stated:

> Once we get out to three months, we are really starting to test the boundaries of are the two [vaccination and MS] really connected with one another, and **it's totally arbitrary, to be honest with you**. I think we can use immunology to some degree to help guide us and say look, if somebody is vaccinated and we're going to say that that vaccine was the cause of their injury, wouldn't we expect to see some stigmata, some evidence of that injury, by that three month timeframe?
> Certainly within a month makes sense and two months makes sense, but by three months isn't that really kind of the cutoff point where it's going to be too hard to say vaccine or maybe something else that happened in between.
> **It's arbitrary. I will admit that**, but I think just from my own understanding of immunology and how the immune response can work, and given that you can have inflammation in the brain that may not be evidence, but may show up later, **again being arbitrary** I think a three month timeframe to me is a reasonable

> timeframe to say you had a vaccination. Three months later you had symptoms. Is that reasonable? Sure.
> You had inflammation that just may not have been in a part of the brain that gave you symptoms, but then subsequently that part that did give you symptoms and so **I fully recognize there is an arbitrariness in our cutoffs.** [Emphasis added.]

Tr. at 95-96.

The undersigned asked Dr. Tornatore if, when petitioner saw her doctors in 1996 and she had an upper respiratory infection (URI) about a week before her worsened symptoms began, the URI was an immunologic challenge which worsened her MS. Tr. at 96. He responded that it is very probable that petitioner had a pseudo exacerbation, i.e., she had an infection and her immune system became primed against that infection and stayed active, leading to symptoms. Tr. at 96-97. Petitioner had an MRI afterward showing multiple white matter foci of abnormal signal bilaterally ranging in size from almost 10 mm, which is large, to two to three mm, and there were two small lesions that enhanced. She could not have had this degree of change on MRI just three weeks after her URI. Tr. at 98. The changes in her brain MRI indicate demyelination that had been occurring for some time and clearly more than three weeks, yet she had not symptoms other than optic changes in May earlier in 1996. He suspects the changes began earlier than that. *Id.*

Dr. Tornatore believes that the cold must have exacerbated petitioner's ongoing MS, but it was not the sole cause of it. Tr. at 99. On cross-examination, Dr. Tornatore stated that he does not know when the abnormality in petitioner's brain started:

> You know, all I can really say is three weeks [between her URI and the worsened MS symptoms] was really too fast to get these changes on an MRI, and then when they actually started is really too difficult.

> Just looking at the MRI, whether it was three months ago or three years ago, no one is able to look at an MRI and say oh, this is when your MS symptoms started. We can state that they certainly didn't start three weeks ago, but beyond that I'm not going to be able to give you any other information.

Tr. at 102.

Petitioner also had a urinary infection in May 1996. Tr. at 103. Dr. Tornatore admitted that any infection can bring out MS symptoms. *Id.* It caused a pseudo relapse and made the symptoms worse. *Id.* A real relapse would occur in the absence of any infection. Tr. at 104. In his first report filed with the court, Dr. Tornatore mistook the date of the medical examination as August 20, 1994 which actually was the date of petitioner's last menstrual period. The date of the medical examination was instead September 7, 1994. Tr. at 105. In that examination, Dr. Fernandez-Maitin wrote that petitioner's toes had normal sensation, but that petitioner said her toes felt numb. Tr. at 107. There is no objective component to a sensory examination. *Id.* Dr. Tornatore admitted that one has to be cautious in making a diagnosis of MS without MRI findings. Tr. at 113. Had petitioner's doctors in 1994 looked, "they might have seen inflammatory lesions. Two years later when she had almost identical symptoms, but more profound, they did find inflammation and there was no other alternate reason for that." Tr. at 114.

Dr. Tornatore was referred to the McDonald criteria for diagnosing MS and asked whether petitioner had symptoms lasting at least 24 hours in 1994 in order to justify a diagnosis of MS in 1994 according to the McDonald criteria. Tr. at 115. Dr. Tornatore disagreed, stating petitioner testified that numbness would come and go, and the September 1994 record does not indicate what the timing was. *Id.* Petitioner testified that they were persistent and the same each

time, which means to Dr. Tornatore that they came from a lesion in the spinal cord or in the brainstem. *Id.* That the symptoms came and went but were the same each time was very important to him. *Id.*

Dr. Tornatore explained the gap in petitioner's records through 1994 and 1995 in that they do not reflect persistent tingling by saying that petitioner's doctors explained that the reason for her symptoms was stress. Tr. at 116. Only when her symptoms became bad in 1996 did she speak up and the doctors made the wrong diagnosis initially, giving her Naprosyn and not doing an x-ray. *Id.*

Dr. Tornatore believes that petitioner's symptoms in June 1994 are the same as she had in 1996. Tr. at 118. The medical records between 1994 and 1996 say petitioner was stressed and anxious. *Id.* But today her diagnosis is MS. *Id.*

If Dr. Tornatore's interpretation of petitioner's ophthalmological examination of May 28, 1996 is correct, i.e., that she complained of decreased day and night vision for two years, this visual problem would have occurred on May 28, 1994, three days prior to the third hepatitis B vaccination administered on May 31, 1994. Tr. at 124-25. Dr. Tornatore responded, "All right. So it's very close. I mean, two years. Are we going to say two years is exactly to the day? It's pretty darn close." Tr. at 125.

Dr. Tornatore agreed that her vision decrease could have been due to a change in her prescription except that she had subjective worsening of her visual acuity with heat. Tr. at 126. He does not know if that worsening with heat was going on for two years. *Id.*

Petitioner went to her primary care physician on August 27, 1996 and went to the emergency room. Tr. at 128. This was the first recognized neurological event. *Id.* When

petitioner saw the neurologist Dr. Carrazana in September 1996, she did not report numbness and tingling for two years. Tr. at 129. But the record is incomplete because he does not mention the eye symptoms in May 1996. Tr. at 130. Petitioner did describe her visual symptoms to Dr. Zwibel in October 1996. *Id.*

Dr. Thomas Leist testified for respondent. Tr. at 132. He is a neurologist. Tr. at 133. He is director of the Comprehensive MS Clinic at Thomas Jefferson University. Tr. at 134. His opinion is that petitioner's hepatitis B vaccinations on September 7, 1993, November 4, 1993, and May 31, 1994 are not causally related to her MS. Tr. at 135. She did not have any adverse reaction to her first two hepatitis B vaccinations. Tr. at 136. In the written record, there is no medical examination after her third hepatitis B vaccination on May 31, 1994 until September 7, 1994. *Id.* She complained of lightheadedness and transient tingling. Tr. at 137. The sensory examination was reported as normal, but the patient had a feeling of bilateral numbness. *Id.* The doctor was looking for a potential metabolic disturbance. Tr. at 138.

Petitioner's lumbar spine MRI done on December 13, 1996 showed a loss of disk space, dessication, and hyperlordosis. Tr. at 139. This can cause transient numbness by irritating the nerve roots. *Id.* Petitioner indicated in her testimony that this tingling in her legs sometimes occurred when she was sitting, without changes in mechanical characteristics. *Id.* He thinks this indicates a structural abnormality. Tr. at 140.

After petitioner's September 7, 1994 medical visit, her next interaction with her physician was by telephone in August 1995, in which she complained of insomnia, anxiety, and stress. *Id.* These symptoms are not directly associated with MS. Tr. at 141. Between September 1994 and August 1995, we have no independent, verifiable source for the symptoms

about which petitioner testified. Tr. at 142-43. It would be unusual in his practice for someone with persistent tingling, numbness, and lightheadedness not to have medical records confirming those symptoms. Tr. at 143.

Petitioner went to the emergency room on April 21, 1996 for chest tightness and had heartburn relieved with antacids and medications that control gastroesophageal reflux. *Id.* This is not in itself a neurological event. *Id.* During the time frame of April 21-24, 1996 and during petitioner's visit on May 7, 1996 to Dr. Fernandez-Maitin, petitioner had perioral numbness, which can occur with hyperventilation. *Id.* Rebreathing in a paper bag partially relieved the dysesthesia, the perioral numbness. Tr. at 144. Since petitioner's perioral numbness was not described as numbness on the left or the right makes it more likely that it is associated with a psychological state such as frequent breathing rather than with a neurologic condition. *Id.* A perioral numbness associated with MS would be unilateral. *Id.*

The fluctuation of petitioner's visual acuity with heat is mentioned for the first time in the record of May 28, 1996. Tr. at 144-45. In 2002, petitioner was suspected of having glaucoma. Tr. at 146. This means that her intermittent blurring of vision could also have other, non-MS associated origins. *Id.* Petitioner had two examinations in the spring of 1996 and in neither was there a lower extremity weakness noted. Tr. at 147. If petitioner had had a significant gait impairment, she would not have been able to do a treadmill cardiac stress test as she did. *Id.* Only in petitioner's testimony did Dr. Leist learn that she did not complete the test. Stoppage is not noted in the contemporaneous records or her affidavit. *Id.* The test must have been performed sufficiently to enable the doctors to interpret it as within normal limits. Tr. at 148.

Dr. Leist believes petitioner's onset of MS was in the summer of 1996. Tr. at 149. Petitioner was evaluated on August 27, 1996 and then she had a crescendo of symptoms. *Id.* She had ascending numbness to the waist, not the same symptoms that she testified today were occurring for years preceding the summer of 1996. *Id.* Petitioner's brain MRI on September 16, 1996 showed acute lesions, i.e., they were gadolinium-enhancing, as well as lesions that were non-enhancing at that time. Tr. at 150. This was not acute disseminated encephalomyelitis (ADEM). *Id.* That petitioner had a crescendo of new symptoms occurring over the prior three to four weeks indicates that the lesion relevant to those symptoms occurred at that point, i.e., in August/September 1996. Tr. at 151. Dr. Leist did not believe that petitioner had optic neuritis in May 1996 because she did not have reported color desaturation or pain on eye movement. *Id.* This seemed to have been a more chronic visual complaint. *Id.*

Dr. Leist did not think that petitioner's respiratory tract infection caused her MS, but the fact that she had an attack at the time of the infection is consistent with viral infections being associated with a higher risk for exacerbations of MS. Tr. at 152. It is very difficult to put an age on an individual lesion. Tr. at 153. A fully and solidly enhancing lesion or gadolinium-enhancing lesion tells you that there is a blood-brain barrier breakdown. *Id.* This lesion arose in close temporal vicinity to the MRI. *Id.*

When someone comes to see a neurologist, Dr. Leist said that the neurologist wants to know the duration of symptoms and when they first arose, as well as family history. Tr. at 156. If Dr. Leist were to agree that hepatitis B vaccine could cause MS, he would put the postvaccinal time frame as probably within the first 15 to 30, at most 40, days after vaccination, using a live virus as a template for timing. Tr. at 157. If petitioner's onset occurred at the end of August or

beginning of September 1994, that is outside this time frame. Tr. at 157-58. The active component of the vaccine has long been eliminated as a peptide and for it to induce a delayed demyelinating illness would be highly unlikely. Tr. at 158.

Dr. Leist thinks that if petitioner had numbness and tingling in her toes in June of 1994, it was due to potential lumbar disk disease because it was restricted and intermittent. Tr. at 158, 159. Toward the end of August 1999, petitioner had an overt transverse myelitis, an inflammation in the spinal cord manifested by ascending numbness affecting the lower part of her body and, since then, she has stereotypical fluctuations of her symptoms, including tingling and numbness in her feet when she has a relapse or recurrence of her MS. Tr. at 159. These were pseudo exacerbations not reflective of a new demyelinating injury but of an injury that was incompletely healed. Tr. at 160. That these symptoms respond to low dose steroids or Medrol dosepaks, indicates that they are not due to a central nervous system inflammation. Tr. at 161. Normally, MS will not cause symmetrical numbness and tingling in the feet. MS causes asymmetrical numbness and tingling. Tr. at 163.

A question arose as to the existence of pre-vaccination medical records. Tr. at 165. Petitioner stated that she did not see a doctor after 1985 when her twins were born until 1991-92 for her next pregnancy because she was very healthy. Tr. at 166, 168.

Petitioner's perioral numbness around her mouth could not have been due to MS because she had no complaints subsequently of facial palsy and there were no bilateral lesions. Tr. at 169-70. Petitioner's visual acuity has been relatively stable. Ultimately, in 2002, glaucoma was suspected. Tr. at 170. After she was diagnosed with MS, petitioner was also diagnosed with optic neuritis without significant changes in her acuity. Tr. at 171. Dr. Leist did not see

significant gait impairment when petitioner walked in the hearing room. *Id.* The examinations done in April and May 1996 do not indicate a lower extremity dysfunction. *Id.* In August and September 1996, there were distinct onsets of lower extremity dysfunction. *Id.* Dr. Carrazana noted that petitioner had a cold a week prior to the onset of her symptoms. Tr. at 173. That would put the symptom onset somewhere in the second part of August. *Id.* Dr. Zwibel also noted this. *Id.* Petitioner's MS is a process independent of her upper respiratory infection, but the infection may have triggered an attack. Tr. at 174.

Dr. Leist regards the incident described in the September 7, 1994 visit to have resolved and, therefore, it did not satisfy the McDonald criteria for diagnosing MS because it did not last more than 24 hours. Tr. at 181, 183. Normally MS is an asymmetrical process and, therefore, petitioner's testimony about a symmetrical presentation of toe tingling and numbness in June 1994 would not be consistent with MS. Tr. at 181. When petitioner was diagnosed with MS, she did have a bilateral presentation, but both sides were not affected equally. Tr. at 183. (Dr. Tornatore then spoke and said he disagreed with Dr. Leist that MS symptoms are asymmetric. He said MS patients have symmetrical sensory symptoms both acutely and subacutely. Tr. at 185.)

Petitioner's husband testified on June 24, 2009. Tr. at 192 (the pagination continues from the prior hearing). His wife did not have any immediate reactions to her hepatitis B vaccinations. Tr. at 194. When his wife was in Washington, DC, for the hearing, she called him in preparation for testifying and asked about the date of the first episode of numbness in her feet. *Id.* They remembered they were celebrating the end of the 1994 school year with the twins, that they were at the beach, and that it was Father's Day. *Id.* The numbness did not last very long

but it bothered her enough for her to tell him about it. Tr. at 195. She told him she had numbness and tingling in her toes. *Id.* The toes had the tingling sensation and the numbness was in her feet. Tr. at 196. She would mention it to him once in a while. Tr. at 196-97. It would not last very long. It would go away each time. Tr. at 197. It would last more than an hour or so. *Id.*

In September 1994, everything got worse. The numbness and tingling went to dizziness and lightheadedness. Tr. at 198. Every time his wife gets an attack, that tingling and numbness start in her feet. Tr. at 199. They call the doctor and he prescribes a Medrol Pack which is a form of steroids and that stops the attack. *Id.* His wife's call to him was the day before the hearing. Tr. at 201. It was he, not his wife, who recalled the incident of his wife telling him about her toes and feet on the beach in 1994. Tr. at 202. They were at the Fort Myers beach all weekend. Tr. at 205. His wife and he were at the living room of their hotel in June 1994 when she told him about the tingling and numbness in her feet. Tr. at 205-06. It was just before lunch and they had gone for their morning walk. Tr. at 206. Her symptoms had gone away. *Id.* She did not complain again during that weekend of tingling and numbness. Tr. at 207. It was a one-time thing. *Id.*

During the rest of June 1994, his wife did not complain about tingling or numbness in her toes. Tr. at 209. She complained a couple of times a month and the tingling and numbness never stopped. Tr. at 209-10. He does not know why the June 1994 episode was not in his first affidavit. Tr. at 212. He did not discuss this episode in 2006 with his wife when she submitted her affidavit. Tr. at 213. Sometimes his wife's episodes of numbness and tingling in her feet and toes would last half a day, and then it would just go away again. Tr. at 215. When his wife

complained to doctors about numbness and tingling, doctors attributed it to stress. *Id.* After his wife was diagnosed with MS in 1996, they discussed when it began and realized it was at the beach in June 1994. Tr. at 219-20. When he told her the day before the hearing about the numbness and tingling in her feet and toes in June 1994 at the beach, his wife remembered it right away. Tr. at 224.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(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 1274, 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...."

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

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

In Werderitsh v. Secretary of HHS, No. 99-319V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the undersigned ruled that hepatitis B vaccine can cause MS and did so in that case. However, the onset interval after vaccination in Werderitsh was one month. Here, the onset interval is either one month (petitioner's testimony), three months (although petitioner's expert was content to opine causation based on a one-month or three-month onset) or two years. Respondent's expert Dr. Martin testified in Werderitsh that an appropriate temporal interval for an immune reaction would be a few days to three to four weeks.

In Pecorella, that onset time was extended to two months because respondent opted not to defend a transverse myelitis case when the onset was two months after vaccination with hepatitis B vaccine. Transverse myelitis was one of the four demyelinating diseases analyzed in the Omnibus proceeding concerning hepatitis B vaccine and demyelinating diseases. MS was another one of the four diseases.

In the instant action, there are three different onsets of MS that could have occurred in this case: (1) if the undersigned were to accept petitioner's description of toe numbness and tingling in June 1994, onset would be one month; (2) if petitioner's onset of toe numbness and tingling occurred around the time of her visit to Dr. Fernandez-Maitin's office on September 7,

1994, onset would be three months and one week; (3) if, however, the onset were in 1996 when she had as respondent's expert Dr. Leist put it a crescendo of symptoms, onset would be two years.

June 1994 Onset

Petitioner readily admitted during her testimony that she had forgotten about her toes tingling and slight numbness around Father's Day in June 1994 until she spoke to her husband right before the hearing in this case. She testified this was in the context of her reviewing her medical records. However, there is no medical record that states the occurrence of these symptoms was in June 1994. Petitioner never told anyone of this onset.

Petitioner's history to Dr. Fernandez-Maitin on September 7, 1994 of toe numbness and tingling did not include an onset. She told the doctor that the onset of her lightheadedness was the day before the visit. She also told Dr. Fernandez-Maitin that when she ate and rested, she woke up feeling better. Because of petitioner's family history of diabetes, the doctor considered that petitioner might have hypoglycemia and ordered a number of tests. According to Dr. Fernandez-Maitin, on physical examination, petitioner's toes had normal sensation. In subsequent medical examinations, petitioner never told any doctor that she experienced toe numbness and tingling starting in June 1994.

The Vaccine Act states, at §300aa-13(a)(1):

> The special master ... may not make such a finding [that petitioner has proved her case] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

Since there is no substantiation of the onset in June 1994 of petitioner's toe tingling and numbness in the medical records, can Dr. Tornatore's reliance at the hearing on this having

occurred in June 1994 satisfy the statutory requirement? The answer is no. If the answer were yes, it would make this statutory provision a nullity since every petitioner with a causation in fact claim would go to hearing with an expert medical witness who would rely on unsubstantiated assertions of medical events. If all the petitioner needed to show is that her own expert believed her, this provision would be voided.

Congress did permit special masters to ignore the medical records and find the onset was what petitioner stated at hearing only in the context of Table Cases. Section 300aa-13(b)(2) states:

> The special master ... may find the first symptom or manifestation of onset or significant aggravation of an injury ... described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury ... did in fact occur within the time period described in the Vaccine Injury Table.

Congress was more lenient in Table cases regarding when the special master could determine onset than Congress's strict limitation on evidence in causation in fact cases. This is consistent with the whole purpose of the Vaccine Injury Table to give petitioners an easier path to prevailing in their cases with the presumption of causation if they fall within the terms of the Table. If the stricter provision of §300aa-13(a)(1) were to be easily obviated just by petitioner's medical expert's testimony, the exception to the stricter rule enunciated in §300aa-13(b)(2) would be superfluous. All petitioners would be able to prove onset by their own testimony regardless of the contents of their medical records. This would make no sense. A basic legal assumption is that statutes are not worded so as to make their interpretation absurd. Walther v.

Sec'y of HHS, 485 F.3d 1146, 1150 (Fed. Cir. 2007), quoting Colautti v. Franklin, 439 U.S. 379, 392 (1979) ("'a statute should be interpreted so as not to render one part inoperative.'"). The only meaning that makes sense for the stricture of §300aa-13(a)(1) is that petitioner cannot prove the onset of her toe tingling and numbness in June 1974 by her own testimony without confirmation from medical records or medical opinion in those records.

There is a further difficulty in accepting petitioner's recent claim on the eve of trial that the onset of her toe tingling and numbness was in June 1994 and not at some indefinite time before September 7, 1994. In general, testimony that conflicts with contemporaneous documentary evidence should be accorded little weight. Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Not only did petitioner not give Dr. Fernandez-Maitin a history of the onset of her toe tingling and numbness (although she did tell her the onset of her lightheadedness was the day before), but every single medical treater petitioner visited for every subsequent appointment also does not have in his or her records the onset of petitioner's toe tingling and numbness. One would assume that if petitioner were ignoring for over two years (from June 1994 until September 1996) her intermittent toe tingling and numbness, and then she has a crescendo of neurologic symptoms, including numbness that spreads from her feet up her leg, she would say to her neurologist and other doctors that she had experienced numbness for two years but thought nothing about it. She never said this. Petitioner impressed the undersigned with her enduring personality. She is a hard worker and she has taken on a demanding job and has a damaged child. She is not a retiring, shy individual. The undersigned has no doubt that when she was seeing doctors for difficulties in her vision or sensations in her legs and feet, she would tell a doctor if those symptoms had been going on for two years. She never did.

Moreover, before petitioner had her third hepatitis B vaccination, she saw Dr. Fernandez-Maitin three times in a row for an upper respiratory infection. Clearly, when petitioner has a medical problem, she pursues medical help. The only reasonable assumption is that she does not see a medical doctor when she does not have a medical problem, as manifest by her failure to seek medical aid in the summer of 1994 and in 1995.

Dr. Tornatore tried to show that petitioner's onset was near the third hepatitis B vaccination by interpreting Dr. Barry Eichenbaum's notes in May 1996 as showing that she had had difficulty in visual acuity for two years, i.e., in May 1994. This is overreaching. Dr. Eichenbaum saw petitioner in August 1998 and reflected that he had seen her in May 1996 on

the same line of his record, with the complaints written below that line. Dr. Eichenbaum saw petitioner in July 2002 and reflected he had seen her four years previously and that she had had an eye examination one year previously on the same line in his medical record, with a listing of petitioner's complaints on the next line. This is the same pattern of notation he made in May 1996 where he wrote the eye examination and the year he last saw the patient (1994) on the same line with petitioner's complaints under that first line. There is no reason to believe in light of the consistency of Dr. Eichenbaum's medical records in 1996, 1998, and 2002 that a different analysis of his records is appropriate for 1996, i.e., that instead of listing the last time he saw the patient when he mentioned two years, he actually meant that her symptoms (which begin on the following line) had been going on for two years. Petitioner's complaints of loss of visual acuity in May 1996 are not noted to have an onset date. She last saw Dr. Eichenbaum in 1994.

The undersigned holds that petitioner's onset of her toe numbness and tingling, whatever its medical significance, did not occur in June 1994, but occurred at some point around September 7, 1994, three months and one week after her third hepatitis B vaccination.

Onset around September 7, 1994

Petitioner visited Dr. Fernandez-Maitin on September 7, 1994, complaining of toe tingling and numbness and lightheadedness. The last symptom occurred the day before and was dispelled by petitioner's eating fruit and resting. The record is silent as to the onset of petitioner's toe tingling and numbness. The concept that it might have occurred in late August 1994 was that there was a notation that referred to petitioner's last menstrual period as occurring on August 20, 1994 and Dr. Tornatore (and the undersigned) initially mistook that date as the date of the medical visit. Actually, there is no reason to ascribe the onset of petitioner's toe

tingling and numbness to the end of August 1994. We have no idea when it began. When Dr. Tornatore wrote his first expert report, he assumed onset was three months or three months and one week. When he testified, he said hepatitis B vaccine caused petitioner's MS whether the onset was in June 1994 (one month after her third vaccination) or August 1994 (three months afterward).

Petitioner filed medical literature consisting of the Schonberger epidemiological study of swine flu vaccination with onset of GBS going out to 10 weeks. However, if the undersigned were to accept onset of MS here in September 1994, that would be three months which is 12 weeks. Even Dr. Tornatore admitted this was the outer edge of causation. (In the Omnibus proceeding, Dr. Vera Byers, petitioners' expert, opined causation onset would go out to one month.) Dr. Leist would not go out beyond 40 days, although respondent has accepted two months as a temporal limit (see Pecorella). Petitioner also filed a meta-analysis by Hernán, but the author would not admit causation of MS within one year after hepatitis B vaccination, which is the very opposite of the undersigned's holdings in these cases. Dr. Tornatore admitted in his testimony herein that a three-month onset interval between vaccination and symptoms was "arbitrary" (his word). He also stated that he does not know when the abnormality in petitioner's brain began. The undersigned can hardly hold that petitioner's onset of MS, even if it were in September 1994, is due to her hepatitis B vaccination(s) based on an opinion that is admittedly arbitrary with a further admission that the onset of her MS is unknown.

After petitioner's September 7, 2004 visit to Dr. Fernandez-Maitin, petitioner did not see a doctor again until 2005 and then she telephoned her doctor about insomnia and anxiety. The constellation of her symptoms that led to her diagnosis of MS occurred in 1996. Dr. Tornatore's

interpretation of petitioner's May 1996 ophthalmologic examination reads too much into some very crude notes. He states that "LEE/REE 2 yrs" represents that petitioner had been complaining of loss of visual acuity for two years. That is not what the record says. It does not give an onset for petitioner's visual acuity decrease.

One point Dr. Leist made was that petitioner's claimed onset of numbness and tingling in her toes and feet was of symmetrical symptoms, but MS manifests in asymmetrical symptoms. Dr. Tornatore disagreed. However, when petitioner unquestionably had MS in 1996 and afterward, her symptoms were asymmetrical. She started with left leg and right hand numbness. When she had a recurrence of MS in August 1997, her whole left leg went numb.

Even Dr. Tornatore does not accept the thesis of the Hernán article because Dr. Tornatore said he would barely go out to three months as an appropriate interval between vaccination and onset, whereas Hernán goes out to three years.

What seems most important in this case are the McDonald criteria set forth by an international team of experts (the Panel) to make uniform the requirements for diagnosing MS. Under the Panel's criteria, petitioner fails to meet these requirements in the assertion of an earlier onset of numbness and tingling in her toes during Father's Day weekend at the beach in June 1994. She never gave a history of this event to any medical doctor so there is not even the basic requirement of a history. Moreover, she testified it was just a few minutes and the Panel requires the symptom to last 24 hours. Petitioner's complaint of numbness and tingling in her toes to Dr. Maitin in the September 7, 1994 visit does not specify onset date. Petitioner testified those symptoms were also just brief. The Panel states that in order for a doctor to diagnose MS, the lesions must be separated in space and time. Here, if the two incidences of toe tingling were

separated in space by the Panel's required three months, qualifying for the right time, they were not separated in space. That is, this is the same lesion, not a separate lesion, because the symptoms were the same both times.

But, petitioner's transient tingling and numbness in her toes could also be due to overheated core body temperature, as the Panel describes in the McDonald criteria. This was August in Florida right before petitioner saw Dr. Maitin on September 7, 1994. If petitioner actually had toe numbness and tingling at the beach in June 1994, she could also have had overheated core body temperature. The Panel called these types of events a pseudoattack. Neither incident lasted the Panel's required 24 hours in order to satisfy the criteria for diagnosis of MS. Nor was there any objective confirmation through cerebrospinal fluid analysis, MRI, etc.

Thus, neither the supposed numbness and tingling at the beach in June 1994 nor the recorded numbness and tingling in the September 7, 1994 record satisfies the Panel's criteria for the diagnosis of MS. Petitioner did not have any MS symptomatology for two years (1996). Petitioner explains the absence of symptomatology in the medical records by saying she did not want to report intermittent toe numbness and tingling because doctors told her it was all due to stress. But the medical records do not show any doctor stating her toe numbness and tingling at any time was due to stress. They said her insomnia and anxiety were due to stress. Only in 1996, over two years after petitioner's third hepatitis B vaccination, do we see the requirements of the McDonald criteria being fulfilled: consistent history of more than one lesion in space and time, supported by objective MRIs and other tests.

The undersigned cannot base an onset on a chimera of transient toe tingling and numbness. The onset here is not one month, not three and one-quarter months, but two years and

three months, far too long to be medically appropriate for a causative link with hepatitis B vaccine.

An interesting case parallel to this one is Fisher v. Sec'y of HHS, No. 99-432V, 2009 WL 2365459 (Fed. Cl. Spec. Mstr. 2009), in which the positions of the parties were directly opposite to their positions in the instant action. In Fisher, respondent's defense against petitioner's allegation that hepatitis B vaccine caused her MS two months later was that she had complaints of numbness along the outside of her foot before she ever received hepatitis B vaccine and therefore her MS onset predated vaccination. *Id.* at *3. She complained again of numbness involving her left heel for the prior month or so also before she ever received hepatitis B vaccine. *Id.* There was associated numbness involving the lateral aspect of the foot. *Id.* A year later, petitioner in Fisher complained of paresthesias which started as numbness laterally in the left foot. *Id.* at *4. Foot pain subsided, but numbness persisted. *Id.* Subsequently, petitioner complained to her doctor that her whole leg became numb over the prior 24 hours. *Id.* at *5. After that, petitioner had three hepatitis B vaccinations, followed by optic neuritis in one eye. *Id.* at *6. She also had leg weakness. *Id.* She had subsequent optic neuritis in the other eye and left hand numbness and weakness. *Id.* at *7. She was diagnosed with MS. *Id.* All the complaints that petitioner made about numbness in a foot or leg before she received hepatitis B vaccine were recorded in her medical records to doctors on numerous occasions.

The counsel for petitioner and petitioner's expert witness in Fisher are the same as in the instant action. Dr. Tornatore testified in Fisher that petitioner had no evidence before the first hepatitis B vaccination of anything abnormal in her central nervous system. *Id.* at *13.

Respondent's expert stated that the onset of petitioner's MS preceded her hepatitis B vaccination. *Id.* The undersigned held the following in ruling for petitioner in Fisher:

> But the undersigned is not persuaded that petitioner had MS before her hepatitis B vaccinations merely because of isolated symptoms of numbness. Not all numbness is due to MS. The fact that she had MS after her vaccinations does not mean that any numbness before her vaccinations is symptomatic of MS. The symptom of numbness by itself and undiagnosed as MS does not signify that it is a symptom of MS without objective testing or evidence of lesions occurring over space and time. The undersigned is particularly unwilling to accept that isolated episodes of numbness signify MS when petitioner's contemporaneous doctors did not diagnose or even consider whether she had MS. This is particularly so in light of her testing as normal neurologically before vaccination.

Id. at *18.

So, too, in the instant action, the undersigned is not persuaded that petitioner had MS one month or even three months after her third hepatitis B vaccination. The one-month onset is not persuasive because not only did this timing arise on the eve of trial 15 years after it occurred with nary a mention to a doctor in any record at any time or even in affidavits from petitioner and her husband, but also because it is not accompanied by objective testing or evidence of lesions occurring over space and time. The three-month purported onset, which is recorded in a medical record, is an isolated episode of numbness for which Dr. Fernandez-Maitin did no neurologic testing. Petitioner neglected seeking medical care during the entire subsequent year, even though she testified that the numbness and tingling continued intermittently. It is only her unsubstantiated word that this intermittent numbness and tingling occurred, and its significance is negligible in the absence of objective testing or evidence of lesions occurring over space and time.

Onset in 1996

The only acceptable diagnosis of onset in this case is in 1996, two years after petitioner's third hepatitis B vaccination when she did see doctors and complained of recent onset (not numbness and tingling intermittently occurring over two years) and for which there was objective testing and evidence of lesions occurring over space and time. This objective testing and evidence of lesions occurring over space and time is consonant with the McDonald criteria, created by the most notable international neurologists as a template for the diagnosis of MS. To be consistent with the undersigned's holding in Fisher (where the parties' positions were exactly opposite to their positions in the instant action) and with the McDonald criteria, the undersigned holds that petitioner's onset of MS occurred in 1996, which is too long a period of time to be medically appropriate for causation. Petitioner has failed to prove the third Althen prong.

Petitioner has failed to prove a prima facie case of causation and this petition must be dismissed.

CONCLUSION

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.[3]

IT IS SO ORDERED.

October 30, 2009
DATE

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

[3] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing his right to seek review.