

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 99-450V

February 27, 2009

To be Published

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KARI HAWKINS, \*

Petitioner, \*

v. \*

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, \*

Respondent. \*

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Clifford J. Shoemaker, Vienna, VA, for petitioner.

Ryan D. Pyles, Washington, DC, for respondent.

Entitlement; hep B vaccine;  
onset one month or 75 days;  
ADEM or Marburg MS

**MILLMAN, Special Master**

## **RULING ON ENTITLEMENT**<sup>1</sup>

Petitioner's mother filed a petition on July 13, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., when her daughter was a minor, alleging that

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<sup>1</sup> 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 or designated substantive order 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.

her daughter received hepatitis B vaccine in January, February, and November 1994. Petition, ¶ 2 (this is the second paragraph 2).

Since the daughter of the original petitioner is now an adult, being born July 6, 1979, the undersigned amended the caption sua sponte so that the daughter became the petitioner. Petitioner's adverse reaction was initially diagnosed as multiple sclerosis (MS), whose onset according to petitioner's mother was April 20, 1994, 75 days or two and one-half months after her second hepatitis B vaccination. At the time of the onset of her symptoms, she had had an upper respiratory infection (URI) whose presence was noted in a visit to her doctor on March 15, 1994. Med. recs. at Ex. 4, p. 158. She had also had an upper respiratory infection on April 20, 1994, although she was not hospitalized until 10 days later. Viruses have been associated with MS. Her siblings had strep throat at the time of the April 20<sup>th</sup> upper respiratory infection

A hearing was held on May 20, 2008. Testifying for petitioner were petitioner, her mother, and Dr. Carlo Tornatore, a neurologist. Testifying for respondent was Dr. Arthur Safran, a neurologist. At the hearing, Dr. Tornatore testified that petitioner did not have MS but ADEM (acute disseminated encephalomyelitis).

This case is part of the Omnibus proceedings dealing with hepatitis B vaccine and demyelinating diseases such as 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 undersigned held that hepatitis B vaccine can cause demyelinating diseases 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).<sup>2</sup>

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. In Pecorella, the disease was transverse myelitis.

In the instant action, the question is whether petitioner had a smoldering disease process early on which was not medically noted or whether her onset was indeed two and one-half months (or two weeks beyond the Pecorella limitation which now appears to be the limit of time beyond which respondent will not expend resources to contest causation).

An additional issue is whether petitioner had ADEM (petitioner's expert's view) or acute MS (respondent's expert's view). Petitioner had a virus before her ADEM and, to parse the issue even further, the question became whether the virus was solely responsible for her illness (respondent's position) or was a substantial factor together with her hepatitis B vaccinations in causing her illness (petitioner's position). ADEM is a demyelinating illness which, although not one of the illnesses involved in the four paradigm cases in the Omnibus proceeding dealing with

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<sup>2</sup> Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (hepatitis B vaccine caused TM; onset was 12 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).

hepatitis B vaccine and demyelinating illnesses, is similar to MS in the sense that it involves lesions in space, but different than MS in that it does not involve lesions in time, except in the rare occurrence of repeat ADEM. Both medical experts at trial agreed that after petitioner's viral episode, her neurologic disease came swiftly and catastrophically.

### **FACTS**

Petitioner was born on July 6, 1979.

On October 20, 1989, petitioner saw Noemi Bancod-McInnes, a psychologist, for a confidential psychological examination for the school district. P. Ex. 37, p. 5. Dr. Bancod-McInnes administered tests to petitioner in September 1989 which showed petitioner had reading in the 38<sup>th</sup> percentile, math in the 46<sup>th</sup> percentile, and written language in the 31<sup>st</sup> percentile. *Id.* Dr. Bancod-McInnes stated petitioner had a visual-motor age of three years below her chronological age norm. At least three of her six errors on the Bender-Gestalt test meant that petitioner had significant neurological indicators at her age level. *Id.* These errors were in the areas of distortion, integration, and perseveration of the gestalt. *Id.* Petitioner also had significant weakness (in the low average range) on the test of her immediate auditory recall of numbers forward and backward. *Id.* at 6. Dr. Bancod-McInnes concluded that petitioner had a severe discrepancy between her cognitive abilities and her achievement in reading and written language and, therefore, qualified for special education services. *Id.* at 7.

A VAERS form dated January 28, 1999 lists the vaccination dates as January 7, 1994 and February 4, 1994 (as well as November 7, 1994). Med. recs. at Ex. 4, p. 7. There is a notation in petitioner's medical records that she received hepatitis B vaccine and influenza vaccine on October 4, 1993. Med. recs. at Ex. 4, p. 139. There is also a notation in petitioner's medical

records that she received hepatitis B vaccine on January 7, 1994. Med. recs. at Ex. 4, p. 136. Petitioner did not file medical records for February 4, 1994.

On March 15, 1994, petitioner saw Dr. Maxwell, her pediatrician, complaining of one week's congestion, runny nose, and face pressure. Med. recs. at Ex. 4, p. 158. She did not have fever. She was alert and not in distress. Her head, eyes, ears, nose, and throat were within normal except for audible nasal congestion and baggy red nasal congestion. Dr. Maxwell diagnosed petitioner with sinusitis and prescribed Amoxicillin for two weeks. *Id.*

On April 30, 1994, she was admitted to Kaiser Permanente Medical Center, Hayward/Fremont, from which she was discharged on transfer on May 3, 1994. Med. recs. at Ex. 2, p. 538. She was admitted with mental status change and abnormal CT scan with several white matter lesions. She was transferred for a brain biopsy. On admission, she had lethargy, decreased concentration, change in mental status with blurred vision, occasional diplopia, fatigue, and mild ataxia. She had shown deterioration over the prior two days. *Id.*

Her history and physical on April 30, 1994 revealed that she was in her usual state of health until 10 days prior to admission (April 20, 1994) when she complained of lethargy, lack of concentration at school, and continual sleepiness. Med. recs. at Ex. 2, p. 524. She was not interested in exercise or any activities. She complained of being disoriented, especially when waking from sleep. She was irritable and could not complete a simple task such as tying her shoe. On the day of admission, her symptoms worsened with two episodes of nausea and vomiting. She felt she was losing her coordination and was dizzy when walking. She had blurred vision. She had a two-year history of headaches. *Id.* When asked if she had received any immunizations, the reply was "none." Med. recs. at Ex. 2, p. 523.

On May 3, 1994, a history and physical taken by Dr. Alexander Kleider, a neurosurgeon, reveals that, 12 days earlier, petitioner felt tired and did not want to go to swim practice, which she usually attended enthusiastically. Med. recs. at Ex. 2, p. 511. Five days previous to admission, she took Tylenol for a headache. Four days previous to admission, she was disoriented, tired, and wobbly. Three days previous to admission, she was staggering and car sick on the way to the doctor and her right eye wandered. More recently, she developed more severe diplopia and deteriorated further in mental status. *Id.* Two siblings had strep throat. The MRI showed multiple ring enhancing lesions. *Id.*

MRI scans showed progression of white matter lesions. Med. recs. at Ex. 2, p. 518.

On May 3, 1994, petitioner had a brain biopsy. Med. recs. at Ex. 3, p. 47. Dr. T.J. Cosgrove concluded petitioner had acute MS, the same impression as Dr. Kleider. *Id.* Petitioner had a history of two weeks of progressive neurologic deterioration. Imaging studies showed multiple white matter lesions. The specimen from the right paraventricular region showed strikingly abnormal astrocytes with mitosis and many of the features of an astrocytoma. There were inflammatory changes with lymphocytes and plasma cells in the perivascular area. There were scattered phagocytic elements consistent with demyelination and clear differentiation between the areas of abnormal histology and the surrounding brain, suggesting a plaque. *Id.* Myelin stains showed clear cut demyelination associated with areas of bizarre astrocytic change, confirming that the lesion was demyelinating in plaques typical of acute MS. Med. recs. at Ex. 3, p. 48.

Petitioner was admitted to Kaiser Permanente Medical Center on May 4, 1994, and was discharged on June 21, 1994 to be transferred for rehabilitation. Med. recs. at Ex. 2, p. 519. An

MRI on May 23, 1994 showed significant progression of the bilateral demyelinating lesions since the May 2, 1994 MRI. Med. recs at Ex. 2, p. 43. The optic tracts seemed notably involved. *Id.* On May 9, 1994, the neurologist, Dr. Scott Abramson, noted petitioner was seen to be cortically blind. Med. recs. at Ex. 24, p. 1.

On June 1, 1994, Dr. B. Coplan wrote that petitioner was in good health until April 20, 1994 when she “started c/o lethargy and being sleepy all of the time, having difficulties concentrating at school. No fever. Problems with being irritable and disoriented at times.” Med. recs. at Ex. 4, p. 291.

On June 2, 1994, petitioner saw Dr. Phillip Wasserstein, a neurologist, giving a history of onset of symptoms in mid-April 1994. Med. recs. at Ex. 1, p. 1. At that time, she had a sore throat and other symptoms of an upper respiratory infection. *Id.* She deteriorated rapidly so that she was unable to see and walk, and was confused or aphasic. *Id.* A brain biopsy was performed May 3, 1994, the results being consistent with a demyelinating disease. Med. recs. at Ex. 1, pp. 1, 2. Dr. Wasserstein diagnosed ADEM or MS. Med. recs. at Ex. 1, p. 2.

A progress note dated June 10, 1994 states that a neurologist at Stanford felt her diagnosis could be post-viral encephalitis. Med. recs. at Ex. 2, p. 32. Laboratory results were compatible with either MS or post-viral demyelination. *Id.* Dr. E. McGovern’s note of June 18, 1994 states that petitioner made dramatic improvements in the prior week. She could see normally at times and, at worst, lost colors. Her ability to speak included short sentences. She had increased strength and muscle coordination. She could get up and use a commode. Med. recs. at Ex. 2, p. 23. Her cerebrospinal fluid was normal except for one oligoclonal band. Med. recs. at Ex. 2, p. 22.

On June 10, 1994, Dr. B. Coplan wrote a pediatric progress report. Med. recs. at Ex. 4, p. 61. Petitioner was well until about one and one-half months prior when she became confused, lethargic, and sleepy. She was seen in clinic and admitted on April 30, 1994 after two episodes of vomiting with dizziness, poor coordination, and blurry vision. She exhibited rapid deterioration with weakness and poor feeding. *Id.* On May 9, 1994, she became cortically blind and could not longer walk. Laboratory results were compatible with either MS or post-viral demyelination. *Id.*

A physical therapy discharge summary dated June 21, 1994, states that petitioner, on April 20, 1994, started complaining of lethargy and difficulty in school. Med. recs. at Ex. 3, p. 33.

From June 21, 1994 to July 14, 1994, petitioner was hospitalized at Kaiser Permanente. Med. recs. at Ex. 4, p. 38. She had no significant past medical history, and developed lethargy at the end of April 1994. *Id.* Dr. Ward Gypson wrote the history and examination record. Med. recs. at Ex. 7, p. 7. Petitioner did not have a significant past medical history when she developed the onset of lethargy around April 20, 1994. She subsequently developed difficulty concentrating in school and then became disoriented and irritable. On April 30, 1994, she was admitted to Kaiser Hayward after vomiting and complaining of dizziness, decreased coordination, and blurred vision. Her spinal tap was normal. Her CT scan showed multiple white matter lesions suggesting a demyelinating process. *Id.* Past medical history was negative except for childhood asthma which she outgrew. She was up to date on immunizations. Med. recs. at Ex. 7, p. 8. Petitioner denied any headache, difficulty swallowing, cough, fever, chills,



sweats, nausea, vomiting, diarrhea, chest discomfort, abdominal discomfort or extremity pain.

*Id.*

On June 24, 1994, social worker Donna Terdiman wrote that petitioner's mother stated petitioner's illness began some time during the last week of April 1994 when petitioner seemed to develop a viral-like illness and became increasingly irritable with nausea, dizziness, blurred vision, and coordination difficulties. Med. recs. at Ex. 7, p. 11. Within four days of petitioner's admission, petitioner's condition had deteriorated to the point that she was blind, incontinent, unable to recognize her family, and combative. *Id.* Petitioner's parents reported that petitioner was "a sweet, even tempered and independent child prior to her illness." Med. recs. at Ex. 7, p. 13.

On July 13, 1994, Dr. Ward Gypson wrote a discharge summary, stating that petitioner had no significant past medical history and developed lethargy at the end of April 1994. Med. recs. at Ex. 24, p. 23. She subsequently became more disoriented and irritable. On April 30, 1994, she was admitted to Kaiser Hayward after vomiting and complaining of dizziness, decreased coordination, and blurred vision. *Id.*

From August 30-October 18, 1994, petitioner had physical therapy. The history was that petitioner had an acute onset of MS in April 1994. Med. recs. at Ex. 4, p. 43.

On September 13, 1994, petitioner had an outpatient neuropsychological consultation with Ernest T. Bryant, Ph.D., Director of Neuropsychology and Head Trauma Services. Med. recs. at Ex. 4, p. 33. Petitioner contracted a demyelinating disease approximately April 30, 1994. *Id.*

The medical record for November 7, 1994 reflects administration of hepatitis B vaccine to petitioner. Med. recs. at Ex. 4, p. 177.

On January 4, 1995, petitioner went to the ER with a history of 24 hours duration. Med. recs. at Ex. 4, p. 31. Dr. Alejandro Dorenbaum wrote that, on the day before, she was more tired than usual. That morning, she went to school and, around noon, she first noted a blurred line in the middle of her vision field. Eventually, she could not see well in the center. In the prior two hours, she had completely blurred vision, predominantly in the left eye field. Also she had severe headaches for the prior two days but no other symptoms. She may have had non-significant symptoms related to an upper respiratory infection two to three days previously. *Id.*

On February 10, 1995, petitioner and her mother went to see Dr. William Likosky for an additional opinion regarding MS. Med. recs. at Ex. 4, p. 29. Petitioner was well until late April 1994. About April 20, 1994, she started to complain of tiredness and sleepiness. She had difficulty concentrating in school. She was hospitalized on April 30, 1994 because of vomiting, dizziness, lack of coordination, and blurred vision. She became increasingly agitated, weak, confused, aphasic, incontinent, and unable to walk. *Id.* She continued to improve over the fall of 1994 but, on January 5, 1995, she had blurry vision, as if there were a white line down the center of the field. She lost vision in both eyes and had pain behind her eyes. *Id.* Before her illness, she got mostly Bs and Cs in school with a recent D. *Id.* She had significant improvement since. Med. recs. at Ex. 4, p. 30. There are six children in the family, all of whom have had dyslexia which ultimately improved to good function. *Id.*

On May 30, 1995, petitioner had an occupational therapy re-evaluation. Med. recs. at Ex. 4, p. 27. Petitioner had an acute onset of MS in April 1994. She continued to recover from that severe episode, but had a mild flare-up in January 1995. *Id.*

On January 28, 1999, Dr. Spencer Larsen filled out a VAERS form, stating petitioner received hepatitis B vaccine on January 7, 1994, February 4, 1994, and November 7, 1994, and had the onset of her adverse reaction approximately May 4, 1994. Med. recs. at Ex. 4, p. 7. A letter where the signature has not been photocopied, dated February 2, 1999, states that petitioner had her third hepatitis B vaccination in November 1994 and a significant relapse in January 1995 (two months after the third hepatitis B vaccination). Med. recs. at Ex. 4, p. 6. The author notes that the initial MS episode was in May 1994, three months after petitioner's second hepatitis B vaccination in February 1994. *Id.*

On May 22, 2003, Dr. Steven L. Pugh of the Rockwood Clinic diagnosed petitioner with relapsing-remitting MS. Med. recs. at Ex. 17, p. 36. Curiously, petitioner told him that she had the onset of her MS symptoms and the onset of optic neuritis nine months later (which was considered a separate incident) each six months after receiving hepatitis vaccine with a mercury preservative. Med. recs. at Ex. 17, p. 35. Apparently, petitioner did not consider the onset of her MS to follow closely her first two hepatitis B vaccinations, or consider the onset of her optic neuritis to be in close proximity to her third hepatitis B vaccination.

On November 13, 2003, petitioner returned to Dr. Pugh with worsened headaches of unclear etiology. Med. recs. at Ex. 23, p. 10. She has stable, relapsing remitting MS with a high risk of progression. Recent MRI did not show any evidence of T1 enhancement or any increased burden of disease. *Id.* The MRI of November 3, 2003 is at Ex. 23, p. 12.

On June 18, 2008, petitioner filed Exs. 42-45. Ex. 43 is a letter dated June 10, 2008 from Dr. Steven L. Pugh, a treating neurologist. He states:

The early course and severity of her illness suggests a diagnosis of acute disseminated encephalomyelitis (ADEM) rather than a typical course of relapsing multiple sclerosis (MS). Early in the course of either illness the exact diagnosis can be difficult to establish. In Kari's case she has been very stable for several years supportive of a diagnosis of ADEM rather than MS.

*Id.*

Exhibit 44 is a medical record dated December 13, 2007 from Dr. Michael Olek, a neurologist, stating petitioner had a hepatitis B vaccine, and then, one to two months later, developed a headache, irritability, fatigue, and disorientation. *Id.* at 1. Dr. Olek reviewed a brain MRI petitioner underwent on September 11, 2007 as well as the previous MRI from January 3, 2007. He states there were extensive white matter lesions throughout the white matter in a pattern consistent with acute demyelinating encephalomyelitis. The scans had not changed in appearance and there were no gadolinium-enhanced lesions. *Id.* Petitioner told Dr. Olek that there is always a recurrence of the old symptoms when she gets either another vaccination or an infection. *Id.* at 2. Dr. Olek's impression was that patient's pattern and MRI are consistent with ADEM. "I do not feel that this represents relapsing or remitting multiple sclerosis." *Id.*

Exhibit 45 is a letter dated June 12, 2008 from Dr. Roy A. Kanter to petitioner's mother stating he remembered petitioner well enough to confirm that her diagnosis is likely not MS. *Id.*

#### **Other Submitted Material**

Petitioner filed excerpts from her diary. One entry dated March 3, 1994 (seven weeks before the onset of her MS symptoms) sounds just like a normal teenager, discussing her swim

team and her crush on a fellow. Med. recs. at Exc. 8, p. 1. There is no indication of any medical problem in this entry. The remaining entries are obviously written after the onset of her MS.

Petitioner filed her mother's journal, which consists of 564 pages, as Exhibit 9. The initial entry is dated May 5, 1995. In that journal, petitioner's mother states that she had to go back to the beginning, Saturday, April 31<sup>st</sup>. (There are only 30 days in April. April 30, 1994 was a Saturday.) Med. recs. at Ex. 9, p. 1. Petitioner's mother recounts how, on that Saturday, petitioner was very ill, extremely tired, could not tie her shoes, and had a sore throat. She took petitioner to the doctor who took a throat culture. Med. recs. at Ex. 9, p. 2. Petitioner was unsteady on her feet. *Id.* When she took petitioner home, the doctor called later at 5:30 p.m. and requested petitioner's parents bring her to the ER at 7:30 p.m. Med. recs. at Ex. 9, p. 4. The next day in the hospital, May 1, 1994, petitioner was "her normal sunny self." Med. recs. at Ex. 9, p. 7. It had taken her but 10 minutes to orient herself after she woke up. She seemed to be getting better with more rest. *Id.*

Petitioner's mother wrote the next section in January 1999. Med. recs. at Ex. 9, p. 8. She did not write anything in her voluminous and detailed records indicating that petitioner had any symptomatology before the end of April 1994.

Petitioner filed Ex. 11, her school records which predate her hepatitis B vaccinations. This exhibit includes an Individualized Education Program, dated December 18, 1992, stating that petitioner was eligible for special education because she was learning disabled. Her original placement in special education was October 25, 1989. Med. recs. at Ex. 11, p. 82. Petitioner received poor grades for not turning in homework. Med. recs. at Ex. 11, p. 88. She had improved since her prior evaluation on October 26, 1991 when she made careless mistakes,

mixed letter sequences in words, and left off word endings. She was weak in visual processing. Med. recs. at Ex. 11, p. 91. On October 25, 1989, she was below average in reading and language. Med. recs. at Ex. 11, p. 105.

On November 5, 1993, again before her hepatitis B vaccinations, petitioner received a D- in Spanish 1 for poor oral participation, poor test scores, and incomplete or missing work. Med. recs. at Ex. 11, p. 54. On January 7, 1994, the same date as her first hepatitis B vaccination, petitioner was evaluated once more for special education and her IEP states that she was still eligible for special education due to being learning disabled. Med. recs. at Ex. 11, p. 48. She continued to exhibit visual motor difficulties. *Id.* In visual memory, she could not remember the sequence of letters. Med. recs. at Ex. 11, p. 52. On February 25, 1994, petitioner received a D in introduction to physical science because her homework/classwork was incomplete and she did not take a test. Med. recs. at Ex. 11, p. 55. She received the same mark in the same subject for incomplete or missing assignments on March 25, 1994. Med. recs. at Ex. 11, p. 56. She also received a D in Algebra 1 for missing tests and work. *Id.*

Petitioner's mother submitted an affidavit, filed as Ex. 30, dated November 1, 2004. In this affidavit, for the first time, petitioner's mother gives a history that petitioner began to feel ill in the second week of February with severe headaches. P. Ex. 30, ¶ 7. She quit her swimming team at the end of March because she was too tired and her attitude changed. P. Ex. 30, ¶ 8. Petitioner's mother states that she told several doctors about petitioner's headaches but they thought they had nothing to do with her MS. P. Ex. 30, ¶ 12. (None of the medical records show a history of two months of headaches.)

Petitioner filed the statement of her younger sister as Ex. 26, which is undated and unsworn. She writes that she noticed petitioner's personality change right after she received the first hepatitis B vaccination. P. Ex. 26, p. 1. A week later, her parents took petitioner to the emergency room thinking that petitioner was taking drugs because of her personality change. Petitioner has not filed any records of this emergency room visit which would presumably be in January 1994. Apparently, petitioner's sister believes that petitioner was found to have lesions in her brain between her first and second hepatitis B vaccinations i.e., between January 7, 1994 and February 4, 1994, because she next states that petitioner had a slow period of recovery after she was unable to walk, see, or communicate. Then she recovered enough to received her second hepatitis B vaccination. (This is clearly not the sequence of events in petitioner's case as per the medical records.) According to petitioner's sister, after the second hepatitis B vaccination, petitioner relapsed. Petitioner's sister does not seem to remember a third vaccination.

The mother of a longtime friend of petitioner submitted a statement, dated December 3, 2003, which is unsworn, that petitioner filed as Ex. 27. During the summer of 1992, the friend's family moved 200 miles away. The friend's mother's statement does not bear on the issue of the onset of petitioner's symptoms.

A friend of the family for 25 years submitted a statement, dated April 15, 2002, that petitioner filed as Ex. 13. This friend has known petitioner all her life, and began noticing a change in petitioner around the end of February or March 1994. She became moody, very tired, and frustrated.

Another family friend for over 20 years submitted a statement, dated April 13, 2002, that petitioner filed as Ex. 14. “When [petitioner] became ill in April of 1994...” is her statement of the onset of petitioner’s symptoms.

Petitioner’s aunt submitted a statement, dated December 1, 2003, which is unsworn, that petitioner filed as Ex. 20. She contrasts what petitioner was like before she had MS to what she is like currently.

A friend of petitioner’s family for 28 or 29 years submitted a statement, dated December 22, 2003, which is unsworn, that petitioner filed as Ex. 25. She comments on petitioner’s current personality.

Respondent filed as Ex. N chapter 36 entitled “Multiple Sclerosis and Allied Demyelinative Diseases” from *Adams & Victor’s Principles of Neurology* (8<sup>th</sup> ed. 2005), eds. A.H. Ropper and R.H. Brown, at 771-96. The authors classify demyelinating disease into, inter alia, acute MS and ADEM. They classify ADEM into two categories: (1) postinfectious after various infections, either viral or bacterial, and (2) postvaccinal, following rabies or smallpox vaccinations and rarely other types of vaccination. *Id.* At 771 (Table 36-1).

The authors state, at 777:

The conventional view of MS as a disease that strikes young people at a time when they are enjoying perfect health is not always accurate. In some patients, the history discloses that fatigue, lack of energy, weight loss, and vague muscle and joint pains had been present for several weeks or months before the onset of neurologic symptoms. Nor is it generally appreciated that the neurologic disorder may have an acute, almost apoplectic onset. ... [I]n about 20 percent the neurologic symptoms were fully developed in a matter of minutes, and, in a similar number, in a matter of hours. In about 30 percent the symptoms evolved more slowly, over a period of a day or several days, and in another 20 percent more slowly still, over several weeks to months. In the



remaining 10 percent the symptoms had an insidious onset and slow, steady, or intermittent progression over months and years. The classic relapsing-remitting pattern of disease is more likely to appear in patient who are less than 40 years of age.

The authors discuss a variant of MS called acute MS, at 780-81:

Rarely, MS takes a rapidly progressive and highly malignant form; Marburg's name has been attached to this variant. A combination of cerebral, brainstem, and spinal manifestations evolves over a few weeks, rendering the patient stuporous, comatose, or decerebrate, with prominent cranial nerve and corticospinal abnormalities. Death may end the illness within a few weeks to months without any remission having occurred, or there may be partial recovery .... Two of our most striking examples of this rapidly fatal form were in a 6-year-old girl and a 16-year-old boy, both of whom died within 5 weeks of the onset of symptoms. Another was a 30-year-old man who lived 2 months. In none of them had there been a preceding exanthem or inoculation or any symptoms suggestive of demyelinating disease. ... It seems to the authors that more than one disease is being included in the clinical category of acute MS. One type conforms in its temporal profile to a rather protracted form of acute disseminated encephalomyelitis—an acute monophasic illness extending over 4 to 8 weeks. Others subsequently prove to be typical polyphasic MS.

The authors then discuss ADEM, starting at 790:

[I]t represents an acute inflammatory and demyelinating disease, distinguished pathologically by numerous foci of demyelination scattered throughout the brain and spinal cord and some restricted to the cerebellum or spinal cord. ... Multifocal meningeal infiltration is another invariable feature but is rarely severe in degree. With the exception of this last feature, ADEM is indistinguishable on histopathologic grounds from acute MS. It is the setting, further course, and certain special features of each that set them apart. ... [I]t is believed that the disorder represents an immune-mediated complication of infection rather than a direct infection of the CNS, a process comparable to the Guillain-Barré syndrome.

They then discuss postvaccinal encephalomyelitis following the old formulation of rabies vaccine and smallpox vaccine, at 792:

Mundane inoculations such as those for influenza or hepatitis must have a very small rate of ADEM, judging from surveillance studies.... The mortality rate of postvaccinal encephalomyelitis is high, between 30 and 50 percent. If recovery occurs, it may be surprisingly complete. However, a significant proportion of patients show residual neurologic signs, mainly in the form of seizures, intellectual impairment, or behavioral abnormalities.

Petitioner filed Ex. 42, an article entitled “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). Following an increase in Guillain-Barré syndrome (GBS) among people who had received swine flu vaccine in 1976, the authors did an epidemiologic study to see what the period of risk was. They concluded this period was concentrated primarily with five weeks after vaccination, although it lasted approximately nine or 10 weeks. *Id.* at 105. Prior to the 10<sup>th</sup> week after vaccination, all relative risks were significantly greater than 1, but after the 10<sup>th</sup> week, the relative risks no longer remained significantly different from 1. *Id.* at 112.

Respondent filed Ex. O, an article entitled “Hepatitis B Vaccination and the Risk of Childhood-Onset Multiple Sclerosis,” by Y. Mikaeloff, et al., 161 *Arch Pediatr Adolesc Med* 12:1176-82 (2007), and a related editorial at 1214-15. The authors of the article conducted a case-control study of 143 patients matched with 122 controls. *Id.* at 1177. Exposure to hepatitis B vaccine was not associated with a significant increase in the risk of a first episode of MS. *Id.* at 1179. The main risk period that the authors considered was three years. *Id.* at 1181. They note that “statistical power was not high enough for the evaluation of short risk periods (< 6 months), which was not our primary objective.” *Id.*

Respondent filed Ex. P, an article entitled “Hepatitis B vaccine and risk of relapse after a first childhood episode of CNS inflammatory demyelination,” by Y. Mikaeloff, et al., 130 *Brain* 1105-10 (2007). The authors comment that prior reports discussing the lack of an association between immunization and an increase in the risk of MS could not exclude small increases in the risk of MS. *Id.* at 1105. They decided to focus their study on whether children who had a first episode of demyelination had an increased risk of a second episode (and, therefore, a diagnosis of MS) after receiving hepatitis B vaccine compared to those children with a first episode of demyelination who then received tetanus vaccine. *Id.* at 1106. The authors state that MS has a variable rate of relapse over time and the true risk period after hepatitis B vaccination has not been established. *Id.* at 1108. They also state that the time sequences of white matter and axonal destruction in MS after stimulation with external antigens, such as vaccines, has also not been defined. *Id.* They found that their study, due to the low numbers of patients with relapses (which they term “a certain lack of power”), could not exclude a small increase in risk and that the risk of an initial episode of demyelination after hepatitis B vaccination in childhood requires further study. *Id.* at 1109.

Respondent filed Ex. Q, 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 emphasize objective demonstration of dissemination of lesions in time and space and note that other recurring demyelinating diseases, such as ADEM with a stuttering onset, have been viewed as separate diseases, while others view them as variants of MS. *Id.* at 126. They conclude the diagnosis of MS is partly subjective and partly objective. *Id.*

Respondent filed Ex. R, an article entitled “Application of the New McDonald Criteria to Patients with Clinically Isolated Syndromes Suggestive of Multiple Sclerosis” by C.M. Dalton, et al., *52 Ann Neurol* 47-53 (2002). By using the new McDonald criteria, the authors could predict in clinically isolated syndromes the subsequent arising of clinically silent MRI lesions that increased the chances of developing clinically definite MS. *Id.* at 47.

### TESTIMONY

Petitioner testified first. Tr. at 4. Her health was excellent as a child. *Id.* Before she reached high school, she had special education because she was behind in reading. Tr. at 5. Special help continued through junior high school and high school. Tr. at 6. She was on the swimming team in high school. *Id.* Another favorite activity was photography. Tr. at 9.

Petitioner stated that after she received the second hepatitis B vaccine on February 4, 1994, she started not to understand what the school teacher was saying. Tr. at 10. So she would go to the back of the class to goof off with the rowdy kids back there. *Id.* She does not recall when this happened. *Id.* She recalls it was before Easter. Tr. at 11.

In the past, she had a problem with headaches. *Id.* They would occur around the time she was menstruating. *Id.* After the second hepatitis B vaccination in February, she had really intense headaches that would not go away. *Id.* Her mother took her to the doctor in March for these headaches. *Id.* She had problems concentrating in class which occurred before Easter. *Id.* Petitioner’s counsel informed the undersigned that Easter that year was April 3<sup>rd</sup>, so this problem with concentration would have occurred in March. Tr. at 12. She was sad because she could no longer do photography and ended up quitting the swim team because of fatigue. *Id.* Her problems with swim team began before Easter as well. *Id.* She stopped doing her chores at

home because she was too tired. Tr. at 13. Her mother took her to the doctor on April 30<sup>th</sup> because she had had enough of her daughter's problems. Tr. at 14.

At the doctor on April 30<sup>th</sup>, petitioner did not give a history of her condition. *Id.* From that point on, she never gave a history to anyone. *Id.* She does not remember this April 30<sup>th</sup> visit or her hospitalization except for when she had her brain biopsy, the hospital staff put a halo on and it hurt a lot. She wanted it off. Tr. at 14-15. Her headaches became worse and she was in constant pain. Tr. at 15. The pain was behind her eyes. Tr. at 16. These headaches were more intense than the ones she had before her vaccinations. *Id.*

She was excited about going to her brother's wedding, but then she ended up back at the hospital because she could not see or communicate. Tr. at 17. She wanted to watch cartoons, but she could not see them. Her mother's friend came and sang three hours of camp songs to her. *Id.* She hated physical therapy, but enjoyed movie nights and bingo. Tr. at 17-18.

She finally returned home in July from rehabilitation. Tr. at 18. She could not move. Tr. at 19. She had physical, occupational, and speech therapy at home. *Id.* In November 1994, she stopped taking steroids. *Id.* Also in November 1994, she received her third hepatitis B vaccination. *Id.* She did not have headaches when she returned from rehab. Tr. at 20. After the third hepatitis B vaccination, she had severe headaches. *Id.* Then her vision became bad. Tr. at 21. She saw a doctor for her vision in January 1995. *Id.* Her vision was cut in half. *Id.*

Petitioner was put back on IV steroids. Tr. at 22. After her optic neuritis in January 1995, she gradually got better. Tr. at 23. Once a month, she receives intravenous gamma globulin (IVIG). Tr. at 25.

Petitioner's mother testified next. Tr. at 33. Petitioner is her eldest daughter and one of six children. Tr. at 34. All of petitioner's mother's children have had learning disability. Tr. at 35. She and her husband both had learning disabilities. *Id.*

Petitioner got extra time to do her assignments in school and sometimes half a spelling list instead of the whole list because spelling was a real issue for her. Tr. at 39. She did not do well in Spanish. Tr. at 41. The last month and one-half before petitioner became ill, she was not taking pictures any more. Tr. at 42. That would be in March. *Id.* From the time they got back from Easter vacation, petitioner became difficult about doing her chores. Tr. at 43. Petitioner said she was too tired. Tr. at 44. When petitioner's mother and father returned from their Easter vacation, petitioner's father told petitioner's mother that petitioner's swim coach told him petitioner had been missing practices. *Id.* Petitioner's teachers called petitioner's mother to tell her that petitioner was not getting her homework in. Tr. at 45. Easter vacation would have been the week before Easter. *Id.*

After the February vaccination, petitioner started having headaches. Tr. at 47. This was late February which she remembers because she thought they were migraines and she wrote her son a letter saying the headaches looked like the migraines he used to have. *Id.* Petitioner's headaches were intense and severe. *Id.* Petitioner's behavior began to change and she was more irritable and tired. Tr. at 48. Petitioner was slipping back into the old patterns of not getting homework in and not being attentive. Tr. at 49. Petitioner and her mother went to the doctor on March 15<sup>th</sup> for the headaches. *Id.* The doctor felt that petitioner's headaches were related to her sinus issue. Tr. at 50. His medical records do not reflect that petitioner complained about headaches and just indicate a week of congestion, runny nose, pressure of the face, and no fever.

*Id.* Petitioner's mother stated she talked about the headaches with the doctor. *Id.* The doctor sent petitioner home with a decongestant. She had seasonal allergies. *Id.* The headaches continued. *Id.*

When petitioner's parents returned from their Easter vacation, petitioner's sister told her that petitioner had fallen asleep while they were gone during a television program and woke up much later in a rage thinking her sister had changed the channel. Tr. at 52-53. Petitioner's sister was really angry with petitioner and with petitioner's mother because petitioner's sister kept telling petitioner's mother that there was something wrong with her sister, that she was not acting right and was mean and yelling at her, saying things were happening that were not happening. Tr. at 53. Petitioner's sister felt that part of the reason petitioner got so sick was that petitioner's mother did not pay attention to what petitioner's sister was telling her. *Id.*

As April progressed, petitioner became more and more irritable and less willing to do chores or take direction. *Id.* Petitioner did not want to get out of bed even to do things she enjoyed. Tr. at 54. On the Friday that was before the Saturday on which the hospital admitted petitioner, petitioner could not get out of bed. *Id.* All of the hospital histories were from petitioner's mother. Tr. at 56. These histories focus on April 20<sup>th</sup>, which was a Wednesday, when petitioner refused to her mother's face to do things because she was too tired. Tr. at 57.

On April 30<sup>th</sup>, her youngest son's Boy Scout troop was going to San Mateo to ride in little biplanes. Tr. at 58. The family was going along and petitioner was as well. *Id.* But petitioner's mother told petitioner she could not go because she had to do an assignment. Tr. at 59. Petitioner's mother left petitioner with her father and said when petitioner's mother returned home, she expected to see the paper written. *Id.* When petitioner's mother returned, she found

petitioner asleep on her bed with her papers around her and not one word written. *Id.* She got petitioner up and took her to Kaiser Urgent Care Clinic. *Id.* The doctor examined petitioner and did a urine test and a blood test. Tr. at 60. They went home and petitioner looked as if she had had a stroke. Tr. at 61. She was watching television with one hand covering an eye. *Id.* A CT scan was done on petitioner's brain which detected seven lesions. Tr. at 62.

Petitioner's mother did not recall that petitioner had a cold around April 20<sup>th</sup>, but she would not be surprised if petitioner did. Tr. at 63. After petitioner's second hospitalization in January of the following year, she was diagnosed with acute MS. Tr. at 66. An MRI of petitioner's brain showed 20 lesions. Tr. at 70. Kari had plasmaphoresis, which helped. Tr. at 89. Petitioner no longer had headaches. Tr. at 93.

On November 7, 1994, petitioner had her third hepatitis B vaccination. *Id.* A little bit before Christmas, petitioner began to have headaches again. Tr. at 94. They became very severe. *Id.* In January 1995, her vision started bothering her. *Id.* She was hospitalized and put on IV steroids. *Id.* She came home after 24 hours and this attack did not seem as severe. Tr. at 95.

There has never been a change in petitioner's MRIs since her initial attacks. Tr. at 97. Every time petitioner seems to get worse, she has headaches. Tr. at 98. She is treated with steroids. Tr. at 99. Petitioner is stronger today and more cognitively aware. Tr. at 100. Petitioner's current doctor does not think she has MS, but has ADEM. Tr. at 101. Any times petitioner becomes ill, she has terrible symptoms. Tr. at 102.

Petitioner's mother admitted on cross-examination that prior to petitioner's first hepatitis B vaccination, petitioner would miss five or six days of classes per quarter. Tr. at 115.



Petitioner's mother began to think of petitioner's symptoms before April 20, 1994 after petitioner had had a second episode with preceding headaches. Tr. at 125.

Dr. Carlo Tornatore, a neurologist, testified next for petitioner. Tr. at 135. He is the director of the MS clinic at Georgetown but also sees patients with ADEM and other neurologic diseases. Tr. at 139. He examined petitioner before the hearing. Tr. at 140. His diagnosis is that petitioner has ADEM. *Id.* He has four reasons for this diagnosis: (1) headaches are atypical for MS; (2) petitioner's brain MRI was grossly abnormal, not something seen with MS, and it showed increased contrast without gadolinium which signified that some of the brain lesions had blood around the rim; bleeding associated with lesions is not seen with MS and, on enhancement, there was a ring-enhancing lesion; (3) the brain MRI showed dural enhancement in the right sylvan region which never happens with MS (the dura has no myelin and would not have an MS lesion; but it could have inflammation from ADEM); and (4) the brain biopsy showed strikingly abnormal astrocytes with mitosis which we never see in MS. Tr. at 140-46. Seeing mitosis in an astrocytoma (what the pathologist thought it was) means a process has been ongoing for six to eight weeks. Tr. at 147. One does not see this within two or three weeks. *Id.* Something else must have been going on and smoldering that caused the astrocytes to divide. *Id.*

Petitioner did not have a tumor. Tr. at 148. She had some inflammation that caused the astrocytes to multiply, but when the inflammation was gone, the astrocytes stopped multiplying. *Id.* Astrocytes with mitosis is unusual with ADEM, but one can have inflammation that is so striking and intense that the person has some astrocytes that have some mitosis. *Id.*

The undersigned questioned how ADEM which is acute can have an underlying process going on for six to eight weeks. Tr. at 149. Dr. Tornatore said that petitioner received two hepatitis B vaccinations. The first one primed her immune system and the second one led to a brisker response. *Id.* He imagined a cascade initially with some inflammation getting into the brain and some antigen. More T-cells come in, but there are no symptoms until the patient reaches a critical threshold and everything comes to a head clinically. *Id.* There has to be a period of time where there is some general inflammation occurring. Tr. at 149-50. The enhancement of petitioner's dura would account for her headaches. Tr. at 150.

Dr. Tornatore said that if petitioner had had a cold on March 15, 1994, that would have been an appropriate immune antagonist to set off this process. Tr. at 151. If someone has an immune system that is already sensitive or stimulated and then has an interceding infection, this can lead to MS, as happens to a lot of his patients. *Id.* They get a cold and, since their immune systems are already overactive, they have pseudorelapses of MS all the time. *Id.* An infection could have made petitioner's situation worse. *Id.*

The undersigned asked Dr. Tornatore if petitioner's upper respiratory infection on April 20, 1994, which was closer in time to her rapid downhill course starting April 30, 1994, played a role in her disease. *Id.* Dr. Tornatore thought it could play a role but the astrocyte mitosis could not be due to the April 20<sup>th</sup> cold because it occurred only two or three weeks after the cold which is too quick to get that kind of change in the brain. Tr. at 152.

Dr. Tornatore does not think that petitioner had optic neuritis in January 1995. *Id.* She had visual loss in both eyes. Tr. at 154. One could have recurrent ADEM. *Id.* Petitioner had inflammation in a part of the brain with a lot of myelin in it a second time. Tr. at 155. One

never sees cortical blindness with MS. *Id.* In cortical blindness, light goes into the eyes to the optic nerves and then to the part of the brain that interprets the image called the occipital cortex. Tr. at 155-56. If one loses or has very severe inflammation of the back part of the brain, even though the retina perceives the light, the person cannot interpret what has come in. Tr. at 156. It is called cortical blindness because the brain cannot perceive the input even though the eyes receive the light. *Id.* Patients with cortical blindness cannot perceive their surrounds and, if it is bad, they will hallucinate (called Anton's syndrome). *Id.* Dr. Tornatore wondered if petitioner's psychosis was actually Anton's syndrome. Tr. at 157.

Dr. Tornatore thinks that petitioner had some inflammation happen in her optic track on January 4 and 5, 1995, but he was inclined to say it was a recurrence of the demyelination. *Id.* Petitioner really does not fit into a diagnosis of MS. *Id.* He disagrees with her treating doctor's diagnosis of retrobulbar neuritis, left eye, and this made the diagnosis of MS definitive. *Id.* He is suspicious because he saw the MRI report and knows that petitioner's headaches preceded this. *Id.* There is no clinical test for MS. It is a diagnosis of exclusion. Tr. at 157-58. Once petitioner stopped taking MS drugs, she felt better. Tr. at 158. The people treating petitioner initially thought she did not have MS and gave her oral steroids, which you do not give to MS patients because they will provoke more attacks. *Id.* IVIG or intravenous immunoglobulin (which petitioner received) is a nonspecific treatment for any kind of inflammation. Tr. at 159.

Dr. Tornatore testified that ADEM usually occurs only once, maybe a second time. *Id.* Usually it is young adults who have ADEM. Tr. at 160. When petitioner's treaters tried to taper her steroids, the ADEM would just keep returning. The immune system was still on. *Id.* In Dr. Tornatore's opinion, after the third hepatitis B vaccination, petitioner got more headaches and

then it caused this optic issue subsequently in January. *Id.* That is not typical of ADEM and he does not know if it is because she was rechallenged a third time. *Id.* Petitioner does not fit neatly into any category. She has a “weird” immune system to Dr. Tornatore because of the way the vaccine interacted with her. Tr. at 161.

The nerves controlling petitioner’s bladder started in her brain and got inflamed as they were going down, causing her bladder problems. *Id.* He agreed with petitioner’s mother when petitioner had influenza and regressed to almost the psychotic part that this was probably a pseudorelapse. Tr. at 163. Petitioner’s immune system got turned on trying to fight the influenza virus. *Id.* Some of the chemokines and cytokines may have actually gotten into the brain and caused more inflammation. *Id.*

Summing up, Dr. Tornatore stated that petitioner’s first hepatitis B vaccine probably provided very mild stimulation of petitioner’s immune system. Tr. at 165. Petitioner’s second hepatitis B vaccination caused petitioner to mistake the vaccine for brain antigen. Tr. at 165-66. The white blood cells started circulating and found their way into the brain and began stimulating some of the astrocytes and oligodendrocytes, causing a low grade inflammation. Tr. at 166. Perhaps, the immune systems could have turned itself off. But when petitioner got this March cold, the immune system got turned on again. *Id.* That caused the helper cells to return and resulted in more brain inflammation. *Id.* The astrocytes are antigen-presenting cells and may have aggravated the situation. *Id.*

When petitioner received her third hepatitis B vaccination on November 7, 1994, her headaches returned. Tr. at 167, 168. It took until early January (two months) to have a problem with her eyes. Tr. at 168. Petitioner had been on steroids for a long time and had very

significant Cushingoid features. The steroids shut down her immune system for a good period of time. *Id.* Because petitioner had been immunosuppressed from her steroid treatment, it took a little longer for her to have an immune response that she had after her second vaccination. Tr. at 169. Petitioner's headaches were the prodrome for her delayed response. *Id.* Dr. Tornatore stated that but for the hepatitis B vaccinations, petitioner would not have developed ADEM. Tr. at 171.

On cross-examination, Dr. Tornatore denied that petitioner's pre-vaccination learning disability was consonant with a loss of previously-acquired neurologic milestones. Tr. at 174. This was a comparison of petitioner to everyone else. *Id.* They are neurological indicators because she was behind others in her class. But they are not an indication of a loss of function. Tr. at 175. He did not think petitioner's learning disabilities would have been a major problem later on. Tr. at 179. He does not believe that the vaccinations aggravated her learning disabilities. The vaccine reaction actually injured her brain, causing very striking, frank changes. *Id.* Petitioner's 2002 and 2003 MRIs showed atrophy, i.e., black holes meaning punched out areas of the brain. *Id.* What petitioner has now is not reflective of a previous developmental disorder. Tr. at 179-80. What she has are sequelae of her leukoencephalitis. Tr. at 180.

Petitioner had headaches after vaccination because her dura was inflamed. *Id.* Whenever one has dural inflammation, that is considered a meningitis. *Id.* It is not a bacterial or a viral meningitis, but this was inflammation and the dura have a lot of pain fibers. *Id.* Inflammation in the meninges, particularly if it is mild, is not always reflected in the spinal fluid. Tr. at 181.

Petitioner's MRI showed unbelievable inflammation which is yet not reflected in her spinal fluid. *Id.*

Dr. Tornatore was asked how he differentiated Marburg syndrome from ADEM. Tr. at 182. He said that Marburg was more progressive and its pathology does not look anything like this. *Id.* It also has a different presentation. *Id.* Usually ADEM presents with seizures; Marburg does not. *Id.* Marburg is the worst form of MS. *Id.* Marburg involves a lot of inflammation, but not hemorrhaging as petitioner had. *Id.* Petitioner had a grossly abnormal and diffusely slow EEG, but that would be most unusual to see with Marburg. *Id.* Leukoencephalitis causes headache, but that would be unusual with Marburg. *Id.* Someone can get ring enhancement with MS, but petitioner had many ring enhancements. *Id.* MS can present in a tumor-like fashion. Tr. at 183. But one would not see ring enhancement of the meninges. *Id.* Dr. Tornatore admitted it was unusual to get dividing astrocytes in ADEM. *Id.*

Dr. Tornatore admitted that a scotoma is characteristic of optic neuritis and petitioner had scotoma. Tr. at 184. Eye pain is also characteristic of optic neuritis. *Id.* Dr. Tornatore stated he was not saying petitioner did not have optic neuritis. But she had visual acuity in both eyes that was off. *Id.* To Dr. Tornatore, it does not matter whether petitioner had optic neuritis, optic chiasm problems, or a worsening of her previous vision difficulties because it all came down to the same thing. *Id.* If the inflammation was further back from what the doctors could see, we call that retrobulbar (behind the eye) and can actually see inflammation on the MRI but the nerve when we visualize it in the eye looks fine. Tr. at 185-86. That would be retrobulbar neuritis. Tr. at 186. The episode after the third hepatitis B vaccination was inflammatory but where in the eye the inflammation was does not matter because it was autoimmune. Tr. at 187. It is

autoimmune because petitioner had pain behind the eye and some inflammation. Tr. at 188. Because petitioner's doctors did not test petitioner's visual evoked responses or do an MRI of her orbits, we do not know if she had optic neuritis in January 1995. *Id.* The fact that petitioner had dissemination in space and time does not make her diagnosis MS. Tr. at 189. Dr. Tornatore thinks that petitioner had the second event with her eyes because the third hepatitis B vaccine rechallenged her. Tr. at 190. Petitioner was on steroids for almost five months after the second vaccination. *Id.*

ADEM is probably both T-cell and B-cell mediated. Tr. at 193. Dr. Tornatore thinks petitioner's onset of ADEM was the beginning of March because he estimates that it took two months for petitioner to develop the number of lesions she had at the end of April 1994. Tr. at 200. To see mitosis in the brain, something would have been going on for about six to eight weeks. Tr. at 202. That would put onset at either mid-March or the beginning of March. *Id.* Petitioner's course does not resemble MS. Tr. at 206. Petitioner is getting better, whereas MS is a progressive disease. *Id.* Petitioner has not had new lesions over time. Tr. at 207.

Dr. Arthur Safran, a neurologist, testified for respondent. Tr. at 208. Half of the 200 patients he sees monthly have MS. Tr. at 210. Although Dr. Safran disagreed with the undersigned's prior decisions that hepatitis B vaccine can cause MS, he based his testimony on the presumption that hepatitis B vaccine can cause MS at least up to a month post-vaccination.<sup>3</sup>

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<sup>3</sup> The date of this hearing was May 20, 2008, which was four months before the undersigned issued the Pecorella decision on September 17, 2008 in which petitioner prevailed in her allegation that hepatitis B vaccine caused transverse myelitis, another demyelinating illness, and in which respondent decided not to expend resources to defend even though onset was two months. Up until Pecorella, the undersigned held that the appropriate temporal interval between vaccination and onset of demyelinating illness was one month.

Tr. at 212. His opinion is that petitioner has MS and that hepatitis B vaccine did not cause it. Tr. at 213. One of the bases for his opinion is that petitioner had an oligoclonal band in her spinal fluid, which is characteristic of MS. Tr. at 214. He was unsure about the significance of the gadolinium enhancement of the dura. Tr. at 215. He does not think headache is a major feature of ADEM. *Id.* It took a long time for petitioner's symptoms to evolve. Tr. at 215-16. Dr. Safran stated that new MS lesions were discovered on MRI. Tr. at 216. On April 3, 1995, petitioner was described as having worsening gait and more weakness in her left leg. In February 2002, she developed a bladder problem. Tr. at 217. In her brain MRI of January 3, 2003, there was a new lesion in the right frontal lobe. Tr. at 218, 219. The January 14, 2002 brain MRI noted a possible tiny focus of T2 signal intensity in the right brachium pontus which was new. Tr. at 219. (Dr. Tornatore said enhancing lesions do not necessarily have significance. Tr. at 221.) Dr. Safran agreed with Dr. Tornatore that lesions come and go. However, it means the disease is active. Tr. at 222.

The MRI done on April 24, 2003 showed no new lesions and a stable pattern. Tr. at 299. The MRI done on November 3, 2003 also showed the lesion had gone away. Tr. at 230. This means to Dr. Safran that there is an active process here which is MS and not ADEM. *Id.*

Dr. Tornatore agreed there was ongoing inflammation, but it did not mean petitioner had MS. Tr. at 231. Her pathology looks more like ADEM but there was mitosis, which was unusual, and even though petitioner has gotten better, she has some ongoing inflammation. *Id.* There is an autoimmune process here. Tr. at 232. Dr. Tornatore denied that petitioner had an oligoclonal band in her spinal fluid because that would require more than one band. She had a monoclonal band. Tr. at 234. A single band means you are dealing with a specific antigen. *Id.*



Dr. Safran said he did not know how long it took for an astrocyte to make mitoses. Tr. at 236. Dr. Tornatore stated petitioner clearly had a lot of inflammation and she had mitotic spindles. Tr. at 237-38.

Dr. Safran stated petitioner had Marburg MS, a particularly severe form of MS. Tr. at 241. Dr. Safran thought something was going on in petitioner's brain before vaccination when her reading, language, and mathematics abilities declined greatly. Tr. at 245.

On cross-examination, Dr. Safran did not feel qualified to answer whether a vaccination can cause an autoimmune condition like GBS up to 10 weeks after vaccination. Tr. at 250. Dr. Safran considered petitioner's first symptoms of MS to be unsteadiness and lethargy. Tr. at 253. He does not think that, if one accepts the testimony over the medical records, petitioner's headaches, personality changes, fatigue, lethargy, and cognitive difficulties lasting over six weeks were due to demyelination but to a virus. Tr. at 258. This would not be the usual onset of a demyelinating process because it took so long. *Id.* ADEM does not take that long. Tr. at 259. Dr. Safran believes the onset of petitioner's disease was April 20, 1994. *Id.* He agreed that MS can have various methods of presentation (acutely or slowly). Tr. at 260-61. MS can present with increasing confusion over long periods of time. Tr. at 261. If petitioner had a cold or sore throat on April 20, 1994 before her onset, that could have been a trigger for an attack of MS. Tr. at 261-62, 264. She also had a cold during her March 1994 visit. Tr. at 262.

## **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 ADEM or acute MS, but also that the vaccine was a substantial factor in bringing about her ADEM or acute MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Werderitsh v. Secretary of HHS, No. 99-310V, 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. The onset interval of MS after petitioner’s second hepatitis B vaccination in Werderitsh was one month (with onset of possible optic neuritis as the beginning of her MS occurring six days after her second hepatitis B vaccination). Respondent’s expert, Dr. Roland

Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute demyelinating reaction, would be a few days to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at \*15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

Here, petitioner's onset of numbness began two and one-half months after her second hepatitis B vaccination in the context of an upper respiratory infection. Although her friends and relatives attribute symptoms (personality changes, temper tantrums) much closer in proximity to the first hepatitis B vaccination, the consistent history that petitioner's mother gave to at least 10 medical personnel was that her onset of symptoms occurred around April 20, 1994 in the context of cold symptoms. It was at that time that petitioner had extreme fatigue and was unwilling to attend her swimming practice.

Since 1989, petitioner had been categorized in an IEP as learning disabled, having particular difficulties in doing homework, taking tests, and visual processing. The upshot was that petitioner was not working up to the level of her abilities. Petitioner's problems with school that some of these relatives and friends describe during the January through April 1994 period fit within the IEP category of learning disabled for petitioner from 1989-1994.

In addition, petitioner's sisters had strep throat in April 1994. Petitioner's mother stated petitioner had been in normal health before her mid-April fatigue, lack of interest in swim practice, and inability to tie her shoes. As for her headaches during the period of January - April 1994, petitioner and her mother gave a history in 1994 of petitioner's having headaches for two years.

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).

But the question of onset of petitioner's demyelinating disease does not rest here solely on when her clinical symptoms began. Petitioner's expert neurologist Dr. Tornatore testified that petitioner's 20 brain lesions detected on MRI soon after her April 30, 1994 hospital admission could not have occurred sooner than six to eight weeks beforehand. He admitted that if she had had a cold March 15, 1994 when she saw a doctor, that might also have triggered her symptoms. Respondent's expert neurologist Dr. Safran did not have any opinion about the length of time it would take for mitosis of astrocytes. As for onset of petitioner's Marburg variant of MS, he opined it occurred 10 days before hospitalization at the time of her sore throat. The undersigned holds that petitioner's onset of demyelinating illness, whether ADEM or acute MS, occurred in early or mid-March 1994 based on Dr. Tornatore's testimony. This would be one month to six weeks after her second hepatitis B vaccination. The undersigned accepts Dr.

Tornatore's testimony about the length of time it would take for 20 lesions to occur in petitioner's brain.

When this case was in trial, respondent had not yet taken the position as it did in Pecorella that it would not expend resources to defend cases whose onset was two months post-vaccination. This decision is dated after the undersigned's opinion in Pecorella reflecting respondent's current position on its defense. Petitioner's onset herein of one month to six weeks after her second vaccination is within that two-month parameter and is therefore medically appropriate.

The undersigned finds the dispute over whether petitioner had ADEM or Marburg MS puzzling since both are demyelinating diseases. The four paradigm cases in the Omnibus proceeding on hepatitis B vaccine and demyelinating diseases included TM, MS, GBS, and CIDP. That they did not include ADEM does not prevent the undersigned from holding that the same principles the undersigned enunciated in these paradigm decisions applies here. The evidence is more in favor of petitioner's having ADEM than Marburg MS, but since both are demyelinating diseases and doctors frequently confuse ADEM and acute MS, the undersigned fails to see what difference the actual diagnosis makes. The undersigned is cognizant of petitioner's treating physicians ultimately concluding she has ADEM and not MS. It would be perverse for the undersigned to hold that hepatitis B vaccine can cause demyelinating diseases such as MS, TM, GBS, and CIDP, but not any other type of demyelinating disease. The medical theories underlying those paradigm decisions apply here, from molecular mimicry as an aberrant response to an antigenic challenge to the understanding of how autoimmune diseases work out over time. Respondent's Exhibit N, a textbook chapter on MS, was extremely informative in

discussing MS as well as ADEM. Interestingly, it analogized the immune-mediated process of MS to GBS, which calls to mind petitioner's Exhibit 42, the Schoenberger article stating the relationship of swine influenza vaccine to GBS went out to 10 weeks. The argument in this case probably could have been avoided if respondent had decided not to defend two-month onset cases before the Pecorella case.

The undersigned finds that petitioner's relapse in January 1995 two months after her third hepatitis B vaccination in November 1994 at the time she also had a cold is reminiscent of a positive rechallenge. As petitioner's medical records and her mother attest, whenever petitioner gets sick, she has a relapse. With the third hepatitis B vaccination, she also had the antigenic challenge that promoted her disease in the first place. Whether the colds on March 15, 1994 and April 20, 1994 after her second hepatitis B vaccination in February 1994, and the cold in January 1995 after her third hepatitis B vaccination in November 1994 were substantial factors in triggering her demyelinating disease does not affect the undersigned's holding that petitioner's hepatitis B vaccinations caused her ADEM.

The undersigned finds that petitioner's medical theory is biologically plausible, that there is a logical sequence of cause and effect here, and that the time frame between vaccination and onset or relapse are medically appropriate for causation in fact. Without receiving hepatitis B vaccine, petitioner would not have had ADEM.

The undersigned found Dr. Tornatore's testimony to be more incisive and probative, as well as more credible, than Dr. Safran's. The undersigned was also impressed by the testimony of petitioner and her mother who is particularly proactive, intelligent, and well-intentioned.

## **CONCLUSION**

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement and will set a telephonic status conference to discuss damages.

**IT IS SO ORDERED.**

February 27, 2009

DATE

s/ Laura D. Millman

Laura D. Millman  
Special Master