OFFICE OF SPECIAL MASTERS
No. 99-450V
October 25, 2006

KARI HAWKINS,	*	
	*	
Petitioner,	*	
	*	
v.	*	Hepatitis B vaccine followed
	*	75 days later by acute MS;
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	causation?
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

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 Ms. Hawkins was still Kari Johnson, alleging that Ms Hawkins received hepatitis B vaccine in January, February, and November 1994. Petition, ¶ 2 (this is the second paragraph 2). A VAERS form lists the vaccination dates as January 7, 1994, February 4, 1994, and November 7, 1994. Med. recs. at Ex. 4, p. 7.

[1] Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). 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.

Since Ms. Hawkins is now an adult, being born July 6, 1979, the undersigned sua sponte amends the caption so that Ms. Hawkins is the sole petitioner.

Petitioner's adverse reaction was ultimately diagnosed as multiple sclerosis (MS), whose onset 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 was experiencing an upper respiratory infection (URI). Viruses have been associated with MS. Her siblings had strep throat at the time of the onset of her symptoms. Petitioner will have a difficult time proving that a vaccination 75 days before the onset of her MS is its cause.

Petitioner is ORDERED TO SHOW CAUSE by **December 4**, **2006** why this case should not be dismissed.

FACTS

Petitioner was born on July 6, 1979.

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's. *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 mitoses 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 demyelinization and clear differentiation between the areas of abnormal histology and the surrounding brain, suggesting a

plaque. *Id.* Myelin stains showed clear cut demyelinization 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 by being 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 May 2, 1994's 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 acute disseminated encephalomyelitis (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 demyelinization. *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 Maya 9, 1994, she became cortically blind and could not longer walk. Laboratory results were compatible with either MS or post-viral demyelinization. *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.*

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, incoordination, 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.* She had significant improvement since. Med. recs. at Ex. 4, p. 30.

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 either of her first two hepatitis B vaccinations, nor did she 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.

Other Submitted Materal

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 from 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 31st. (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. Mrs. Johnson does not write anything in her voluminous and detailed records indicating that Kari had any symptomatology before the end of April 1994.

Petitioner filed Ex. 11, her school records. This includes an Individualized Education Program, dated December 18, 1992, stating that Kari 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. Kari 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, Kari 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, Kari was evaluated once more for special education and her IEP concludes 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, Kari 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.*

Mrs. Johnson submitted an affidavit, filed as Ex. 30, dated November 1, 2004. In this affidavit, for the first time, Mrs. Johnson gives a history that Kari 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. Mrs. Johnson states that she told several doctors about Kari'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 Jennifer Lynn Kentner as Ex. 26, which is undated and unsworn. She noticed Kari's personality change right after she received the first hepatitis B vaccination. P. Ex. 26, p. 1. A week later, her parents took Kari to the emergency room because they thought she 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. If such records exist, petitioner must file them. Apparently, Jennifer believes that Kari 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 Kari 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 Jennifer, after the second hepatitis B vaccination, Kari relapsed. Jennifer does not seem to remember a third vaccination.

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

Mary Barnum submitted a statement, dated April 15, 2002, that petitioner filed as Ex. 13. Mrs. Barnum has been friends with the Johnson family for 25 years and knows Kari all her life. Mrs. Barnum began noticing a change in Kari around the end of February or March 1994. She became moody and very tired and frustrated.

Marlis Grow submitted a statement, dated April 13, 2002, that petitioner filed as Ex. 14. Mrs. Grow has been friends with the Johnson family for over 20 years. "When Kari became ill in April of 1994..." is her statement of onset of symptoms.

Karen J. Moore, 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.

Marsha Daines, 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.

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. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

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. 99-310V, 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 and her mother gave to at least ten 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.

It is understandable that petitioner's mother, sister, and close friends would try to help petitioner prevail in her case, but the clear and consistent history that Mrs. Johnson and petitioner gave to at least ten medical providers was that the onset of her difficulties was around April 20, 1994, in the context of viral symptoms. In addition, her sisters had strep throat at the time. She had been in normal health before her mid-April fatigue, lack of interest in swim practice, and inability to tie her shoe. As for her headaches during the period of January - April 1994, petitioner and her daughter gave a history of petitioner's having had 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).

Petitioner must file a medical expert report supporting that hepatitis B vaccine caused petitioner's MS two and one-half months later. Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **December 4, 2006**.

IT IS SO ORDERED.

October 25, 2006
DATE

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