

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 00-748V

June 8, 2007

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JENNIFER POLCARI, \*

Petitioner, \*

v. \*

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

Respondent. \*

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Hepatitis B vaccinations followed by weakness and various symptoms; ultimately diagnosed as MS

## ORDER TO SHOW CAUSE<sup>1</sup>

Petitioner filed a petition dated December 11, 2000, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered in December 1997 and on June 30, 1998 caused her adverse reactions. Onset of various symptoms changed depending on which doctor petitioner went to. Sometimes the onset was two

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<sup>1</sup> 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.

or three days after the first vaccination but at other times, it was five days or a month. Her symptoms varied from weakness to dizziness to disorientation to one-sided numbness to loss of hearing to achy joints. She interestingly told one doctor that her symptoms after the first vaccination were worse than her symptoms after the second vaccination, which would stand positive rechallenge on its head. All of her medical examinations have shown her to be normal neurologically, including nerve conduction, strength, and sensory testing. She has always shown negative Babinskis. A brain MRI, however, revealed numerous plaques, suggesting multiple sclerosis (MS) to the radiologist. Petitioner's symptoms are not those of typical MS. Petitioner has a high titer showing Epstein-Barr virus disease. Her last ANA test was normal.

Because more than one doctor has considered her to have a post-vaccinal reaction (based on the histories she gave them), and one of her doctors, Dr. Waisbren, has diagnosed her not with MS but with multiple antigenic-mediated autoimmunity due to hepatitis B vaccine, petitioner has made a prima facie case.

Respondent is ORDERED TO SHOW CAUSE by **August 31, 2007** why this case should not proceed to damages.

### **FACTS**

Petitioner was born on April 24, 1970.

On May 31, 1988, petitioner was diagnosed with allergies to pollen, mold epidermoids, house dust and mites. Dr. Scott Osur, an allergist, could not find the cause of petitioner's hives. Med. recs. at Ex. 10, p. 17.

On June 16, 1997, petitioner saw Geri H. Garfinkle, CSWR, for psychotherapy. Med. recs. at Ex. 10, p. 36. Petitioner said she suffered from irrational fears of fatal diseases which

resulted in symptoms associated with panic attacks. As a result, petitioner avoided normal social events and avoided going out in public with her son. When she went out, she returned and engaged in excessive hand-washing. Petitioner cancelled her next two appointments with her therapist. Petitioner told therapist Garfinkle that she did not want to continue in treatment with her because of lack of trust. Therapist Garfinkle concluded petitioner had an anxiety disorder.

*Id.*

Petitioner received her first hepatitis B vaccination on December 29, 1997. Med. recs. at Ex. 11, p. 12.

On April 6, 1998, petitioner saw her doctor, complaining of achiness and sluggishness. Her doctor diagnosed probably viral illness and pharyngitis. Med. recs. at Ex. 10, p. 14.

On April 10, 1998, petitioner saw her doctor, complaining of recurring dizziness. *Id.* It was intermittent for the last three months, but was more constant in the last five days. Her neurologic test was normal. *Id.*

On June 30, 1998, petitioner received her second hepatitis B vaccination. Med. recs. at Ex. 10, p. 14.

On July 14, 1998, petitioner saw her doctor, complaining of fatigue, joint pain, and a decreased appetite. Med. recs. at Ex. 10, p. 15. Ten days previously, she started to have flu-like symptoms with dizziness, nausea, joints aching, no appetite, and a severe headache. She did not have any fever. *Id.*

On July 16, 1998, petitioner saw her doctor, complaining she was not better and felt worse. *Id.* She had lack of coordination which was now better. She still had no fever. She was quite shaky and weak. *Id.*

On July 17, 1998, petitioner telephoned her doctor and said she was possibly worse. Her doctor said she could start antibiotics. *Id.*

On August 6, 1998, petitioner saw her doctor and said she was no better. She had the same symptoms. Med. recs. at Ex. 10, p. 16. She did not take the antibiotics. *Id.*

On October 22, 1998, petitioner saw her doctor saying the symptoms were back. *Id.*

On November 24, 1998, petitioner saw Dr. Geraldine Keyes. Med. recs. at Ex. 5, pp. 64-66. Petitioner reported a long history of illness dating to late December 1997 to January 1998 when she experienced extreme dizzy spells. Med. recs. at Ex. 5, p. 65. She would reach past things she was trying to reach. She did not have true vertigo. She saw Dr. Taylor in March 1998. She had numbness in the right half of her body which went away. In July 1998, she had nausea accompanied by hot and cold feelings followed by extreme weakness, fatigue, and achiness, causing her to become bedridden on July 14, 1998. Dr. Taylor treated her with Ceftin for three weeks, beginning August 10, 1998 even though she did not have tick bites or a positive Lyme titer. Her symptoms improved daily and she had no further joint pain by the end of the course of Ceftin. One week later, she noted her joint pain was increased. She saw Dr. Taylor in October 1998 and had a positive ANA titer of 1:80. She saw a Lyme disease specialist in NYC who advised her to stop eating dairy. She reported that she was less achy and less fatigued since eliminating dairy products from her diet. *Id.* Petitioner had frequent headaches starting in the back of her neck and spreading over her head. She got more breathless than she used to. She did not have fevers. She was not lightheaded. Her bowels tended to be loose. She did not have joint swelling. Her neurological examination was normal. The doctor's assessment was petitioner had a long history of fatigue, malaise, muscle aches and joint pains without a history of

objective synovitis. She had a history of a positive ANA. She might have an undiagnosed connective tissue disorder. Dr. Keyes asked petitioner if she had a history of anxiety or depression and she acknowledged that she had a history of anxiety. Med. recs. at Ex. 5, p. 66.

On March 12, 1999, petitioner saw Dr. Hilare J. Meuwissen, an allergist and immunologist. Med. recs. at Ex. 5, p. 24. Petitioner stated she had had a reaction to hepatitis B vaccination in December 1997 and on June 30, 1998. Five days after the first vaccination, she developed dizziness, decreased hearing on the right, numbness, confusion, inability to grasp objects accurately from one to four hours in duration, occurring one to several times a day, improving in April 1998. *Id.* She did not have visual, hearing, or taste disturbance. She recovered her usual state of good health. Five days after the second hepatitis B vaccination, she was fatigued, dizzy, nauseated, and had flu-like feelings. Ten days later, she developed joint pains and swelling or redness in wrists, fingers, knees, ankles and toes which caused her to stay on the couch in July and August, feeling nauseated. *Id.* She did not lose weight. She took Ceftin for Lyme disease and improved. In September/October 1998, she again experienced fatigue, joint pains, weakness, dizziness intermittently, which had not improved. She had a history of severe asthma, allergies, eczema, and sinusitis as did her parents and brother. Since July 4, 1998, she had had a frequent wheeze and cough with occasional severe asthma. She also developed loose, mucoid stool with some cramps three times a day. She had had some eczema. In November 1998, she was found to be allergic to certain foods. *Id.* On October 22, 1998, she had an ANA which was reactive with a titer of 1:80. Dr. Meuwissen diagnosed two possible reactions to hepatitis B vaccine, but the reaction seemed not to have been of an IgE type. She

was allergic to pollen, pets, and mites. She had hives for the prior four to five weeks. Med. recs. at Ex. 5, p. 15.

On May 7, 1999, petitioner saw Dr. Uma S. Alampur, a neurologist. Med. recs. at Ex. 10, p. 37. She told Dr. Alampur that after she had her first hepatitis B vaccination, after two or three days, she became completely numb and weak on the left side and could not speak. This resolved over the next few weeks to few months. Six months later, petitioner received her second hepatitis B vaccination and had a lesser reaction than the first one with generalized weakness, pain, numbness, headaches, and lightheadedness. She got better but she still noticed the lightheadedness, numbness, headaches, and pains. She became very weak during these episodes. She could not concentrate and function. She said that an immunologist at Albany Medical Center told her this was a post-vaccinal reaction. Petitioner has not filed these records. *Id.* Dr. Alampur examined petitioner and found that she had most likely a post-vaccinal-caused demyelination which gave her weakness and numbness, but her symptoms totally resolved since she was neurologically normal. Med. recs. sat Ex. 10, p. 38.

On June 24, 1999, petitioner had a nerve conduction study and F wave test done to test her sensory and motor abilities. Med. recs. at Ex. 4, p. 9. Dr. Alampur found the results to be normal. Med. recs. at Ex. 4, p. 10.

On June 27, 1999, petitioner had an MRI of her brain done. Med. recs. at Ex. 9, p. 11. Dr. David Ryon noted multiple foci of demyelination and suggested strong consideration of MS. Petitioner, on FLAIR imaging, had multiple hyperintensities in the pericallosal region in the right periventricular region. She had one or perhaps two demyelinating plaques in the left periventricular region as well. *Id.*

On September 20, 1999, petitioner saw Dr. Saud A. Sadiq. Med. recs. at Ex. 9, p. 16. She had her first hepatitis B vaccination on December 30, 1997 followed by dizziness and the sensation of spinning. Dr. Sadiq's handwriting is difficult to decipher. Perhaps, he wrote that the onset of this dizziness was April 7, 1998. Petitioner's recent complaints were fatigue, dizziness, nausea, and joint pain. *Id.*

On January 31, 2000, petitioner saw Dr. Susan Righi, complaining of difficulty breathing with some shortness of breath. One week earlier, she had fever, chills, and arthralgias which had improved. Med. recs. at Ex. 5, p. 69. She saw Dr. Alampur and was referred to Dr. Sadiq, a neurologist in NYC, who diagnosed her with MS post-hepatitis B vaccine. She continued having nausea, vertigo, and joint aches. Dr. Righi diagnosed petitioner with viral bronchitis. *Id.*

On April 20, 2000, petitioner saw Dr. Burton A. Waisbren. Med. recs. at Ex. 6, p. 23. He diagnosed her with post-hepatitis B vaccinal-acquired autoimmunity affecting myelin and joints which he called "multiple antigenic-mediated autoimmunity." Med. recs. at Ex. 6, p. 27. He prescribed Copaxin, Valtrex, Doxycycline, and gamma globulin, stating he did not know if they would help, but did not feel they would be dangerous to petitioner. *Id.* Petitioner's test for antinuclear antibodies (ANA) was less than 1:40, which is negative. Med. recs. at Ex. 6, p. 36. Her IgA, IgM, IgG, and IgE were all normal. Med. recs. at Ex. 6, p. 38. Her test result for Epstein Barr virus was 4.8 when the normal range is 0.0 to 0.9. Med. recs. at Ex. 6, p. 40.

On April 24, 2000, Dr. Waisbren wrote to petitioner that he would help her in any way he could with her claim for compensation. Med. recs. at Ex. 6, p. 18. He stated that hepatitis B caused petitioner to suffer a demyelinating disease. Med. recs. at Ex. 6, p. 20.

On May 19, 2000, Dr. Waisbren sent petitioner a letter stating she had antibodies to Epstein-Barr virus and mycoplasma bacteria. Med. recs. at Ex. 6, p. 22.

On May 23, 2000, Dr. Waisbren wrote a letter to petitioner's counsel, encouraging litigation against the US for hepatitis B vaccine-caused MS. Med. recs. at Ex. 6, p. 13.

On April 30, 2001, petitioner saw Dr. Michael Jaworski for a follow-up of a motor vehicle accident she was involved in the day before. Med. recs. at Ex. 5, p. 71. She was rearended and denied paresthesias, muscle weakness, headache, or visual disturbances. She complained of mild discomfort and dull achiness to the lateral side of her neck on the left. He advised moist heat. Her upper extremities muscle strength was 5/5 bilaterally. Sensorily, she was intact to light touch. She did not have paresthesias. *Id.*

## **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 (6<sup>th</sup> 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. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute reaction, would be a few days to three to four weeks. *Id.* at \*18. In the instant action, petitioner's onset of TM was either days or one month, which fits well within the appropriate temporal time frame for a vaccine reaction.

The Federal Circuit in Capizzano emphasized the importance of the opinions of treating physicians. In Capizzano, four of Mrs. Capizzano's treating physicians viewed her rheumatoid arthritis as caused by hepatitis B vaccine. 440 F.3d at 1326. In the instant action, three of petitioner's treating physicians opined that her MS was caused by hepatitis B vaccine.

As the undersigned stated at the beginning of this Order, petitioner's symptoms do vary according to the histories she gave to numerous doctors. Dr. Waisbren is a well-known advocate

for causation from hepatitis B vaccine. What seems most bewildering in this case is that, although petitioner has an abnormal brain MRI which depicts lesions consistent with MS, her medical examinations are normal neurologically. She claims weakness, but she has maximum strength. She has never had visual problems. She has no sensory deficit and no delay in nerve conductivity. In light of her severe allergies and her active Epstein-Barr virus, the undersigned wonders if petitioner had any reaction to hepatitis B vaccine, or if those reactions do not constitute neurologic manifestations of her MS and did not last for more than six months. However, the opinions of the treating doctors do make a prima facie case for causation in fact.

Respondent is ORDERED TO SHOW CAUSE why this case should not proceed to damages by **August 31, 2007**.

**IT IS SO ORDERED.**

June 8, 2007  
DATE

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