In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. [redacted]V
July 20, 2009
To be Published
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JANE DOE/41,	*	
	*	
Petitioner,	*	
	*	
v.	*	Entitlement: Hep B vaccination;
	*	11 days later, optic neuritis; MS;
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	was psoriasis the cause of neuritis
	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner.
Alexis B. Babcock, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition dated February 14, 2003, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on October 8, 2000 caused her optic neuritis, a demyelinating disease. Petition at ¶¶ 5 and 6.

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. On August 4, 2009, petitioner moved to redact her name from this case. The undersigned grants the motion.

Petitioner in her affidavit states that this hepatitis B vaccine was administered on September 26, 2000. Med. recs. at Ex. 1.

The medical records show that the onset of her optic neuritis was October 7, 2000, 11 days after her third hepatitis B vaccination, when she had diminished vision in the lower field of her right eye. Although initial examinations of petitioner showed nothing abnormal on MRI, she was ultimately diagnosed with optic neuritis. Eventually, she was diagnosed with multiple sclerosis (MS) because of a subsequent episode of optic neuritis, this time in her left eye, one year after her first episode.

On February 14, 2003, the chief special master assigned this case to himself.

On March 7, 2003, this case for some unknown reason received a notice from the Omnibus Autism Proceeding to stay the case.

On March 14, 2003, the chief special master stayed proceedings in this case until resolution of causation in an omnibus proceeding on hepatitis B vaccine causing demyelinating injuries.

On May 7, 2003, the chief special master transferred this and 36 other demyelinating cases alleging causation from hepatitis B vaccine to former special master Margaret M. Sweeney.

On November 7, 2003, petitioner moved to obtain authority to issue subpoenas in this case to obtain medical records. Petitioner had not filed any medical records since she filed her petition.

On January 6, 2004, former special master Sweeney issued an order concerning the Omnibus hepatitis B vaccine-demyelinating diseases proceeding and the designation of four

cases (not the instant action) to represent four demyelinating diseases at issue: transverse myelitis (TM), Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating disease (CIDP), and multiple sclerosis (MS). There were 65 cases encompassed within the Omnibus proceedings.

The Omnibus proceeding was held before former special master Sweeney from October 13-15, 2004. At the end of 2005, former special master Sweeney left to become a judge on the United States Court of Federal Claims.

On January 11, 2006, the chief special master transferred the instant action and all the 65 hepatitis B vaccine-demyelinating disease cases that were part of the Omnibus proceeding to the undersigned.

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

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

On June 18, 2007, the undersigned issued an Order to Show Cause for respondent to show cause why this case should not be in damages.

On September 14, 2007, respondent filed an opposition with an expert report by Dr. Mitchell S. Fineman, a retinal surgeon, stating that psoriasis, not hepatitis B vaccine, caused petitioner's optic neuritis. Ex. A.

On February 13, 2009, petitioner filed a supplemental report by Dr. Carlo Tornatore, a neurologist, responding to Dr. Fineman's expert report. Ex. 31. Dr. Tornatore states that psoriasis is not a cause of MS. *Id.* at 1. He also states that no one can tell from the medical records whether petitioner had subclinical optic neuritis prior to her third hepatitis B vaccination. *Id.* at 2. In addition, "the optic neuropathy associated with psoriasis is one of indolent change in the physiology of the optic nerve as opposed to acute visual loss seen with optic neuritis. The tempo of the visual changes of [petitioner's] case is [sic] much more typical of acute demyelination vs. that of indolent physiologic changes of the optic nerve." *Id.* Finally, Dr. Tornatore states that if petitioner did have subclinical optic neuritis prior to her third hepatitis B vaccination, the vaccine was a substantial factor in causing her acute optic neuritis and MS. *Id.*

A hearing was held on February 18, 2009. Testifying for petitioner were her daughter, petitioner, and Dr. Tornatore. Testifying for respondent was Dr. Fineman.

FACTS

Petitioner was born on November 11, 1948.

On February 21, 2000, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 10, p. 3.

On March 21, 2000, petitioner received her second hepatitis B vaccination. *Id.*

On September 26, 2000, petitioner received her third hepatitis B vaccination. Med. recs. at Ex. 10, p. 4.

On October 11, 2000, petitioner saw Dr. Leon A. Bynoe, a specialist in the retina and vitreous. Med. recs. at Ex. 11, p. 12. Petitioner noticed an inferior field defect in her right eye for the prior four days. She denied any ocular pain, flashers, or floaters. *Id.* Dr. Bynoe's impression was optic neuropathy of the right eye, possible sectoral anterior ischemic right eye, and lattice degeneration of the left eye. He strongly suspected it was an ischemic optic neuropathy which involved only a small segment of the optic nerve head. Med. recs. at Ex. 11, p. 13.

On October 24, 2000, petitioner saw Dr. Gary Hopen, stating her inferior visual field was in shadow on October 7, 2000. She saw her optometrist, Mark Goldberg. Med. recs. at Ex. 11, p. 3. There was no definite change since then. *Id.*

On October 25, 2000, Dr. Hopen wrote a letter to Dr. Leon A, Bynoe. Med. recs. at Ex. 10, p. 9. Petitioner had a swollen right optic nerve that could represent either an anterior ischemic optic neuropathy or papillitis from optic neuritis. Med. recs. at Ex. 10, p. 10. Dr. Hopen could not distinguish between the two diagnoses in petitioner. *Id.* Dr. Hopen expressed the view that petitioner's "psoriasis does not seem severe enough to be a likely etiology." *Id.* Dr. Hopen states at the bottom of this record that, although petitioner had found internet information of a "questionable association [of hepatitis B vaccine] with MS and nerve inflammation," he regarded this as one more unprovable item to add to the list of etiologies. *Id.*

On October 25, 2000, petitioner had an MRI of the brain and orbits with and without gadolinium. Med. recs. at Ex. 11, p. 6. The MRI was unremarkable. *Id.*

On October 31, 2000, petitioner saw Dr. Daniel Kan, a neurologist. Med. recs. at Ex. 10, p. 6. On October 7, 2000, petitioner developed a shadow of the right lower field which had been constant and getting worse. An MRI of her brain with gadolinium was unremarkable. *Id.*

On November 10, 2000, petitioner had an MRA (magnetic resonance angiography) of the brain. Med. recs. at Ex. 11, p. 26. Dr. Joseph Kozlowski's impression was marked decreased identifiable flow in the A1 segment of the right anterior cerebral artery. That could represent normal variant hypoplasia or a marked stenosis. *Id.* Otherwise, the MRA was unremarkable. Med. recs. at Ex. 11, p. 27.

On November 15, 2000, petitioner saw Dr. Joel S. Glaser, a neuro-ophthalmologist, telling him that she awoke on the morning of October 7, 2000 with a sensation of diminished vision in the lower field of her right eye. She saw Dr. Gary Hopen on October 24, 2000, who recorded right eye vision of 20/25 +2, with an inferior altitudinal field defect and afferent pupil. Med. recs. at Ex. 9, p. 64. A neurologist saw her but made no specific neurologic findings. She was otherwise well. *Id.* The MRI showed no defects, but there was no FLAIR sequence for white matter disease. Med. recs. at Ex. 9, p. 65.

On April 11, 2001, petitioner had another MRA of her brain done. Med. recs. at Ex. 11, p. 9. Dr. Joseph Kozlowski's impression was that there was a lack of identifiable flow in the A1 segment of the right anterior cerebral artery, most compatible with hypoplasia (normal variant). Otherwise, it was an unremarkable MRA of the circle of Willis and vertebrobasilar system. *Id.*

Also on April 11, 2001, petitioner had another brain MRI done with and without contrast. Med. recs. at Ex. 13, p. 6. Dr. Joseph Kozlowski's impression was mild nonspecific bilateral white matter disease. Med. recs. at Ex. 13, p. 7. An additional FLAIR sagittal sequence was

performed. Med. recs. at Ex. 13, p. 6. There were scattered foci of hyperintense T2 and FLAIR signal in the white matter bilaterally, involving the periventricular, deep, and subcortical white matter. These white matter lesions were indeterminate. The differential diagnosis included MS, a vasculitis, and mild chronic small vessel ischemic disease. *Id.* Petitioner also had a mildly asymmetric enhancement in the left cerebral hemisphere, most likely representative of a normal variant of a prominent blood vessel or venous angioma. Med. recs. at Ex. 13, p. 7.

On March 12, 2002, April 15, 2002, and August 14, 2003, Dr. Joel Glaser wrote notes that petitioner had bilateral optic neuritis. Med. recs. at Ex. 9, pp. 6, 7, and 21.

Other Submitted Materials

Petitioner filed an article entitled "Vaccinations and multiple sclerosis" by O. Gout, 22 Neurol Sci 151-54 (2001). Gout admits that epidemiologic studies have not demonstrated that hepatitis B vaccine causes MS, but it "could be a triggering factor in susceptible individuals in the same manner as infections." *Id.* at 153. Gout posits three possible pathogenic mechanisms: (1) molecular mimicry between hepatitis B vaccine proteins and myelin components; (2) indirect immunologic stimulation by the large quantity of exogenous hepatitis B surface antigen; and (3) direct or indirect immunologic toxicity of vaccine contaminants. *Id.* Ex. 22.

Petitioner filed an article entitled "A study of molecular mimicry and immunological cross-reactivity between hepatitis B surface antigen and myelin mimics" by D-P Bogdanos, et al., 12 Clinical & Developmental Immunology 3:217-24 (Sept. 2005), as exhibit 28. The authors found that people who received hepatitis B vaccine were more likely to have reactivity to at least one of the small hepatitis B virus surface antigens than controls did. However, none of the

vaccinees reported symptoms of demyelinating disorders and most lost their cross-reactivity at six months after vaccination. Ex. 24.

Petitioner filed 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). Ex. 29. The authors represent the International Panel on MS Diagnosis and presented revised diagnostic criteria for MS. *Id.* at 121. Their focus was "on the objective demonstration of dissemination of lesions in both time and space." *Id.* They begin the article by stating, "Because no single clinical feature or diagnostic test is sufficient for the diagnosis of multiple sclerosis (MS), diagnostic criteria have included a combination of both clinical and paraclinical studies." *Id.* The last formal review of criteria for MS diagnosis was in 1982.

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

To diagnose MS, the authors state that there must be dissemination of lesions both in space and in time. *Id.* at 125. "[I]f MRI tests are not performed, the occurrence of a second clinical attack implicating a different site will fulfill criteria for dissemination in time and

space." *Id.* The Panel states in conclusion, "The International Panel on MS Diagnostic Criteria built upon diagnostic recommendations for MS that have served the community well for decades." *Id.* at 126.

Petitioner filed an article entitled "Multiple sclerosis and chronic inflammatory diseases. A case-control study" by R. Midgard, et al., 93 Acta Neurol Scand 322-28 (1996). Ex. 33. The authors studied 155 MS patients and 200 controls to learn if there were a statistically significant coexistence of MS with other autoimmune diseases. *Id.* at 322, 323. They found 12 cases of psoriasis among 12 MS patients compared to eight cases of psoriasis among controls. *Id.* at 324. However, in first-degree relatives of MS patients and controls, there was almost double the cases of psoriasis in control families (23) than in MS families (12). *Id.* The authors concluded that in a relatively small cohort of MS patients, it was not unusual to find MS patients with a coexistent autoimmune disorder. *Id.* at 325. In the families of MS patients, there was a significantly lower prevalence of psoriasis not only compared to the control families but also to the general population. *Id.*

Respondent filed an article entitled "Visual evoked potentials in patients with psoriasis vulgaris" by A. Grzybowski, et al., 103 Documenta Ophthalmologica 187-94 (2001). Attachment 1 of Ex. C. The authors state that patients with psoriasis have an increased risk of MS development, although psoriasis occurs significantly more rarely in families which suffer from MS compared to healthy families. *Id.* at 188. The authors found in the medical literature only a few reports on central nervous system function in the course of psoriasis. *Id.*

Respondent filed an article entitled "Pattern VEP alterations in psoriatic patients may indicate a sub clinic [sic] optic neuritis" by M. Perossini, et al., 110 Documenta

Ophthalmologica 203-07 (2005). Attachment 2 of Ex. C. The authors performed visual evoked potentials (VEP) on a group of 44 patients with psoriasis and found subclinical optic neuritis with a probable toxic autoimmune origin due to tumor necrosis factor alpha (TNFα) in 77.3% of them. *Id.* at 204, 206.

Respondent filed an article entitled "Clinical study. The Occurrence of Autoimmune Diseases in Patients with Multiple Sclerosis and Their Families" by R.D. Henderson, et al., 7 Journal of Clinical Neuroscience 5:434-37 (2000). Attachment 3 of Ex. C. Recognizing that MS is an autoimmune disease, the authors set out to determine if MS patients had a higher incidence of other autoimmune diseases. Of 11 autoimmune diseases about which the authors asked the patients, one of them was psoriasis. Respondent's pagination at page 4. There were 117 cases of MS patients and 221 controls in the study. *Id.* In Table 3, the authors list how many MS patients had psoriasis vs. how many controls. There were six MS patients with psoriasis and seven controls with psoriasis. Page 5. The authors note "there was no excess of inflammatory bowel disease or psoriasis" among MS patients. *Id.* In other words, there was almost the same number of psoriasis cases whether someone had MS or not, with a small predominance of psoriasis among controls. In Table 4, the authors list the number of first-degree relatives of MS patients with psoriasis vs. the number of first-degree relatives of controls. There were nine first-degree relatives of MS patients with psoriasis and 17 first-degree relatives of controls with psoriasis. Page 6. In other words, there was almost double the cases of psoriasis among first-degree relatives of those without MS compared to first-degree relatives of those with MS.

TESTIMONY

Petitioner's daughter testified first. Tr. at 7. She testified about the effect of optic neuritis on her mother's life.

Petitioner testified next. Tr. at 21. She testified that she has had psoriasis for at least 25 years. Tr. at 24. It has always been under control with topical cortisone creams. Tr. at 25. It affects basically her elbows, scalp, and hands. *Id.* Petitioner opined that her psoriasis is mild to moderate. Tr. at 26. She treats flare-ups with cortisone, and it has never become severe. *Id.* Currently, she is being treated with UV light. *Id.* She recounted her experience with optic neuritis and how it affected her professionally and personally. Right now she is stable. Tr. at 45.

Dr. Carlo Tornatore testified next for petitioner. Tr. at 51. He is the director of the MS Center at Georgetown. Tr. at 52-53. The Center follows 2,000 patients. Tr. at 53. He has had many patients with optic neuritis. Tr. at 54. Probably 40 to 50 percent of the MS Center's patients have optic neuritis or vision problems. *Id.* Petitioner in the instant case had optic neuritis and her brain MRI showed a few lesions, indicating inflammation elsewhere. That means petitioner has MS. Tr. at 55, 56.

Very few of Dr. Tornatore's MS Center patients have psoriasis. Tr. at 58. Based on the McDonald criteria which petitioner filed as Ex. 29, petitioner meets the criteria for MS because she had two separate episodes of optic neuritis in each eye and she has an MRI showing dissemination of lesions in space. Tr. at 60.

Dr. Tornatore's opinion is that hepatitis B vaccine caused petitioner's first episode of optic neuritis and then subsequent episodes of optic neuritis. *Id.* He thought all three vaccinations were contributory. The first two primed petitioner's immune system and the third vaccination was the stimulus leading to the demyelinating event. Tr. at 61. Eleven days after

her third hepatitis B vaccination, petitioner had optic neuritis in her right eye. Her doctor, Dr. Hopen felt that petitioner's psoriasis did not seem severe enough to be the cause. Tr. at 65. Her brain MRI showed just one spot. Tr. at 66. The reason that petitioner's psoriasis had nothing to do with her right optic neuritis is that when people such as Grzybowski (Ex. C, attachment 1) tested the visual evoked responses of persons with psoriasis, both eyes, not just one, were affected. Tr. at 70-71. In petitioner's case, only her right eye had optic neuritis after the third hepatitis B vaccine while the visual evoked response in her left eye was perfect. Tr. at 71-72. You cannot say therefore that psoriasis affected petitioner's optic nerves. Tr. at 72. The same is true for petitioner's eyes' amplitude. The right eye was affected, but the left was not. In the Grzybowski article, however, both eyes in the psoriasis group were affected. *Id.*

When petitioner had a subsequent brain MRI on April 11, 2001, it showed scattered foci of hyperintensive T2 and FLAIR signal in the white matter bilaterally. Tr. at 76. This MRI tells us clearly there is dissemination of the lesions. Tr. at 70. Then, in November 2001, petitioner had her second episode of optic neuritis in the other eye. *Id.* An MRI showed enhancement of the left optic nerve. Tr. at 81.

As for the cause of petitioner's optic neuritis and MS, Dr. Tornatore stated that it was not psoriasis because petitioner's left eye was initially normal and psoriasis does not cause clinical visual loss. Tr. at 84. With psoriasis, you would not get acute optic neuritis and sudden loss of vision as petitioner did on two occasions. *Id.* Animal experimentation leading to experimental allergic encephalitis or EAE, which is a model of MS, begins with vaccinating the animals with myelin basic protein or myelin-associated glycoprotein. Tr. at 85. Bogdanos in the study that is exhibit 24 said that hepatitis B vaccine, which is basically a protein, cross-reacted with myelin

basic protein. Tr. at 85-86. This study shows it is biologically plausible for hepatitis B vaccine, just as in EAE, to induce demyelination. Tr. at 86. A number of subsequent articles report a higher incidence of MS among hepatitis B vaccinees compared to controls. *Id.*

There is also a logical sequence of cause and effect here and 11 days is appropriate medical timing for causation. Tr. at 87, 88. Petitioner had two previous vaccinations, priming her immune system, and after the third vaccination, the white blood cells were stimulated and caused inflammation. Tr. at 87. The logical sequence of cause and effect is that when the vaccine stimulated petitioner's immune response, it was directed at petitioner's brain inadvertently, causing her optic neuritis. Tr. at 88. The white blood cells did not go away and she continued to have inflammation, MRI changes, and another episode of optic neuritis in November 2001. *Id.* Dr. Tornatore stated that if petitioner had not received hepatitis B vaccine, she would not have had optic neuritis. *Id.* There was no other reason than the vaccine for her to develop optic neuritis, the vaccine was a clear precipitating cause, and psoriasis was not the cause because the visual evoked response of petitioner's left eye was initially normal. Tr. at 88-89.

Dr. Tornatore stated that psoriasis in and of itself or the immune response that causes psoriasis does not cause MS because if one treats psoriasis with tumor necrosis factor alpha (TNFα), people develop demyelination although their psoriasis gets better. Tr. at 98-99. The thinking is that the immune system is making tumor necrosis factor which causes psoriasis, and if you can block this chemical, you block the immune system's irritation of the skin, and the psoriasis plaque gets better. Tr. at 99. But using anti-tumor necrosis factor agents worsen MS. Tr. at 99-100. This means psoriasis is different than MS and, if you try to treat psoriasis, you

can cause MS. If psoriasis caused MS, when we treat psoriasis, people would not have MS outbreaks but would get better. Doctors never use the drugs that treat psoriasis to treat MS. Tr. at 100.

Petitioner received oral steroids in December 2000 after her first episode of optic neuritis and oral steroids are known to lead more likely to a second attack compared to IV steroids. Tr. at 101-02. Dr. Tornatore said petitioner's receipt of oral steroids may have led to her second attack, but did not cause the increase of petitioner's changes on brain MRI in April 2001. Tr. at 102. She had her first spot on brain MRI before she ever received oral steroids. *Id.*

Dr. Tornatore agreed that people with psoriasis are more likely to have MS than people without psoriasis, but people with MS are less likely to have psoriasis. Tr. at 108-09. Psoriasis is more specific in its triggers than MS. Tr. at 109. The immune system is an incredibly complicated network of cells, anywhere between 50 to 100 different white blood cells all interacting with one another. Tr. at 110. The article respondent submitted saying that psoriasis can affect the optic nerves subclinically does not say psoriasis causes acute optic neuritis. Tr. at 113. Psoriasis does not cause an acute clinical optic problem. Tr. at 114.

Dr. Mitchell Fineman, an ophthalmologist, testified for respondent. Tr. at 116, 117. His practice is limited to the retina and uveitis, involving patients with macular degeneration, diabetic retinopathy, infectious causes of retinal disease, and retinal detachment. Tr. at 117-18. He often diagnoses patients with optic neuritis, but he does not manage or treat them because it is a neuro-ophthalmologic disease. Tr. at 118. He refers patients with optic neuritis to a neuro-ophthalmologist. *Id.* He has also had patients with psoriasis. *Id.* Psoriasis does not play a significant role in the retinal diseases in which he specializes. Tr. at 118-19.

His opinion is that hepatitis B vaccine did not cause petitioner's optic neuritis. Tr. at 120. Petitioner should not have been treated with oral Prednisone because it is associated with a higher risk of developing MS and is contraindicated for optic neuritis. Tr. at 121. Intravenous steroids are the appropriate treatment. Tr. at 122. He agrees that petitioner has MS. *Id.* His opinion is that petitioner's 25-year history of psoriasis contributed to her optic neuritis and MS. Tr. at 124. People with a pre-existing autoimmune disease, including psoriasis, are at higher risk of developing MS. Tr. at 126. He thinks petitioner's psoriasis, by increasing her risk of MS, caused her four abnormal foci on her second brain MRI. Tr. at 127. He does not think that psoriasis itself causes it, but it increases the risk for developing MS via whatever genetic immunologic factors bind psoriasis and MS. *Id.*

Dr. Fineman agreed with the statement that someone at risk for having autoimmune diseases will have more than one autoimmune disease. He prefers that statement to the statement that once someone has one autoimmune disease, that disease in itself increases his risk of having another one. Tr. at 128-29. The fact that petitioner has psoriasis made her more likely to develop MS. Tr. at 130. Patients with psoriasis show signs of optic nerve dysfunction and optic neuritis on physiologic testing. *Id.*

Dr. Fineman agreed that the two episodes of acute optic neuritis that petitioner experienced in which her vision acutely dropped are not the type of optic neuritis associated with psoriasis. Tr. at 132. Although Dr. Fineman saw occasions of indolent changes of vision in petitioner's eyes due to psoriasis between and after her two cases of acute optic neuritis, he admitted that she did have acute onsets of optic neuritis. Tr. at 135. His opinion is that petitioner had an underlying optic neuritis (due to the psoriasis) and superimposed on that were

her acute episodes related to MS. *Id.* One does not see acute optic neuritis related to psoriasis. Tr. at 136. He attributed petitioner's vision deterioration in 2003 to psoriasis because her July 9, 2003 brain MRI showed no increase in demyelination. Tt. at 140. Dr. Tornatore disagreed, stating that someone with acute optic neuritis can have a worsening of vision without evidence of enhanced demyelination of the optic nerves. Tr. at 143. For 25 years, petitioner's psoriasis had never affected her eyes. *Id.* Dr. Fineman stated that, once petitioner had MS, she might be much more sensitive to any subactive changes now that her optic nerves were compromised and this low-grade optic neuritis is associated with psoriasis. Tr. at 144.

Dr. Fineman's opinion is that there is no link between hepatitis B vaccine and MS, based on his review of the medical literature, specifically the Institute of Medicines report on neurologic demyelinating diseases. Tr. at 146. Dr. Fineman does not believe that MS is triggered. Tr. at 150. He believes that although psoriasis did not cause either of petitioner's acute episodes of optic neuritis, now that she has vision difficulties due to MS, her psoriasis is worsening her vision. Tr. at 150-51. Dr. Fineman is not a neurologist, immunologist, or epidemiologist, and he does not treat MS. Tr. at 152. He has never treated psoriasis. Tr. at 153. He agrees that MS is an autoimmune disease. *Id.* He said there is no known cause of MS. Tr. at 155.

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, 956 F.2d 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 optic neuritis and MS, but also that the vaccine was a substantial factor in bringing about her optic neuritis and MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). In Shyface,

Optic neuritis is not one of the demyelinating illnesses making up the four paradigmatic cases discussed in the Omnibus proceeding on hepatitis B vaccine and demyelinating disease. However, it is not unusual for the onset of multiple sclerosis to include optic neuritis. In this case, both experts agreed that petitioner has MS, based on the dissemination of lesions over time and space.

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. Here, petitioner's onset was 11 days after her third hepatitis B vaccination, fitting within the appropriate time frame for medical causation.

The only reason for having this hearing was to explore respondent's defense that petitioner's psoriasis, another autoimmune disease, was the cause of her MS. However, at the hearing, this position was further nuanced because Dr. Mitchell Fineman, respondent's expert retinal specialist, testified that psoriasis would not cause acute optic neuritis, just an indolent form. Dr. Tornatore, petitioner's expert neurologist, testified that after petitioner's first episode of acute optic neuritis, she had visual evoked potentials (VEPs) done on each eye. The right eye which was causing her visual problems had an abnormal VEP. The left eye's VEP was normal. Dr. Tornatore stated that if psoriasis were causing her optic problem, it should have occurred in both eyes. Dr. Fineman did not rebut this testimony.

For the 25 years pre-vaccination that petitioner has had psoriasis, she never had visual problems. Eleven days after her third hepatitis B vaccination, she experienced acute optic neuritis in her right eye, followed one year later with acute optic neuritis in her left eye. Dr. Fineman admitted on the witness stand that psoriasis would not cause either of these episodes. His view was that having developed MS, petitioner's eyes were now more sensitized to the affects of psoriasis and her other visual problems were due to psoriasis. Frankly, if hepatitis B

vaccine caused petitioner's optic neuritis and MS, then the sequelae of her vaccine injury includes sensitizing her eyes to the effects, if any, of psoriasis.

The Federal Circuit in Capizzano emphasized the special masters' taking into serious consideration the opinions of treating doctors. 440 F.3d at 1326. The undersigned thus takes seriously the treating physician Dr. Hopen's opinion on October 25, 2000 that petitioner's "psoriasis does not seem severe enough to be a likely etiology [of her acute optic neuritis]." But in light of Dr. Fineman's testimony that psoriasis does not cause acute optic neuritis (consistent with Dr. Tornatore's testimony) and did not cause petitioner's acute optic neuritis episodes, the undersigned does not need to rely on Dr. Hopen's opinion.

The medical literature that both parties supplied and the expert testimony confirms states that people with an autoimmune disease tend to develop other autoimmune diseases. As Dr. Fineman testified, that does not mean that one autoimmune disease causes the other autoimmune disease. Thus, in this case, neither expert believed that petitioner's psoriasis caused her MS. The undersigned therefore rejects that psoriasis played any causal role in petitioner's acute optic neuritis and MS. The medical literature is not in agreement over whether someone with MS has less or more of a likelihood of having psoriasis. In light of psoriasis not being a cause of MS, it does not matter in the instant action whether someone with MS has more of less of a risk of psoriasis or whether someone with psoriasis has more or less of a risk of MS. That petitioner was more susceptible to the effects of immune stimuli due to her already having an autoimmune disease does not make her less suited for recovery of compensation. Rather, it just reinforces in this unusual case that she is more suited for recovery of compensation because she was more vulnerable to the effects of an immune stimulus.

Petitioner's initial brain MRI showed a spot and her subsequent brain MRI showed four spots, confirming her diagnosis of MS. That she received the contraindicated oral Prednisone in between these MRIs does not negate that she already had had one episode of acute optic neuritis and one brain MRI with a spot and, therefore, the undersigned does not see any causal role for the oral steroid in worsening petitioner's condition. In the tort world, if defendant's wrongful action caused plaintiff to be subsequently malpracticed, that malpractice would be foreseeable, defendant would be liable for all damages stemming from his negligence, and defendant could then sue the malpracticing doctor to recover damages due to the malpractice. This principle applies under the Vaccine Program in respondent's right of subrogation. 42 U.S.C. §300aa-17. If hepatitis B vaccine caused petitioner's acute optic neuritis and MS, any sequelae due to improper medical practice (the administration of oral Prednisone) does not negate the initial causation and petitioner's entitlement to compensation. Respondent may sue the medical treaters under the right of subrogation in §300aa-17 of the Act if respondent wants to recover any damages for sequelae presumably due to the administration of oral Prednisone to petitioner.

The undersigned is left with no defense from respondent's expert except that vaccines do not cause MS. The undersigned has held otherwise in the Omnibus proceeding paradigm case Werderitsh and subsequent cases. As Dr. Tornatore testified, there is a biologically plausible medical theory here in that petitioner's white cells interpreted the hepatitis B surface antigen as having some similarity to brain tissue and proceeded to attack the tissue. There is a logical sequence of cause and effect in that petitioner's receipt of her first two vaccinations primed her immune system, and the third vaccination in effect pushed her over the immunologic edge. And there is an appropriate medical interval between vaccination and injury. Dr. Tornatore also

testified that without the hepatitis B vaccinations, petitioner would not have had optic neuritis and MS. Respondent's expert's complaint that there are no epidemiologic studies to support that hepatitis B vaccine causes MS does not legally stop petitioner from prevailing once petitioner has satisfied the three prongs of Althen. The Federal Circuit has expressly stated that petitioner may prevail without epidemiologic support. Knudsen, Althen, Capizzano.

Petitioner has prevailed in proving that hepatitis B vaccine caused her optic neuritis and MS.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and will set up a status conference soon to discuss further proceedings in this case.

IT IS SO ORDERED.

July 20, 2009
DATE

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