

Although initially, petitioner's doctors considered whether or not petitioner had a demyelinating condition, his neurologist Dr. McCormick ultimately diagnosed him as having a stroke, possibly caused by hepatitis vaccine.

FACTS

Petitioner was born on August 20, 1950.

Petitioner has a history of papilledema¹ dating from before the vaccinations. On August 8, 1989, seven years before the vaccinations at issue, petitioner saw Dr. Hugh L. Jones. Med. recs. at Ex. 3, p. 2. Petitioner had a pain in the left side of his neck which he had had three years previously. He saw Dr. Stauffer and received antibiotics. His neck got better, but he was referred to Dr. Seltzer who referred him to a neurologist, Dr. Warsett, who thought petitioner had papilledema and put petitioner in the hospital for a week. Papilledema was there even as late as 1989. He had been asymptomatic until he developed pain again. On physical examination, petitioner's eye grounds did not look normal. He had rather poor contrast, suggestive of mild papilledema. It looked like he had venous pulsations. *Id.*

On November 29, 1993, petitioner was diagnosed with arthritis, CVA (cerebrovascular accident or stroke) with visual loss. Med. recs. at Ex. 3, p. 2.

Petitioner alleges his first hepatitis B vaccination was on September 1996 and his second on October 8, 1996. On October 25, 1996, petitioner went to the ER at the Bert Fish Medical Center, complaining of a headache which started one week before (or October 18, 1996). Dr. Choi saw him the prior Friday and told him it was probably a sinus infection. Med. recs. at Ex.

¹ Papilledema is "edema of the optic disk (papilla), most commonly due to increased intracranial pressure, malignant hypertension, or thrombosis of the central retinal vein; called also *choked disk*." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1359.

15, p. 1. His headache worsened on October 24, 1996. He had intermittent blurred vision. The headache was not constant until noon on October 24th. He had dots in his visual field. He said he had a past history of papilledema and pseudotumor cerebri.² On examination, his visual acuity was 20/15 in his left eye and 20/20 in his right eye. There was slight blurring of the disk. *Id.*

On October 25, 1996, petitioner told the examiner that he could only see the largest letters on an eye chart with his glasses on. *Mec. recs. at Ex. 15, p. 2.*

On October 25, 1996, petitioner had a CT scan of his head with and without IV contrast. It was normal. There were no lesions. The ocular globes, optic nerves, and extraocular muscles were bilaterally symmetrical and unremarkable. *Med. res. at Ex. 15, p. 3.*

On October 27, 1996, petitioner went to Halifax Medical Center ER. *Med. recs. at Ex. 16, p. 1.* He complained of a headache for one week with pain in the right temporal area. *Id.* Dr. Robert Frost saw petitioner on that date and diagnosed cephalgia³ probably carotodynia.⁴ In the past, when petitioner had a headache and neck ache, he was diagnosed with inflammation of the carotid artery. His sed rate was 20. His pupils were equal, round, and reactive to light. *Id.* Petitioner was given Motrin. *Id.*

² Pseudotumor cerebri is “a condition caused by venous sinus occlusion and cerebral edema associated with a number of pathologic conditions, marked by raised intracranial pressure with normal cerebrospinal fluid, headache, nausea, vomiting, and papilledema, but without neurological signs except for occasional abducens paralysis. Called also *benign intracranial hypertension*.” Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 1537.

³ Cephalgia is a headache. Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 333.

⁴ Carotodynia or carotidynia is “episodic, usually unilateral neck pain with tenderness along the course of the common carotid artery.” Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 300.

On October 28, 1996, petitioner saw Dr. Edward McDonough. Med. recs. at Ex. 17, p. 1. Petitioner had right-sided headaches that began several days earlier in the right temporal area, but also involved the right side of his face and up into his right ear. He had some increased nasal congestion, difficulty breathing through the right side of his nose, and a blocked feeling in his right ear. He had some sinus symptoms and problems in the past, but was never treated or x-rayed. He did not have significant headaches in the past but was diagnosed with a pseudotumor at one time. On examination, the right ear drum was intact, but somewhat dull with decreased aeration of the middle ear. Nasal mucous was somewhat congested. The right airway was poor even after topical decongestion. There were some thick secretions in the nose. Dr. McDonough diagnosed a right-sided sinus infection. He did not know if this was the cause of the headache. He prescribed Augmentin, Medrol Dosepak, Vancenase AQ, and Vicodin. He recommended a CT scan of petitioner's sinuses. *Id.*

On October 30, 1996, petitioner had a CT of his paranasal sinuses. Med. recs. at Ex. 17, p. 2. He had slight deviation of the nasal septum to the right. Dr. Alan J. Stern's impression was minimal anterior ethmoid sinusitis, mild mucosal thickening in the nasal cavity, possibly on an allergic basis, and partial concha bullosa on the right. Otherwise, this was an unremarkable CT scan of the paranasal sinuses. *Id.*

On October 30, 1996, petitioner saw Dr. Daniel F. Miller, an ophthalmologist. Med. recs. at Ex. 19, p. 1. Two weeks earlier, petitioner had severe pain in his left eye and loss of visual acuity. He said he could not make out facial features. Dr. Miller did not see SVP (spontaneous venous pulse) in either eye. *Id.* Petitioner's symptoms began with visual acuity and dots. He had a sensation of euphoria. Since the prior week, he had worse visual acuity, but that day, it

was slightly better. Ten years before, he was diagnosed with cerebral pseudotumor and papilledema, but they were not the same symptoms, he said. Med. recs. at Ex. 19, p. 3.

On October 31, 1996, petitioner saw Dr. Miller again. *Id.* On a test of seeing color plates, he missed 10 of them on the right and 11 of them on the left. Dr. Miller diagnosed optic neuropathy. He ordered an MRI of the brain and optic nerves with contrast. *Id.*

On November 5, 1996, petitioner had an MRI of the brain and orbits with and without contrast. Med. res. Ex. 20, p. 2. There was a 22 x 22 x 12 mm. lesion in the right splenium of the corpus callosum accounting for slight effacement of the posterior horn of the right lateral ventricle. A similar area involved the subcortical white matter of the right inferior occipital lobe. A third abnormality was a confluent sheet-like area of intense post-gadolinium contrast-enhancement involving the inferomedial right temporal lobe including the hippocampus, parahippocampal gyrus, and the lateral occipito-temporal gyrus. This communicated with areas of patchy and somewhat plaque-like enhancement along the right medial margin of the tentorium, involving the right posterior temporal and medial occipital lobes generally corresponding to the distribution of the right optic radiation and the inferior lip of the right visual cortex. There were some prominent vascular structures that also enhanced in this region. There was striking absence of mass effect or midline shift. A prominent draining venous angioma⁵ was over the right hemisphere at the occipito-temporoparietal junction. There were no abnormal left-sided enhancing lesions. The orbits were unremarkable. *Id.*

⁵ A venous angioma of the brain is a “congenital angioma of the brain, composed of abnormal branches of veins, usually with a common center, found most often near the ventricular wall; it is often asymptomatic.” An angioma is “a tumor whose cells tend to form blood vessels....” Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 84.

Dr. Alan J. Stern's impression was that there were multifocal abnormalities which appeared to represent a biphasic process. These included nonenhancing areas of demyelinating disease in the right splenium of the corpus callosum and the posterior inferior right occipital lobe subcortical white matter and also a fairly extensive tract of confluent patchy, plaque-like and vessel-like enhancement along the floor of the tentorium extending in the right temporal and occipital lobes along the general distribution of the optic radiation and visual cortex on the right. Med. recs. at Ex. 20, p. 3. The lack of mass effect would be atypical for tumor. The general pattern of enhancement would be atypical for posterior cerebral artery ischemic infarction. Possible considerations included demyelinating disease, particularly multiple sclerosis or some sort of exotic infectious process (possible viral neuroencephalitis) or vasculitis. Petitioner also had an incidental venous angioma in the right fronto-temporo-parietal junction. Involvement of the corpus callosum without mass effect raised the possibility of MS or lymphoma. Dr. Stern thought it would be interesting to know if petitioner had any clinical evidence of being immunocompromised. He suggested a neurologic consultation. *Id.*

On November 19, 1996, petitioner saw Dr. Lyn A. Sedwick, a neuro-ophthalmologist. Med. recs. at Ex. 21, p. 1. Petitioner said that, on October 25, 1996, he had the sudden onset of blurring and disorientation while getting into his truck. His vision was still blurry although somewhat improved and, at times, he was still disoriented. Dr. Miller saw him and suggested he might have a stroke. He had a problem with headaches over the last 10 years, but this recently had worsened. Ten years previously, he was diagnosed with pseudotumor cerebri which Dr. Warsett treated with a 14-day course of steroids and two years of Lasix therapy. He was told he would have to learn to live with the headaches. He had hypertension for five years for which he

was taking Accupril and Procardia. He was taking Vicodin for a shoulder problem after an auto accident. He had bilateral hip replacements five years earlier for an avascular necrosis of the hips. Two weeks before the start of his current symptoms, he had just finished hepatitis A and B vaccinations which were 30 days apart. *Id.*

On examination, petitioner had visual acuity with his glasses of the right eye 20/25 with no improvement with pinhole, and of the left eye 20/20. His external examination was normal. The disk margins were blurred in each eye, and Dr. Sedwick could not appreciate spontaneous venous pulsations. *Id.* Petitioner's MRI was quite interesting, showing all findings on the right side of his brain, including a venous angioma and two areas of abnormality which might be stroke vs. demyelination vs. lymphoma vs. post-viral encephalitis or even vasculitis. Med. recs. at Ex. 21, p. 2. Given that petitioner showed some improvement, Dr. Sedwick would be most suspicious of stroke or demyelinating disease. She wanted a local neuroradiologist to review the scans. Petitioner was going to see Dr. John McCormick, a neurologist. Petitioner should have a lumbar puncture. *Id.*

In a follow-up note dated November 21, 1996, Dr. Sedwick stated that she had petitioner's MRI reviewed by Dr. Rippe, a neuroradiologist at Florida Hospital, who opined that the changes on the scan probably represented diffuse disseminated encephalomyelitis secondary to petitioner's hepatitis vaccination. He thought it would improve spontaneously. *Id.*

On November 26, 1996, petitioner had an MRI of his brain with and without magnevist contrast to compare with the MRI of his brain done on November 5, 1996. Med. recs. at Ex. 22, p. 1. Dr. Larry R. Sadler stated there was an interval decrease in the amount of enhancement involving the medial right temporal lobe since the prior MRI. Most of the enhancement in the

right occipital lobe had also decreased, but there was an area of greater enhancement involving the inferior aspect of the right occipital lobe adjacent to the tentorium. The high signal lesion involving the right splenium of the corpus callosum showed a small focus of enhancement where it did not enhance before. There was suggestion of decreased volume. Differential considerations continued to include a demyelinating process such as acute disseminated encephalomyelitis. This would be an unusual appearance for MS, but that and vasculitis were also potential diagnoses. *Id.*

On December 3, 1996, petitioner saw Dr. John R. McCormick, a neurologist. Med. recs. at Ex. 23, p. 1. Petitioner had a history of hepatitis vaccination, the first one a month and one-half prior to this episode and the second one about a week prior to this episode. *Id.* at p. 2. On examination, petitioner had visual acuity of 20/20 to 20/25. He had a right lower field defect in each eye. With hand confrontation, he could not see the entire homonymous right visual field or see above the horizon in a homonymous fashion. *Id.* at 3. His motor examination was normal. His reflexes were symmetrical. He had normal cognitive function. Gait and station were unremarkable. Dr. McCormick's impression was involvement of the optic pathways bilaterally. Although the MRI demonstrated only abnormalities in the right hemisphere, the presence of involvement in the right visual field suggested some left hemisphere involvement either in the optic pathways through the occipital lobe or in the temporal lobe. The most recent (second) MRI did not show any abnormalities on the left side. This could be the result of a monophasic viral process such as post-vaccinal encephalomyelitis or encephalitis or the result of cerebrovascular disease, either thrombotic or embolic. Complicating this situation is the presence of a preexisting diagnosis of pseudotumor cerebri. *Id.* Petitioner's headaches had significantly

improved. Dr. McCormick suspected that he was “looking at an evolving monophasic process, very possibly post-immunization....” *Id.* He recommended a lumbar puncture. Med. recs. at Ex. 23, p. 4.

On December 17, 1996, petitioner returned to Dr. McCormick. Med. recs. at Ex. 23, p. 5. His lumbar puncture was unremarkable except for a slight increase in nonspecific protein. Dr. McCormick suspected petitioner probably had a cerebrovascular accident involving the left and right occipital regions. *Id.*

On March 13, 1997, Dr. McCormick sent a letter to petitioner and his wife after they sent him literature on reactions to hepatitis B vaccine. Med. recs. at Ex. 23, p. 7. He reviewed the information and noted some conditions involved myelin, including Guillain-Barré syndrome and optic neuritis as well as myelitis and transverse myelitis and visual disturbances. Dr. McCormick stated he would expect to see something along the lines of “stroke-like syndrome” with abnormality of the MRI in order to suggest that these reactions were similar to petitioner’s condition. *Id.*

On November 26, 1997, petitioner saw Dr. Norberto Martinez, a neurologist. Med. recs. at Ex. 31, p. 2. Petitioner gave an onset of severe headaches and visual loss with blurring two to three days after a hepatitis vaccination on October 8, 1996. *Id.* He also had a lot of bright spots in front of him. Shortly afterwards, he could not see off to the left side. The headaches eventually resolved. He had an episode of confusion for several days, which also resolved. His vision slowly improved in the last year, although he still had difficulty looking to the left side. *Id.* On examination, petitioner had normal strength, his deep tendon reflexes were 2+ and

symmetric, toes were downgoing bilaterally, and his tone and bulk were normal. Med. recs. at Ex. 31, p. 3. Dr. Martinez's diagnoses was right occipital CVA (stroke). *Id.*

On December 9, 1997, petitioner had an MRI of his brain with and without contrast. Med. recs. at Ex. 31, p. 5. This MRI was compared to the one done November 5, 1996. There was abnormal signal in the right medial occipital lobe. This finding was most consistent with a chronic infarct of the right occipital lobe. Prior patchy areas of enhancement in the right occipital lobe were no longer present. A focal area of abnormal signal just inferior to the area of chronic infarct most likely represented an area of encephalomalacia, which was not present on the prior MRI. The prior focus of abnormal signal in the splenium of the corpus callosum on the right was no longer there. The prior multiple areas of abnormal enhancement in the right temporal lobe and the right medial occipital lobe were no longer there. *Id.* There was a small venous angioma in the right parietal lobe unchanged from the prior MRI. *Id.* Dr. Ralph B. Wheeler's impression was chronic infarct involving the right medial occipital lobe which appeared to be an acute infarct on the MRI dated November 5, 1996. Med. recs. at Ex. 31, p. 6. Dr. Wheeler wondered whether petitioner had previously had a vasculitis with residual infarct. *Id.*

On December 9, 1997, petitioner had an MRA of his head and neck. Med. recs. at Ex. 31, p. 7. There appeared to be a severe stenosis in the mid-portion of the right posterior cerebral artery. *Id.* Dr. Wheeler's impression was severe stenosis in the mid-portion of the right posterior cerebral artery. Med. recs. at Ex. 31, p. 8.

On December 9, 1997, petitioner had an MRV (venogram) of his head. No large vascular malformation was noted. Med. recs. at Ex. 31, p. 9.

On December 16, 1997, petitioner saw Dr. Martinez. Med. recs. at Ex. 31, p. 10.

Petitioner had suffered a reaction to hepatitis vaccine in October 1996 with visual loss on the left. Dr. Martinez's impression was right occipital CVA. *Id.*

Petitioner's subsequent history includes TIAs, heart attack, and arthritis.

DISCUSSION

Because this case does not seem to deal with a demyelinating disease, the Omnibus proceedings do not apply to it. This case appears to deal with a stroke that a number of doctors connect to petitioner's hepatitis vaccination. The undersigned has issued a decision holding that hepatitis B vaccine caused vascular disease: Schrum v. Secretary of HHS, No. 04-210V, 2006 WL 1073012 (Fed. Cl. Spec. Mstr. Mar. 31, 2006). The undersigned ORDERS respondent evaluate whether to engage in a litigative risk settlement in this case and to file a response to this Order by **May 4, 2007**.

IT IS SO ORDERED.

March 30, 2007
DATE

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