

OFFICE OF SPECIAL MASTERS

Filed: December 12, 2005

SHANNON E. CASEY, *

*

Petitioner, *

*

No. 97-612V

v. *

*

TO BE PUBLISHED

SECRETARY OF HEALTH *

*

AND HUMAN SERVICES, *

*

Respondent. *

Clifford J. Shoemaker, Vienna, Virginia, for Petitioner.

Mark C. Raby, United States Department of Justice, Washington, D.C., for Respondent.

DECISION¹

SWEENEY, Special Master

On September 4, 1997, Shannon E. Casey filed a petition for compensation under the National Childhood Vaccine Injury Act (“Vaccine Act”), 42 U.S.C. §§ 300aa-1 to -34 (2000 & Supp. II 2003). The petition alleges that Ms. Casey developed encephalomyeloradiculoneuropathy,² an autoimmune reaction affecting her central and peripheral nervous systems, as a result of the varicella³ vaccination that she received on June 9, 1995.

¹ The court encourages the parties to review Vaccine Rule 18, which affords each party 14 days to object to disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute “a clearly unwarranted invasion of privacy.”

² Encephalopathy describes “any degenerative disease of the brain.” Dorland’s Illustrated Medical Dictionary 610 (30th ed. 2003). Myelopathy describes “any of various functional disturbances or pathological changes in the spinal cord” Id. at 1211. Radiculopathy is the “disease of the nerve roots.” Id. at 1562. Neuropathy describes “a functional disturbance or pathological change in the peripheral nervous system” Id. at 1257. Thus, encephalomyeloradiculoneuropathy is a disease affecting the brain, spinal cord, nerve roots, and peripheral nerves.

³ The varicella vaccination is “a preparation of live, attenuated human herpesvirus 3 (varicella-zoster virus) administered subcutaneously for production of immunity to varicella and

The question presented in this case is whether petitioner's neurological injuries were caused by her June 9, 1995 varicella vaccination. The key factors in the special master's decision were the similarity of petitioner's symptoms to symptoms associated with a natural varicella infection and petitioner's ability to set forth a medical theory connecting her injury and the varicella vaccine. Petitioner presented a medical theory of causation, a logical sequence of cause and effect linking the varicella vaccine to her particular injuries, and an appropriate temporal relationship between the vaccination and the onset of symptoms. Thus, petitioner was able to prove by a preponderance of evidence that the varicella vaccine was the cause in fact of her neurological injuries.

I. FACTUAL HISTORY

Ms. Casey was born on August 10, 1959.⁴ See generally Pet. Ex. 5. Prior to the varicella vaccination at issue in this case, Ms. Casey was in good health and did not suffer from any neurological problems. Pet. Ex. 1 at 1. Because she did not have chickenpox as a child, Ms. Casey was concerned that once she became a parent, she would contract the illness from her son. Pet. Ex. 5 at 5. Thus, on May 24, 1995, she telephoned a nurse at Kaiser Permanente ("Kaiser") to request the new chickenpox vaccination as soon as it became available. Id. On June 9, 1995, after a negative varicella titer,⁵ Ms. Casey received a varicella vaccination at Kaiser. Id. at 2-3, 40.

Within four weeks after her varicella vaccination, Ms. Casey began experiencing fever, neck aches, backaches, and fatigue. Pet. Ex. 1 at 1. On July 10, 1995, Ms. Casey presented to Kaiser and was examined by Lo-An T. Nguyen, M.D., with a four-day history of fever. Pet. Ex. 2 at 2. Ms. Casey was diagnosed with a fever of an unknown etiology. Id. Dr. Nguyen ordered blood tests and a urinalysis, which were all normal. Id. at 11-15. Ms. Casey was advised to take Advil and to return in three to four days if the fever persisted. Id. at 2.

herpes zoster." Dorland's Illustrated Medical Dictionary, supra note 2, at 2000. Varicella is commonly known as chickenpox. Id. at 2008. Herpes zoster, also called shingles, is "an acute infectious, usually self-limited, disease believed to represent activation of latent human herpesvirus 3 in those who have been rendered partially immune after a previous attack of chickenpox." Id. at 845.

⁴ All references to the Petition shall be designated herein as "Pet. at ___." All references to the pertinent Petitioner's Exhibit shall be designated herein as "Pet. Ex. ___ at ___."

⁵ A titer is "the quantity of a substance required to produce a reaction with a given volume of another substance, or the amount of one substance required to correspond with a given amount of another substance." Dorland's Illustrated Medical Dictionary, supra note 2, at 1916.

Ms. Casey telephoned Kaiser the next day, on July 11, 1995. Id. at 3. She expressed her concern that her ten-day history of fever, neck ache, and backache, as well as her conjunctivitis symptoms, could be related to Lyme disease.⁶ Id. She explained that she lived in a wooded area and spent a lot of time outdoors. Id. Dr. Nguyen ordered additional blood and urine tests, which again were normal, and prescribed for Ms. Casey the antibiotic Cipro. Id. at 3-4, 16-17.

Ms Casey returned to see Dr. Nguyen for a follow-up examination on July 12, 1995. Id. at 4. She had complaints of fever and fatigue. Id. Dr. Nguyen ordered some blood tests to check for rheumatological problems, which also were normal. Id. at 4-5, 19. At another follow-up visit with Dr. Nguyen on July 14, 1995, Ms. Casey reported that she no longer had a fever and that she was feeling better to some degree. Id. at 5. Dr. Nguyen ordered blood tests to check for the presence of cytomegalovirus (“CMV”)⁷ and Epstein-Barr virus (“EBV”).⁸ Id. at 5. The blood test was negative for both viruses. Pet. Ex. 3 at 2.

On July 17, 1995, Ms. Casey developed nausea and vomiting. Id. at 1; Pet. Ex. 4 at 168. She saw Dr. Nguyen, who ascribed her symptoms to the Cipro and Advil. Pet. Ex. 4 at 168. During this visit, Ms. Casey also described bilateral thigh pain. Id. The next day, on July 18, 1995, Ms. Casey telephoned Kaiser because she felt worse—she was unable to walk due to dizziness and a lack of control of her legs. Pet. Ex. 2 at 7-8. The nurse advised her to call back later in the day if she did not experience any improvement. Id. at 7. Because Ms. Casey did not improve, she was advised to go to Fairfax Hospital for admission. Id. at 7-8.

Ms. Casey was transported via ambulance to Fairfax Hospital on July 18, 2005. Id. at 7; Pet. Ex. 3 at 1. She was admitted to the neurology unit with a tentative diagnosis of Guillain-Barré syndrome (“GBS”).⁹ Pet. Ex. 3 at 6. Upon admission, Ms. Casey had magnetic resonance

⁶ Lyme disease is “a recurrent, multisystemic disorder caused by Borrelia burgdorferi, having the ticks Ixodes scapularis and I. pacificus as vectors.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 537.

⁷ Cytomegalovirus is “any virus of the subfamily Betaherpesvirinae, highly host-specific herpesviruses [C]ytomegaloviruses can cause a variety of clinical syndromes, . . . although the majority of infections are very mild or subclinical.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 469.

⁸ Epstein-Barr virus is “a virus of the genus Lymphocryptovirus that causes infectious mononucleosis and is associated with Burkitt’s lymphoma and nasopharyngeal carcinoma.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 2044.

⁹ Guillain-Barré syndrome is otherwise known as acute idiopathic polyneuritis. Dorland’s Illustrated Medical Dictionary, supra note 2, at 803. Acute idiopathic polyneuritis is:

images (“MRI”)¹⁰ of her brain and chest. Id. at 2, 40, 43. The brain MRI revealed “[h]igh signal within the mid brain and adjacent to the fourth ventricle within the pons and upper medulla,”¹¹ a pattern that is sometimes seen in postinfectious encephalitis.¹² Id. at 2, 43. The chest MRI revealed separate abnormalities in Ms. Casey’s spinal cord and brainstem, weighing against a diagnosis of GBS. Id. at 40. The results instead suggested a possible diagnosis of multiple sclerosis.¹³ Id.

[a] rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face and is attended by slight fever, bulbar palsy, absent or lessened tendon reflexes, and an increase in the protein of the cerebrospinal fluid without corresponding increase in cells.

Id. at 1482.

¹⁰ An MRI is “a method of visualizing soft tissues of the body by applying an external magnetic field that makes it possible to distinguish between hydrogen atoms in different environments.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 908.

¹¹ The pons is “the part of the central nervous system lying between the medulla oblongata and the [mid brain], superior to the cerebellum” Dorland’s Illustrated Medical Dictionary, supra note 2, at 1131, 1486. The medulla oblongata is “the truncated cone of nerve tissue continuous above with the pons and below with the spinal cord. . . . [I]t contains . . . important collections of nerve cells that deal with vital functions, such as respiration, circulation, and special senses.” Id. at 1113. The mid brain, pons, and medulla oblongata constitute the brain stem. Id. at 246.

¹² Encephalitis is the “inflammation of the brain.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 608.

¹³ Multiple sclerosis is

a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of lesions of the white matter are weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term multiple also refers to remissions and relapses that occur over a period of many years. Four types are recognized, based on the course of the disease: relapsing remitting, secondary

On July 19, 1995, Ms. Casey was transferred to the Intensive Care Unit due to increasing weakness in her legs and difficulty speaking. Id. at 2. Also that day, Ms. Casey had an infectious disease consultation. Id. at 3. During the consultation, the physician noted that Ms. Casey had a varicella vaccination about one month prior to admission and that Ms. Casey's ascending paralysis might be the result of the vaccine or a postviral illness. Id. Ms. Casey was transferred out of the Intensive Care Unit on July 20, 1995. Id.

On July 21, 1995, Ms. Casey underwent a nerve conduction study¹⁴ and electromyography,¹⁵ both of which revealed abnormal results. Id. at 3, 46-48. The results of the two studies were felt to be consistent with a demyelinating¹⁶ type of proximal neuropathy. Id. Repeat studies were performed on July 26, 1995. Id. at 55-56. The results remained consistent with a demyelinating proximal neuropathy. Id.

During her hospitalization at Fairfax Hospital, Ms. Casey underwent a series of seven plasmapheresis¹⁷ treatments, treatment with Solu-Medrol,¹⁸ physical therapy, and occupational

progressive, primary progressive, and progressive relapsing. The etiology is unknown.

Dorland's Illustrated Medical Dictionary, supra note 2, at 1669.

¹⁴ A nerve conduction study, otherwise known as electroneurography, is "the measurement of the conduction velocity and latency of peripheral nerves." Dorland's Illustrated Medical Dictionary, supra note 2, at 598, 1777.

¹⁵ Electromyography is "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." Dorland's Illustrated Medical Dictionary, supra note 2, at 598.

¹⁶ Demyelination is the "destruction, removal, or loss of the myelin sheath of a nerve or nerves." Dorland's Illustrated Medical Dictionary, supra note 2, at 488.

¹⁷ Plasmapheresis is "the removal of plasma from withdrawn blood, with retransfusion of the formed elements into the donor; generally, type specific fresh frozen plasma or albumin is used to replace the withdrawn plasma. The procedure may be done . . . for therapeutic purposes." Dorland's Illustrated Medical Dictionary, supra note 2, at 1446.

¹⁸ Solu-Medrol is the "trademark for a preparation of methylprednisolone sodium succinate," which is "a synthetic glucocorticoid derived from progesterone, used . . . as an antiinflammatory and immunosuppressant." Dorland's Illustrated Medical Dictionary, supra note 2, at 1147, 1719. Solu-Medrol is "chiefly used for the rapid achievement of high blood levels of methylprednisolone in short-term emergency treatment." Id. at 1147.

therapy. Id. at 3-4. Ms. Casey was never able to walk, but did recover her deep tendon reflexes. Id. Ms. Casey's physicians were able to rule out Lyme disease and human immunodeficiency virus ("HIV") as the cause of her problems. Id. At one point, Ms. Casey developed a rash in the perianal¹⁹ area, perhaps in reaction to the latex in the Foley catheter. Id. at 3. The rash cleared after the catheter was changed to one containing silicone. Id. Ms. Casey was discharged on August 4, 1995, with diagnoses that included idiopathic encephalomyeloneuritis²⁰ and elevated transaminases²¹ of unknown etiology. Id. at 4.

After a weekend at home with her family, Ms. Casey was admitted to Mount Vernon Hospital for rehabilitation on August 7, 1995. Id. at 4. See generally Pet. Ex. 4. Upon admission, Ms. Casey continued to have weakness and lack of control in her legs, ataxic dysarthria,²² and other neurological symptoms. Pet. Ex. 4 at 5-6, 39-40. During her hospitalization, Ms. Casey made great strides in functional mobility using a wheelchair and good improvements in her speech. Id. at 6-7. Ms. Casey was discharged from Mount Vernon Hospital on September 8, 1995, with several diagnoses, including idiopathic encephalomyeloneuritis, improving ataxic dysarthria, emerging active motor control that was stronger on the right side, and neurogenic bladder and bowel.²³ Id. at 9.

¹⁹ Perianal means around the anus. Dorland's Illustrated Medical Dictionary, supra note 2, at 1399.

²⁰ Encephalitis is the "inflammation of the brain." Dorland's Illustrated Medical Dictionary, supra note 2, at 608. Myelitis is the "inflammation of the spinal cord" Id. at 1209. Neuritis is the "inflammation of a nerve, with pain and tenderness, anesthesia and paresthesias, paralysis, wasting, and disappearance of the reflexes." Id. at 1252. Idiopathic means "of unknown cause or spontaneous origin" Id. at 905.

²¹ Transaminase, also called an aminotransferase, is a sub-subclass of enzymes. Dorland's Illustrated Medical Dictionary, supra note 2, at 1934. Two transaminases, alanine aminotransferase ("ALT") and aspartate aminotransferase ("AST"), are found in the liver. American Association for Clinical Chemistry, Lab Tests Online: Liver Panel, at http://www.labtestsonline.org/understanding/analytes/liver_panel/glance.html (last modified Mar. 27, 2004). During her hospitalization, Ms. Casey's ALT levels became elevated. Pet. Ex. 3 at 20-21.

²² Ms. Casey's speech problems were labeled "ataxic dysarthria," which is "a speech disorder consisting of imperfect articulation due to loss of muscular control after damage to the central or peripheral nervous system," "seen in patients with cerebellar lesions," and "characterized by slowness of speech, slurring, a monotonous tone, and scanning." Dorland's Illustrated Medical Dictionary, supra note 2, at 572.

²³ A neurogenic bladder (or bowel) refers to dysfunction "caused by a lesion of the central or peripheral nervous system" Dorland's Illustrated Medical Dictionary, supra note 2, at 224.

On October 24, 1995, neurologist Armando Oliva, M.D., evaluated Ms. Casey in follow up to her encephalomyeloneuritis. Id. at 162-63. In his history, Dr. Oliva indicated that Ms. Casey's symptoms were "possibly secondary to a dysimmune reaction to the varicella zoster vaccine." Id. at 162. Dr. Oliva also noted that since her discharge from Mount Vernon Hospital, Ms. Casey had been slowly regaining strength in her legs and could walk a few steps with support. Id. In addition, Ms. Casey's speech had returned to normal. Id. In his assessment, Dr. Oliva wrote: "It is clear today that the lower motor neuron component has resolved and she now clinically resembles a slowly resolving acute disseminated encephalomyelitis."²⁴ Id. at 163.

Ms. Casey returned to see Dr. Oliva on December 4, 1995. Id. at 156. Dr. Oliva noted that she was doing extremely well and was able to walk around her house with support. Id. Dr. Oliva evaluated Ms. Casey again on January 16, 1996. Id. at 153. Dr. Oliva reported that Ms. Casey continued to slowly improve and used a cane for walking. Id. However, Ms. Casey continued to have bladder control issues. Id.

Ms. Casey continued to visit Kaiser for her primary care medical needs from June 2000 through at least April 2004.²⁵ See Pet. Ex. 7 at 3-24. The medical records from Kaiser also include notes from two examinations by neurologist Barbara J. Scherokman, M.D. Id. at 17-18. On December 11, 1998, Dr. Scherokman indicated that despite her residual spastic paraparesis²⁶ and neurogenic bladder, Ms. Casey's pregnancy was going well and that there were no contraindications for a vaginal delivery or epidural anesthesia. Id. at 18. On March 13, 2001, Dr. Scherokman noted that Ms. Casey's condition continued to be stable. Id. at 17.

At the time Ms. Casey filed her petition for compensation in September 1997, she described herself as severely disabled. Pet. Ex. 1 at 1.

²⁴ Encephalomyelitis is "inflammation involving both the brain and the spinal cord." Dorland's Illustrated Medical Dictionary, supra note 2, at 610. Acute disseminated encephalomyelitis is "characterized by perivascular lymphocyte and mononuclear cell infiltration and demyelination" Id.

²⁵ Except for pregnancy and birth-related records dated December 1998 through February 1999, Pet. Ex. 9 at 14-83, petitioner did not submit any medical records dated February 1996 through May 2000.

²⁶ Paraparesis is the "partial paralysis of the lower extremities." Dorland's Illustrated Medical Dictionary, supra note 2, at 1367. Spasticity is the state of being "hypertonic, so that the muscles are stiff and the movements awkward." Id. at 1729.

II. DISCUSSION

A. The Vaccine Act and Federal Circuit Precedent

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if petitioner²⁷ proves, by a preponderance of the evidence, all of the elements set forth in § 300aa-11(c)(1)²⁸ of the Vaccine Act and that the illness is not due to factors unrelated to the administration of the vaccine.²⁹ A petitioner in the Vaccine Program can recover in one of two ways: either by proving an injury listed on the Vaccine Injury Table (“Table”)³⁰ or by proving causation in fact. In this case, petitioner cannot prove a Table injury because even though the varicella vaccine is listed on the Table, petitioner’s alleged injuries are not. Thus, petitioner proceeded on a causation-in-fact theory.

In order to prevail under a theory of causation in fact, petitioner must show by a preponderance of evidence that the vaccine in question caused the injury. Bunting v. Sec’y of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991). The Federal Circuit has explained what is required to meet that burden. Specifically, petitioner must establish that the vaccine can cause the injury in question, as well as show that the vaccine is in fact the cause of the injury alleged. Hines ex rel. Sevier v. Sec’y of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991). To make the requisite showing,

²⁷ Section 11(b)(1) requires that: (1) only the “person who sustained a vaccine-related injury . . . or the legal representative of any person who died as the result of the administration of a [Table vaccine] . . .” can bring an action for vaccine injury-related claims (so long as the requirements of subsection (c)(1) are satisfied) and (2) that no previous civil action was filed in the same matter. Petitioner is the appropriate person to maintain this action.

²⁸ Subsection (c)(1) requires, inter alia, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Vaccine Injury Table; (2) that the vaccine was received in the United States or in its trust territories; (3) that petitioner either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury or death.

²⁹ Of course, the petition must also be filed within the statutory period. 42 U.S.C. § 300aa-16(a). The petition in this case was timely filed.

³⁰ Petitioners can prove a Table injury by showing that they received a vaccine listed on the Table and suffered an injury, or an acute complication or sequela of that injury, associated with that vaccine within the prescribed time period. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), -13(a)(1)(A). However, respondent can rebut the presumption by showing that a factor unrelated to the vaccine(s) caused the injury. Id. § 300aa-13(a)(1)(B).

petitioner must offer “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Shyface v. Sec’y of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999) (quoting Grant v. Sec’y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). Although petitioner need not demonstrate her theory of causation to medical or scientific certainty, Knudsen ex rel. Knudsen v. Secretary of HHS, 35 F.3d 543, 548-49 (Fed. Cir. 1994), causation in fact requires a reputable medical or scientific explanation supporting this logical sequence of cause and effect. Jay v. Sec’y of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993) (quoting Grant, 956 F.2d at 1148). As Congress directed, “[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation” for a petitioner seeking to prove causation in fact. H.R. Rep. No. 99-908, at 15 (1986).

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. Petitioner must not only show that the vaccine was the but-for cause of the injury, but also that the vaccine was a substantial factor in bringing about the injury. Shyface, 165 F.3d at 1352. In essence, the special master is looking for a reputable medical explanation of a logical sequence of cause and effect (Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-49). As the Federal Circuit explained in Knudsen, medical probability means biologic credibility or plausibility: “Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules.” 35 F.3d at 547.

In a recent decision, the Federal Circuit instructed:

Concisely stated, [petitioner’s] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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. If [petitioner] satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994) (alteration in original) (citation omitted).

Althen v. Sec’y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The Federal Circuit further explained that the “heavy lifting” required to establish causation by a preponderance of evidence in causation-in-fact cases should not be misconstrued to indicate that the burden is higher than that required by statute:

While it may be true that proof of causation by preponderant evidence is not as “easy” as proof of causation by operation of law, neither Hodges nor Lampe instructs that the preponderance standard itself is to be made more onerous in

vaccine cases. Nor is it to be made more difficult merely because our cases have referred to it as “heavy lifting.”

Id. at 1280. Finally, the Federal Circuit explained that “close calls regarding causation are resolved in favor of injured claimants.” Id. At hearing, petitioner was able to present a logical sequence of cause and effect that demonstrated how her varicella vaccination could have caused and did cause her encephalomyeloneuritis.

B. Hearing of November 18, 2004

The special master conducted the initial hearing in this matter on November 18, 2004, in Washington, D.C. Petitioner testified on her own behalf and presented the testimony of her husband and two expert witnesses: Carlo Tornatore, M.D., and Joseph A. Bellanti, M.D. Respondent’s sole witness was Thomas P. Leist, M.D., Ph.D.

1. Testimony of Petitioner

Most of petitioner’s testimony did not add to or contradict her petition, affidavit, or medical records. Thus, the special master will not address the bulk of her testimony with respect to her medical history as discussed above. However, the special master will address that portion of her testimony that added relevant and necessary facts to the discussion.

Petitioner testified about one symptom that was not recorded in the medical records: a tingly, burning sensation in her legs that occurred about two or three weeks after her varicella vaccination.³¹ Tr. I at 13-14. In particular, she reported:

I was actually with my husband. All of a sudden I would get a tingly, burning sensation in my legs which felt like it was neither on my skin or like a muscle thing. It was just like something I had never felt before. A strange burning, tingling sensation in my legs. When it first started, it came and went.

Every so often I’d just say now, that’s weird, I’m getting that weird feeling in my leg again, but then it would go away. Then, eventually as it got closer to when I ended up going to Fairfax Hospital it was constant pain.

Id. at 14. Although this symptom was not recorded in the medical records, petitioner was certain that she mentioned it to her physicians. Id.

³¹ All references to the Transcript of the November 18, 2004 proceedings shall be designated herein as “Tr. I at ___.” All references to the Transcript of the November 16, 2005 proceedings shall be designated herein as “Tr. II at ___.”

In addition, according to petitioner, one of her sisters participated in the clinical trials for the varicella vaccine at Massachusetts General Hospital. Id. at 8. At some point thereafter, petitioner's sister began to receive telephone calls from Robert P. Wise, M.D., M.P.H., who was conducting a follow-up study of adverse effects of the varicella vaccine. Id. at 55. Petitioner's sister referred Dr. Wise to petitioner. Id. at 56. When petitioner first spoke with Dr. Wise, she described her symptoms and gave Dr. Wise permission to examine her medical records. Id. Dr. Wise also asked permission to speak with petitioner's neurologist, Dr. Oliva.³² Id. Petitioner agreed and informed Dr. Wise that Dr. Oliva now worked for the National Institutes of Health ("NIH"). Id.

Dr. Wise telephoned petitioner after he reviewed her medical records and spoke with Dr. Oliva. Id. at 57, 59. Then, several years later, petitioner saw a CNN news report discussing the results of Dr. Wise's varicella vaccine safety study, which concluded that the vaccine was safe. Id. at 57. Petitioner sent Dr. Wise an e-mail asking whether he had reported any adverse reactions, such as her own. Id. at 57, 59. Dr. Wise immediately responded to petitioner, writing that she was included in the study and attaching pages from the study with notations about how those sections pertained to her. Id. at 57-59. Petitioner testified that Dr. Wise did not opine as to whether the varicella vaccine caused her injuries. Id. at 58.

The special master finds petitioner to be an extremely credible witness.

2. Testimony of Petitioner's Husband

Like the testimony of petitioner, most of her husband's testimony did not add to or contradict the petition, affidavits, or medical records. Thus, the special master will address only that portion of his testimony that added relevant and necessary facts to the discussion.

Petitioner's husband confirmed petitioner's testimony about the unusual leg sensations she experienced after her varicella vaccination. Id. at 35. He stated that petitioner described the sensation as feeling like sunburn, even though she had no signs of having a sunburn. Id.

Petitioner's husband also described a conversation he had with his wife's neurologist at Fairfax Hospital, Dr. Oliva. Id. at 39-41. Prior to petitioner's first plasmapheresis treatment, her husband asked Dr. Oliva if the varicella vaccination had caused petitioner's injuries. Id. at 40-41, 51. According to petitioner's husband, Dr. Oliva responded, almost dismissively, in the affirmative. Id. at 40, 51. The tenor of Dr. Oliva's response led petitioner's husband to believe

³² The medical records submitted by petitioner include records from three visits with Dr. Oliva: October 24, 1995; December 4, 1995; and January 16, 1996. However, both petitioner and her husband, see infra, testified that Dr. Oliva was petitioner's treating neurologist during her hospitalization at Fairfax Hospital in July 1995. Tr. I at 39-40, 52, 56. Petitioner's counsel was unable to obtain any records generated by Dr. Oliva from the July 1995 hospitalization. Id. at 63.

that Dr. Oliva had no doubt that the varicella vaccine caused his wife's injuries.³³ Id. However, Dr. Oliva never provided petitioner's husband with the basis for his opinion that there was a causative relationship. Id. at 52-53.

The special master finds petitioner's husband to be a credible witness.

3. Testimony of Petitioner's Expert: Carlo Tornatore, M.D.

Dr. Tornatore received his medical degree from Georgetown University, followed by an internship at Providence Hospital and a neurology residency at Georgetown University. Id. at 66. After his residency, Dr. Tornatore spent six years as a postdoctoral fellow at the NIH. Id. His major area of study at the NIH was how viruses got into and caused injury to the nervous system. Id. Dr. Tornatore returned to Georgetown University in 1996. Id. Since 1996, he has become the director of the multiple sclerosis clinic as well as the director of the neurology residency and medical student programs. Id. at 66-67. Dr. Tornatore has published over 30 articles and several book chapters. Id. at 67. The special master finds Dr. Tornatore to be highly qualified to opine on the causes of petitioner's neurological injuries as well as the relevant medical literature.

Based upon his review of the medical records and his examination of petitioner,³⁴ Dr. Tornatore opined that petitioner suffered from an encephalomyeloneuritis, noting that there was evidence of injury to the brain, spinal cord, and proximal nerve roots. Id. at 68, 85. Dr. Tornatore explained that the typical course of encephalomyeloneuritis, as experienced by petitioner, begins with an acute, devastating inflammation or infection of the nervous system. Id. at 68. Then, once the inflammation or infection resolves, a patient is left with residual injuries. Id. at 68-69. Typically, there is no recurrence of injury. Id. at 69.

a. Petitioner's Encephalomyeloneuritis Was Caused by the Combination of a Direct Viral Infection and an Immune-Mediated Inflammatory Response

Dr. Tornatore explained that there were two views as to how encephalomyeloneuritis might occur in the body.³⁵ Id. at 69. One view is that a virus enters the nerves of the brain and spinal cord and destroys the nerves. Id. In other words, a virus directly infects the nervous system. The other view is that an infecting virus contains proteins that are similar to the proteins found on nerves, and the body's white blood cells, as they try to eliminate the virus, instead

³³ As explained infra, Dr. Oliva confirmed at the November 16, 2005 hearing that he believed that the varicella vaccine caused petitioner's injuries.

³⁴ Dr. Tornatore also stated that he reviewed the expert reports of Dr. Bellanti and Dr. Leist. Tr. I at 67.

³⁵ In his expert report, Dr. Tornatore presented only one mechanism, a direct viral infection, to explain how the varicella vaccine can cause petitioner's injuries. Pet. Ex. 6 at 4.

inadvertently cause inflammation in the brain and spinal cord. Id. In short, a virus or proteins in the virus can cause an immune-mediated inflammatory reaction. Dr. Tornatore further explained that the two mechanisms were not mutually exclusive and that it was difficult to separate one mechanism from the other.³⁶ Id. at 69-70, 82-83. He testified that both mechanisms could have been occurring in petitioner's case. Id. at 83.

b. From a Neurological Perspective, Petitioner's Encephalomyeloneuritis Was, More Likely than Not, Caused by the Varicella Vaccine

Next, Dr. Tornatore stated that the causes of encephalomyeloneuritis include natural viral infections, vaccines, and unusual autoimmune diseases. Id. at 70. In this case, Dr. Tornatore noted that petitioner had no prior history of autoimmune disease. Id. He also noted that petitioner's physicians looked for possible viral causes of her encephalomyeloneuritis, such as CMV and HIV, but did not discover such viruses. Id. Thus, according to Dr. Tornatore, petitioner's physicians reached the conclusion that the varicella vaccine was the likely cause of petitioner's encephalomyeloneuritis. Id.; see also id. at 78-79, 92 (Dr. Tornatore's testimony noting that petitioner's treating physicians ruled out the other likely causes of her encephalomyeloneuritis).

Dr. Tornatore found the conclusion that the varicella vaccine caused petitioner's encephalomyeloneuritis to be reasonable. Id. at 70. He explained that the varicella vaccine contains a live varicella virus. Id. However, in the vaccine, the live varicella virus is attenuated,³⁷ which prevents the virus from multiplying normally. Id. However, Dr. Tornatore stated that it is reasonable to assume that the virus in the vaccine still can multiply. Id. at 71. As evidence of the multiplication of the attenuated varicella virus in humans, Dr. Tornatore explained that some people vaccinated with the varicella vaccine develop shingles from the vaccine. Id. In fact, Dr. Tornatore believed that the varicella virus in the vaccine received by petitioner was not completely attenuated, and thus was able to multiply after vaccination. Id. at 82-83.

From Dr. Tornatore's perspective, there was even stronger evidence that the varicella vaccine caused petitioner's encephalomyeloneuritis. He stated that, according to the medical records, petitioner was diagnosed with ataxic dysarthria, which he defined as the inability to

³⁶ Dr. Tornatore testified that the only possible test that might reveal which mechanism was occurring was a brain biopsy. Tr. I at 84.

³⁷ Attenuation is "the reduction of the virulence of a pathogenic organism, usually by adaption to another host or to a different culture medium." Dorland's Illustrated Medical Dictionary, supra note 2, at 178.

control certain muscles affecting speech.³⁸ Id. at 72, 90. Dr. Tornatore then explained that ataxia is the result of cerebellitis, which he defined as an infection in the brain's cerebellum.³⁹ Id. at 72, 88-90. He also noted that ataxia may be caused by injury to the brain stem. Id. at 88-90. According to Dr. Tornatore, ataxia resulting from either cerebellar or brain stem involvement was essentially the same thing because brain stem involvement reflected an injury to the fibers that course from the cerebellum into the brain stem. Id. at 88-90. In petitioner's case, Dr. Tornatore stated that there was involvement of both the brain stem and the cerebellar fibers. Id. at 89, 91-92. Thus, Dr. Tornatore established that petitioner suffered from cerebellitis.

Dr. Tornatore testified that cerebellitis is a peculiar and specific characteristic of a natural varicella infection, and is not typically seen with other viruses.⁴⁰ Id. at 71-73, 78. He then cited an article by Wise et al., Postlicensure Safety Surveillance for Varicella Vaccine,⁴¹ indicating that ataxia was reported as a complication of varicella vaccination. Id. at 73. According to Dr. Tornatore, the article also indicated that because ataxia, encephalitis, and certain other symptoms characteristic of a natural varicella infection were also seen after the vaccination with the attenuated varicella virus, it was plausible that the varicella vaccine caused those symptoms. Id. at 74, 76-77. As a result, Dr. Tornatore found petitioner's ataxic dysarthria to be strong evidence of a varicella infection, and thus strong evidence of the varicella vaccine causing petitioner's encephalomyeloneuritis. Id. at 71-74.

Dr. Tornatore identified additional evidence supporting a causal link between the varicella vaccine and petitioner's encephalomyeloneuritis.⁴² First, Dr. Tornatore noted that the

³⁸ In his expert report, Dr. Tornatore did not present petitioner's diagnosis with ataxic dysarthria as evidence that the varicella vaccine might have caused petitioner's injuries. Pet. Ex. 6 at 2, 4.

³⁹ The cerebellum "is concerned in the coordination of movements. It is a fissured mass consisting of a body, comprising a narrow middle strip (the vermis) and two lateral lobes (the hemispheres[]), connected with the brain stem by three pairs . . . of peduncles." Dorland's Illustrated Medical Dictionary, supra note 2, at 336.

⁴⁰ Dr. Tornatore also testified that the varicella virus also has the propensity to affect the brain stem. Tr. I at 91.

⁴¹ Robert P. Wise, M.D., M.P.H. et al., Postlicensure Safety Surveillance for Varicella Vaccine, 284 JAMA 1271 (2000).

⁴² In his expert report, Dr. Tornatore explained that petitioner's perianal rash was evidence that the varicella vaccine might have caused her injuries. Pet. Ex. 6 at 2, 4. However, at hearing, Dr. Tornatore backed away from that opinion. He testified that "Ms. Casey developed a rash in the [perianal] area between her legs; however, once the catheter was changed the rash went away, so it seems not likely that the rash was a vaccine or a viral related rash." Tr. I at 81.

Wise et al. article described three separate cases of possible positive rechallenge involving myelitis, paresthesias, and convulsions, which supported a causal relationship between the varicella vaccine and neurological injuries. Id. at 74-76. Second, Dr. Tornatore noted that the Wise et al. article also described a case where a patient experienced increased liver enzymes, such as experienced by petitioner. Id. at 79-80. However, Dr. Tornatore could not attribute petitioner's elevated enzyme levels to the varicella vaccine. Id. at 80, 86-87. Third, Dr. Tornatore explained that petitioner's symptoms occurred within an appropriate period of time after vaccination. Id. at 78, 92. Finally, Dr. Tornatore stated that other causes had been excluded by petitioner's treating physicians. Id. at 78-79, 92. In sum, Dr. Tornatore articulated a credible and convincing theory explaining why the varicella vaccine more likely than not caused petitioner's encephalomyeloneuritis, that the varicella vaccine was a substantial factor in petitioner's encephalomyeloneuritis, and that but for the varicella vaccination, petitioner would not have developed encephalomyeloneuritis. Id. at 81-82.

4. Testimony of Petitioner's Expert: Joseph A. Bellanti, M.D.

Dr. Bellanti received his medical degree from the University of Buffalo in 1958. Id. at 95. Subsequent to receiving his degree, Dr. Bellanti did a pediatric residency at Buffalo Children's Hospital, one year of postdoctoral training in immunology at the University of Florida, and three years of researching viral immunology at the Walter Reed Army Institute of Research. Id. In the early 1960s, Dr. Bellanti joined the faculty of Georgetown University, where he currently practices. Id. At Georgetown University, Dr. Bellanti is a Professor of Pediatrics and Microbiology/Immunology. Id. In addition, he has directed the viral immunology laboratory, the Division of Allergy Immunology in the Department of Pediatrics, and the International Immunology Center. Id. Further, in addition to his research, Dr. Bellanti has been involved with clinical care and the teaching of medical students, residents, and fellows. Id. at 97-98.

Dr. Bellanti has received numerous honors and has served on a variety of committees in the fields of immunology and pediatrics. Id. at 95-96. Additionally, Dr. Bellanti has published nearly 400 articles and abstracts and approximately 59 books or book chapters in those fields. Id. at 96. Dr. Bellanti reported that he was currently working on the fourth edition of his immunology textbook that is used by medical students, residents, fellows, and practicing physicians. Id. at 96-97. The special master finds that Dr. Bellanti is well qualified to discuss the immunological causes of petitioner's injuries as well as the relevant medical literature.

a. Dr. Bellanti's Immunologically-Oriented Testimony Supported the Neurological Testimony of Dr. Tornatore

Dr. Bellanti began his testimony with a brief explanation and description of how the body's immune system functions when working properly and when it malfunctions. Id. at 101-03. As part of his discussion, he described four mechanisms of immune injury that involve allergy. Id. at 102-03. Dr. Bellanti then discussed the two mechanisms that can lead to

encephalomyeloneuritis described by Dr. Tornatore, a direct viral infection and an immune-mediated reaction to a virus, and provided examples of both mechanisms.⁴³ Id. at 103-06. Dr. Bellanti acknowledged that a virus could directly attack the nervous system or cause an inflammatory response that leads to a hypersensitivity reaction.⁴⁴ Id. He agreed with Dr. Tornatore that both mechanisms are probably involved in varicella infections and in petitioner's encephalomyeloneuritis. Id. at 104, 129. Dr. Bellanti further agreed that only rarely does the attenuated varicella virus in the varicella vaccine cause a viral infection of the central nervous system. Id. at 128-29.

Dr. Bellanti explained that he had personal experience with neurological reactions to the varicella virus. Id. at 106. Specifically, he has treated children who have presented with chickenpox encephalitis. Id. Dr. Bellanti agreed with Dr. Tornatore that the cerebellar injury of ataxia is a strong indicator of a varicella infection. Id. at 106, 111-12, 130. Other factors considered by Dr. Bellanti to support a causal relationship between the varicella vaccination and petitioner's encephalomyeloneuritis were the appropriate temporal relationship, the predominance of adverse reactions in females, petitioner's clinical course, and the absence of other causes. Id. at 111-12, 130.

⁴³ In his supplemental expert report, Dr. Bellanti stated that he agreed with the biological mechanism proposed by Dr. Tornatore; namely, a direct viral infection. Pet. Ex. 10 at 1. He did not address a possible immune-mediated inflammatory response until hearing.

⁴⁴ In particular, Dr. Bellanti implicates a type IV hypersensitivity reaction. Tr. I at 102-03. A type IV hypersensitivity reaction is "initiated by antigen-specific T lymphocytes; unlike forms of hypersensitivity mediated by antibodies, it takes one or more days to develop and can be transferred by lymphocytes but not by serum." Dorland's Illustrated Medical Dictionary, supra note 2, at 888; see also Tr. I at 102. T lymphocytes ("T cells") are the body's immunologically competent cells responsible for cellular immunity and antibodies are molecules that have "a specific amino acid sequence by virtue of which it interacts only with the antigen that induced its synthesis . . . or with antigen closely related to it." Dorland's Illustrated Medical Dictionary, supra note 2, at 100, 1077. There was no testimony indicating that a type IV hypersensitivity reaction involves molecular mimicry or that petitioner's theory of causation, as explained by Drs. Tornatore and Bellanti, is synonymous with molecular mimicry, as contended by respondent in his posthearing brief. Resp't Posthearing Mem. at 13, 15. Dr. Bellanti mentions molecular mimicry only once, in passing. Tr. I at 104. Dr. Oliva does propound a theory of molecular mimicry to explain how the varicella vaccine might cause encephalomyeloneuritis, but he was offered as a fact witness, not a causation expert, in this case. See Tr. II at 25-26.

b. From an Immunological Perspective, Petitioner’s Encephalomyeloneuritis Was, More Likely than Not, Caused by the Varicella Vaccine

Thus, based upon petitioner’s medical records, petitioner’s affidavit, his review of the expert reports of Dr. Tornatore and Dr. Leist, respondent’s expert, the pertinent medical literature, including the article by Wise et al.,⁴⁵ and his personal examination and testing of petitioner, Dr. Bellanti opined that “within reasonable medical probability and certainty,” there was a causal relationship between the varicella vaccination and petitioner’s encephalomyeloneuritis. Id. at 107-08, 112-13, 122, 130. Dr. Bellanti also opined that the varicella vaccine was a substantial factor in petitioner’s encephalomyeloneuritis and that but for the varicella vaccination, petitioner would not have developed encephalomyeloneuritis. Id. at 122. Dr. Bellanti stated that such a reaction was a rare event, and depends upon a person’s genetic make-up. Id. at 109, 129, 131. Dr. Bellanti’s testimony, like that of Dr. Tornatore, was clear and convincing.

5. Testimony of Respondent’s Expert: Thomas P. Leist, M.D., Ph.D.

Dr. Leist received a Ph.D. in biochemistry and immunology from a European university and subsequently did postdoctoral research in an immunology laboratory in Zurich. Id. at 135-36. Subsequently, Dr. Leist did additional postdoctoral research regarding the latency of herpes viruses at the University of California at Los Angeles. Id. at 136. Dr. Leist then received his medical degree from the University of Miami and did his neurology residency at Cornell University and Memorial Cancer Center. Id. Dr. Leist is board certified in neurology. Id. After his residency, Dr. Leist did additional research in neuroimmunology at the NIH. Id. Currently, Dr. Leist is an Assistant Professor of Neurology at Thomas Jefferson University and the director of both the Division of Clinical Neuroimmunology and the Comprehensive Multiple Sclerosis Center. Id. at 135. Dr. Leist sees patients and teaches residents. Id. Finally, Dr. Leist has served in editorial and reviewer positions for neurological journals and is a member of several neurological societies and academies. Id. at 136-37. The special master finds Dr. Leist to be highly qualified to testify regarding the possible causes of petitioner’s neurological injuries as well as the relevant medical literature.

⁴⁵ Dr. Bellanti indicated that the article by Wise et al. noted that encephalitis, myelitis, neuritis, meningitis, encephalopathy, ataxia, convulsions, and neuropathy had been reported following the varicella vaccine. Tr. I at 112-13. Dr. Bellanti also noted that of all of the cases analyzed in the article by Wise et al., the majority of reports pertained to children under the age of 17 and that of these children, there was a male predominance. Id. at 111. However, after the age of 17, there was a female predominance. Id.

a. A Theoretical Basis Exists Linking the Varicella Vaccine and Petitioner’s Neurological Injuries

Based upon his review of the medical records, the expert reports of Dr. Tornatore and Dr. Bellanti, and the medical literature attached to Dr. Tornatore’s expert report, Dr. Leist opined that “the current data[] that are available are insufficient to come to the conclusion that the varicella vaccine caused” petitioner’ injuries.⁴⁶ Id. at 138-39. Specifically, Dr. Leist asserted that “above and beyond the temporal association, there is no direct evidence in this case that the vaccine strain of varicella zoster was the causative agent.” Id. at 141; see also id. at 147 (Dr. Leist’s agreement that onset occurred within an appropriate time frame). However, Dr. Leist did agree that it was theoretically possible for the varicella vaccine to cause encephalomyeloneuritis. He stated:

On a purely theoretical basis it is conceivable that the varicella vaccine could cause this. This opinion is based on the fact that the live virus can cause this. However, as we have seen, . . . such cases would be extremely rare and they are even rare[r] or relatively rare[r] after the live viral type virus infection.

Id. at 141-42; see also id. at 177-78 (Dr. Leist’s agreement that natural varicella infection could cause encephalomyeloneuritis). Dr. Leist also agreed implicitly that the mechanisms of direct viral infection and immune-mediated inflammatory response were theoretically possible. Id. at 147. However, despite this theoretical causation, Dr. Leist reported that he was unaware of any cases where the varicella vaccine was the demonstrated cause of encephalomyeloneuritis. Id. at 146.

b. Dr. Leist Fails to Rebut Petitioner’s Contention that the Varicella Vaccine Caused Her Neurological Injuries

Dr. Leist addressed the article by Wise et al. He emphasized that the article merely categorized adverse events following a varicella vaccination as reported to Vaccine Adverse Event Reporting System (“VAERS”),⁴⁷ a passive surveillance system. Id. at 142-45. As such,

⁴⁶ Dr. Leist labeled petitioner’s injury as encephalomyeloradiculitis, and not encephalomyeloneuritis, because he found evidence in the medical records of proximal nerve injury. Tr. I at 139-40. However, Dr. Leist declared difference between the two terms as a mere subtlety. Id.; see also id. at 141 (labeling the difference as “deep semantics”), 157-59.

⁴⁷ VAERS is

a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. . . . By monitoring such events, VAERS helps to identify

Dr. Leist stated, one cannot use the article to draw a causal connection between the vaccine and a reported injury. Id. at 143. Furthermore, Dr. Leist stated that merely because the article reported instances of encephalitis, myelitis, neuritis, and cerebellar ataxia, one cannot conclude that the varicella vaccine was the causative agent in someone who experienced all of these symptoms. Id. at 173-74. Instead, the article serves as a starting point for future investigation. Id. at 145. The special master notes that petitioner's experts never claimed that the article by Wise et al. proved causation.

Dr. Leist also addressed the contention that alternative causes of petitioner's encephalomyeloneuritis had been ruled out. He noted that even though petitioner apparently was tested for the presence of CMV, EBV, and HIV, the reported results of these tests were not conclusive due to the lack of information about their timing and the lack of specific results. Id. at 147-49. Further, Dr. Leist estimated that in 40 percent of cases of diffuse demyelinating or cerebral conditions, such as experienced by petitioner, no cause may ever be determined. Id. at 149-50, 191. Dr. Leist noted that petitioner's discharge summary from Fairfax Hospital included a diagnosis of idiopathic encephalomyeloneuritis. Id. at 150. In sum, Dr. Leist stated that in petitioner's case, it is impossible to rule out all other causes.⁴⁸ Id. at 197. Of course, the special master must find only that the varicella vaccine more likely than not caused petitioner's injuries.

In addition, based mainly upon the radiologist's MRI report,⁴⁹ Dr. Leist disputed the contention that petitioner suffered from cerebellitis.⁵⁰ Id. at 154-56. Dr. Leist stated that the MRI report described significant involvement in the brain stem and cerebellar fibers, but failed to describe any involvement of the cerebellum.⁵¹ Id. at 154, 160. Dr. Leist defined cerebellitis as the inflammation of the body of the cerebellum, which he stated does not include the cerebellar

any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

Frequently Asked Questions About VAERS, at <http://vaers.hhs.gov/vaers.htm> (last visited August 6, 2005). Any person can file a report with VAERS. Id.

⁴⁸ Unlike Drs. Tornatore, Bellanti, and Oliva, Dr. Leist has never examined petitioner.

⁴⁹ Dr. Leist refers to the physician who interpreted the MRI as a neuroradiologist. Tr. I at 156. The radiologist, Lyndon K. Goodwin, M.D., is actually a diagnostic radiologist. See Inova Health System, Lyndon K Goodwin, MD, at http://connect.inova.com/physician/mddb.physician.phy_view?p_phy_id=101040792 (last visited Nov. 17, 2005).

⁵⁰ Dr. Leist testified that if petitioner did suffer from cerebellar ataxia, that diagnosis would not detract from petitioner's causation argument. Tr. I at 179.

⁵¹ Dr. Leist concurred with Dr. Tornatore's depiction of the connection between the cerebellum and the brain stem. Tr. at 155, 159-61, 179.

fibers. Id. at 160. He then stated that due to the cerebellar fibers running between the cerebellum and the brain stem, “there is functional cerebellar involvement just because the brain stem is involved.” Id. However, if the cerebellum were truly involved in petitioner’s ataxia, Dr. Leist would have expected the radiologist, “who obviously examined the surrounding structures very carefully,” to have noted such involvement in the MRI report. Id. at 155-56. Dr. Leist also noted that cerebellitis is commonly seen in children, not adults.⁵² Id. at 161. Accordingly, Dr. Leist concluded that petitioner did not suffer from cerebellitis. The special master finds Dr. Leist’s unsupported assertion that cerebellitis must affect the body of the cerebellum, and not just the cerebellar fibers, is not sufficient to rebut petitioner’s experts’ explanation that she did, in fact, suffer from cerebellitis.

To show a relationship between petitioner’s varicella vaccine and her injuries, Dr. Leist would have liked to have seen additional evidence. First, he would have liked to see petitioner’s physicians test or retest (as appropriate) for the presence of antibodies to CMV, EBV, varicella, and other frequently occurring pathogens. Id. at 151; see also id. at 168. Second, Dr. Leist would have liked to see testing for the presence of the varicella virus in petitioner’s spinal fluid through a polymerase chain reaction (“PCR”) test, a type of genetic test. Id. at 151. Dr. Leist explained that PCR testing could differentiate between the wild-type varicella virus and the vaccine-strain varicella virus. Id. at 152; see also id. at 169. Finally, Dr. Leist would have liked to see viral cultures of petitioner’s spinal fluid and urine. Id. at 151-52. The special master believes that Dr. Leist, a good clinician, requires a greater weight of evidence to prove the injury than what petitioner is required to provide in a Vaccine Act case to demonstrate causation. While Dr. Leist’s goal of achieving scientific certainty makes him an excellent treating physician, petitioners in Vaccine Act cases need not demonstrate scientific certainty in order to prevail.

C. Supplemental Hearing of November 16, 2005

At the initial hearing in this matter, petitioner testified about her inclusion in the article by Wise et al. and petitioner’s husband testified regarding Dr. Oliva’s statement that the varicella vaccine caused petitioner’s injuries. However, neither Dr. Wise nor Dr. Oliva were presented as witnesses. The special master indicated to the parties that testimony from these two physicians would be helpful to her resolution of the case. As such, a supplemental hearing was conducted on November 16, 2005. Petitioner presented the testimony of Dr. Oliva. Testimony was also provided by Dr. Wise. Respondent presented supplemental testimony from Dr. Leist.

⁵² Dr. Leist was unable to address whether the higher incidence of cerebellitis in children compared with adults was due to the possibility that people generally experience varicella infections (i.e., chickenpox) as children. Tr. I at 161-63. He did note, however, that the myelinating structures in a child’s brain are different from those in an adult brain. Id. at 163-64. He also noted that children more commonly have a diffuse encephalopathic process whereas in adults, the process is more localized. Id. at 192.

1. Testimony of Armando Oliva, M.D.

Dr. Oliva is currently the Associate Director for Policy in the Office of New Drugs at the Food and Drug Administration's Center for Biologicals Evaluation and Research ("CBER"). Tr. II at 23. Prior to his nine years of employment at CBER, Dr. Oliva treated petitioner. Id. at 23-24. Dr. Oliva was not presented as an expert witness.

Dr. Oliva opined that the most plausible cause of petitioner's encephalomyeloneuritis was her varicella vaccination. Id. at 24-25. He explained that his opinion was based upon his personal experience, the course of petitioner's symptoms, other reports of nervous system inflammation after viral infections, and the temporal relationship between the varicella vaccination and petitioner's onset of symptoms. Id. at 25, 28-29. He then proposed a biological mechanism for petitioner's alleged reaction to the varicella vaccine: "[T]he [vaccine's] interaction with the immune system results in the production of antibodies that cross-react with normal tissue in the body and other tissue, and actually causes an inflammatory reaction in those tissues."⁵³ Id. at 25. Dr. Oliva explained that "the antigen in the vaccine itself emulates [] the patient's own immune system to develop an immune response" Id. at 26.

In support of his opinion, Dr. Oliva referred to reports of encephalomyeloneuritis following a natural varicella infection as well as reports of other vaccines causing a similar immune reaction.⁵⁴ Id. Dr. Oliva also stated that animal models existed for the type of inflammation experienced by petitioner, but he could not identify any specific model. Id. at 27, 30. Finally, Dr. Oliva noted that no other cause could be identified for petitioner's symptoms. Id. at 28.

⁵³ This proposed mechanism is not the specific mechanism advanced by petitioner's expert witnesses, Dr. Tornatore and Dr. Bellanti.

⁵⁴ Dr. Oliva did not refer specifically to any article, paper, or study during his testimony. On February 22, 2005, petitioner's counsel filed a brief opinion written by Dr. Oliva. See Pet. Ex. 14. No medical literature was filed along with Dr. Oliva's opinion letter. On March 25, 2005, petitioner's counsel filed an e-mail exchange with Dr. Oliva, which included an excerpt from a neurology textbook discussing postvaccinal encephalomyelitis and using as examples the rabies and smallpox vaccines. See Pet. Ex. 15. Dr. Oliva was unable to discuss in detail the textbook entry at hearing. Tr. II at 32-33. In addition, attached to the e-mail exchange was an editorial from the Journal of the Neurological Sciences. See Pet. Ex. 15; Donald H. Gilden, Varicella Zoster Virus Vasculopathy and Disseminated Encephalomyelitis, 195 J. Neurological Sci. 99 (2002). Dr. Oliva also was unable to discuss the relevance of the editorial at hearing. Tr. II at 31.

On cross-examination, Dr. Oliva indicated that he had treated less than five⁵⁵ cases of encephalomyeloneuritis and that in none of those cases was he able to demonstrate definitive proof of a causative pathogen. Id. at 34. However, in response to the special master's questioning, Dr. Oliva stated that in the majority of cases, it is not possible to identify the responsible pathogen. Id. at 35.

Dr. Oliva was petitioner's treating neurologist and his opinion as a treating physician regarding his impression as to the cause of petitioner's injuries should be afforded some weight. Dr. Oliva echoed petitioner's husband's testimony that at the time he treated petitioner, he believed that the varicella vaccine caused her injuries. The special master finds that Dr. Oliva's testimony confirms the testimony of petitioner's husband and lends support to petitioner's claim.

Testimony of Robert P. Wise, M.D., M.P.H.

Dr. Wise is currently the Branch Chief for the Therapeutics and Blood Safety Branch in the Office of Biostatistics and Epidemiology at CBER. Id. at 5. Dr. Wise had previously worked in the Vaccine Safety Branch of the same organization and refers to himself as a medical epidemiologist. Id. at 5-6. Dr. Wise is board certified in preventive medicine and clinical pharmacology. Id. at 6. He describes his expertise as pharmacoepidemiology; in particular, in the "safety surveillance of licensed medical products." Id. at 7. Dr. Wise's testimony concerned his interactions with petitioner and her inclusion in his article regarding the varicella vaccine.

Dr. Wise stated that he first learned about petitioner's case through a VAERS report submitted by Merck, the manufacturer of the varicella vaccine. Id. at 38. The VAERS report contained the name and address of the reporter, who provided him with petitioner's name and contact information. Id. at 38-39. Dr. Wise contacted petitioner, who suggested that Dr. Wise consult with Dr. Oliva. Id. at 39. Subsequently, Dr. Oliva spoke with petitioner's current treating neurologist, Dr. Scherokman, who, in turn, provided a VAERS report and copies of medical records to Dr. Wise.⁵⁶ Id. at 39-40.

Then, shortly after his article was published in 2000, Dr. Wise received an e-mail from petitioner expressing some frustration about the apparent absence of her case history from the article.⁵⁷ Id. In a responsive e-mail, Dr. Wise assured petitioner that she had been included in the

⁵⁵ The hearing transcript indicates that Dr. Oliva estimated that he has treated 75 cases of encephalomyeloneuritis. Tr. II at 34. The special master's notes contradict the transcription and indicate that Dr. Oliva has treated less than five cases of encephalomyeloneuritis.

⁵⁶ According to Dr. Wise, he eventually had access to three different VAERS reports concerning petitioner: two from Merck and one from Dr. Scherokman. Tr. II at 69. None of these reports were submitted as part of the record in this case.

⁵⁷ This e-mail exchange was submitted as Petitioner's Exhibit 12.

article and identified those portions of the article where she had been included. Id. at 40. Dr. Wise stated that petitioner replied with an e-mail containing both an apology and compliments. Id. He sent one final e-mail to petitioner with his appreciation. Id.

Dr. Wise next discussed his article. He stated that the purpose of the article was to attempt to describe and summarize over 6,000 reports of adverse events following varicella vaccination. Id. at 42. However, Dr. Wise explained that the existence of an adverse event following vaccination did not, by itself, mean that the vaccine caused the event. Id. at 42, 72. Instead, Dr. Wise was seeking out patterns of adverse events to identify “potential or possible adverse reactions to the vaccine” that would suggest areas for further evaluation with independent data. Id. at 42-43, 45-46, 56; see also id. at 45 (“What we are arguing, rather, is the vaccine might play a role to warrant consideration of that possible risk in making decisions about treatment or administration of a vaccine, and possibly to guide further research.”). Dr. Wise indicated that “there was particular interest” in evaluating conditions that were commonly seen after a natural varicella infection, such as cerebellar ataxia. Id. at 54. Dr. Wise determined that petitioner’s symptoms fit the patterns for demyelinating events, GBS, and encephalopathy. Id. at 42. Dr. Wise did not include petitioner in the cerebellar ataxia category. Id. at 55.

Dr. Wise then responded to questions from respondent’s counsel regarding the interpretation of Dr. Wise’s article by Dr. Tornatore and Dr. Bellanti. First, in regards to Dr. Tornatore’s written opinion, respondent’s counsel asked:

I’m looking at Exhibit 6, which is Dr. Tornatore’s opinion, on page 2, and he says, “The similarity of the findings in the Wise article and Shannon’s hospital course is quite striking. The temporal relationship of a vaccine to the onset of symptoms fall well within the range described by the above article. Moreover, the combination of a rash, elevated transaminases, and encephalomyelitis have all been described [with] varicella vaccination, as noted above.” And he goes on to conclude that, therefore, Ms. Casey’s condition was caused by the vaccine.

Do you have a comment on that? Does your article, in its conclusion, support that conclusion?

Id. at 77 (emphasis added). Based upon counsel’s representations of the contents of Dr. Tornatore’s report, Dr. Wise responded that his article did not support Dr. Tornatore’s conclusion. Id. at 77-79. However, Dr. Tornatore’s written opinion included other factors in support of causation; the symptoms described in Dr. Wise’s article were but one factor considered important by Dr. Tornatore. In fact, Dr. Tornatore never stated in his written opinion that the article by Wise et al. documented evidence of causation. Rather, Dr. Tornatore believed that the article by Wise et al. was relevant to these proceedings because the study identified symptoms that can be caused by a natural varicella infection.

Similarly, respondent's counsel, in regards to Dr. Bellanti's written opinion, asked:

I'm going to read to you from Exhibit 8, which is Dr. Bellanti's opinion, page 2. "The time course of Ms. Casey's illness, which is classic for a post-infectious or post-vaccinal encephalitis, in the absence of any other infectious cause of her illness, strongly implicates the varicella vaccine as the cause of her neurologic condition. The paper by Wise confirms and strongly supports my opinion."

Your comment on that portrayal of your study results, please.

Id. at 81. Dr. Wise again indicated that his article was being misinterpreted. Id. at 81-82. However, Dr. Bellanti did not explain, in either of his written reports, how or why the article by Wise et al. confirmed and strongly supported his opinion. In fact, the only information the special master has about how and why the article by Wise et al. was important to Dr. Bellanti's opinion is from his testimony at the first hearing, where he commented on the types of cases reported and the demographics of the affected individuals. See supra note 45. Like Dr. Tornatore, Dr. Bellanti never contends that the article by Wise et al. provides direct evidence of causation.

Dr. Wise did not read Dr. Tornatore's or Dr. Bellanti's expert reports. The only information at his disposal was respondent's counsel's characterization of their reliance on Dr. Wise's article. Respondent's counsel's representations were, at least, imprecise.⁵⁸ Thus, Dr. Wise could not comment fairly on whether petitioner's experts misunderstood or misused his article. Moreover, based upon the information at his disposal, Dr. Wise could not opine on petitioner's diagnosis or whether the varicella vaccine caused her symptoms with any certainty. Tr. II at 55-56, 79-81, 93. Dr. Wise explained that in petitioner's case, there were no laboratory or clinical findings that identified specifically the attenuated varicella virus or that identified the attenuated varicella virus as the cause of petitioner's symptoms. Id. at 74-76. He also stated that there are other possible causes for the symptoms experienced by petitioner. Id. at 77. In sum, in Dr. Wise's view, it is "still an entirely open question whether the varicella vaccine virus can cause this kind of neurologic problem." Id. at 61.

Supplemental Testimony of Dr. Leist

Dr. Leist presented supplemental testimony pertaining to the editorial attached to Dr. Oliva's e-mail, submitted as Petitioner's Exhibit 15. Dr. Leist explained that he reviewed the editorial as well as an article by Häusler et al. from the same issue of the Journal of the

⁵⁸ The special master is not suggesting that respondent's counsel, a respected attorney, acted improperly. Rather, counsel's questions were framed in a manner that was too broad to characterize fairly the findings of Dr. Tornatore and Dr. Bellanti.

Neurological Sciences.⁵⁹ Id. at 97. He noted that the article was essentially two case reports of adverse reactions following a natural varicella infection. Id. at 98, 101. Thus, Dr. Leist stated that the article did not support petitioner's claim of causation. Id. at 102. Of course, the special master notes that petitioner did not submit this article on her behalf.

Dr. Leist also testified that in the majority of cases, if a patient experienced a complication from the varicella vaccine, one would expect that the patient would also experience a chickenpox-like rash. Id. at 99-101.

Additionally, Dr. Leist expanded upon his testimony during the initial hearing that “[o]n a purely theoretical basis, it's conceivable that the varicella vaccine could cause this.” He stated:

This is an attenuated strain of the live virus. In the live virus, on very rare occasions, CNS complications are seen Of the central nervous system complications, the majority of cases are cerebellitis, which is self-limited and clear. The majority of these central nervous system complications, as described in the literature, are seen in young children when they first acquire the virus. And so from that point of view, the virus can cause certain complications.

If we look at what has been reported in the literature as case reports, or if we look at what has been reported by Dr. Wise, or if we even look at what Dr. Oliva submitted as a proof of his, the majority of these cases come from young children. Sometimes if we go into the literature first, the majority of cases of reactivation of the virus in adults comes actually from severely immune-depressed individuals: HIV patients, patients with cancer in its various forms.

So as a theoretical basis, the live virus certainly can do this. The attenuated virus has—that's where the problem comes in—the attenuated virus would most likely, because of its replication characteristics and what it can do, have a much, much, much lower chance of ever causing this than the live virus. In the live virus, it's low compared to the cases observed.

Id. at 109-10. Thus, Dr. Leist continued to assert that, as rare as it may be, the attenuated virus can cause encephalomyeloneuritis.

Finally, Dr. Leist expanded upon what information he would require to make a finding of causation, or what he labels as “clinical, reasonable cause.” Id. at 112. The identification of a virus that caused a preceding viral illness would not be sufficient, in Dr. Leist's mind, to show causation. Id. at 112-13, 115. Dr. Leist would require additional evidence, such as evidence

⁵⁹ M. Häusler et al., Encephalitis Related to Primary Varicella-Zoster Virus Infection in Immunocompetent Children, 195 J. Neurological Sci. 111 (2002) (submitted at hearing as Respondent's Exhibit D). This article was not presented by petitioner in support of her case.

from spinal fluid or blood tests or the results of PCR testing. *Id.* at 113. Also, it is just as important for Dr. Leist to determine what other viruses were not present as it is to determine what viruses were present. *Id.* at 117. Dr. Leist concluded that “[t]here are no indications in this case that clearly tell me that this goes beyond an idiopathic encephalomyelorradiculitis.” *Id.* at 112. The special master continues to believe that Dr. Leist requires more evidence of causation than required by the Vaccine Act and by Federal Circuit precedent.

D. Petitioner Has Met Her Burden

As summarized by the Federal Circuit in *Althen*, petitioner will prevail only if she proves, more likely than not, “(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.” 418 F.3d at 1278. The special master is convinced that petitioner has made the requisite showing in this case.

First, petitioner has provided sufficient proof of a medical theory of causation. Petitioner’s experts proposed two possible mechanisms of injury, which they suspected were working in concert in petitioner’s case. One theory was a direct viral infection and the other was an immune-mediated inflammatory response, both of which can occur in the nervous system. Then, petitioner’s experts explained that a natural varicella infection can trigger both of these reactions. Further, Dr. Tornatore explained that even though the virus in the varicella vaccine is attenuated, it is reasonable to assume that the virus can multiply once inside the body and thus also trigger the two reactions. In essence, petitioner’s experts demonstrated that the attenuated virus in the varicella vaccine could lead to two distinct responses, which in turn could be directed at and negatively affect the nervous system. Respondent’s expert did not dispute the theoretical possibility of causation, but did contend that such a reaction would occur very rarely. It is precisely because individuals experience adverse reactions to safe vaccines on rare occasions that Congress created the Vaccine Program.

Second, all three experts, Dr. Tornatore, Dr. Bellanti, and Dr. Leist, agreed that if the varicella vaccination was the cause of petitioner’s injuries, petitioner’s onset of symptoms occurred within an appropriate time period after vaccination.

Finally, petitioner was able to prove a logical sequence of cause and effect. Petitioner suggested that the varicella vaccine caused both a direct infection of her nervous system as well as an immune-mediated inflammatory response in her nervous system. Then, both the direct infection and the inflammatory response resulted in damage to her brain, spinal cord, and peripheral nervous system (*i.e.*, her encephalomyeloneuritis). This damage was evidenced by weakness and lack of control of her legs, speech difficulties, and a neurogenic bladder and bowel.

Petitioner further suggested that her speech difficulties, also known as ataxic dysarthria, were caused by cerebellitis, a distinctive feature of a natural varicella infection and thus a

possible result of vaccination with the attenuated varicella virus. Dr. Tornatore, a well-credentialed neurologist, asserted that injury to the cerebellar fibers alone, without evidence of injury to the body of the cerebellum, is considered to be cerebellitis. Dr. Leist, another well-credentialed neurologist, disagreed with Dr. Tornatore and asserted that injury to the cerebellar fibers alone was not cerebellitis. Unfortunately, Dr. Leist did not provide any evidence in support of his assertion or discounting the assertion of Dr. Tornatore. Accordingly, Dr. Leist's testimony did not rebut petitioner's position that, more likely than not, she suffered from cerebellitis. Therefore, the special master finds that petitioner did suffer from cerebellitis, as evidenced by her diagnosis with ataxic dysarthria. Further, the special master finds that the cerebellitis, a symptom particularly associated with a natural varicella infection, more likely than not was a result of petitioner's varicella vaccination.

In sum, petitioner was vaccinated against varicella on June 9, 1995. The attenuated virus in the varicella vaccine both directly attacked petitioner's nervous system and caused an immune-mediated inflammatory response in her nervous system. As a result, within four weeks of her varicella vaccination, petitioner began to experience the onset of symptoms of her encephalomyeloneuritis. One such symptom was cerebellitis, a condition particularly associated with a natural varicella infection, which resulted in petitioner's speech difficulties. Thus, there is a logical sequence of cause and effect connecting petitioner's varicella vaccination to her subsequent injuries.

Therefore, because petitioner has satisfied all three elements laid out by the Federal Circuit in Althen, the special master finds that petitioner has met her burden of showing that, more likely than not, the varicella vaccine she received on June 9, 1995, caused her encephalomyeloneuritis. The varicella vaccine was both a substantial factor in petitioner's encephalomyeloneuritis as well as the but-for cause of petitioner's encephalomyeloneuritis.

CONCLUSION

Based upon a review of the medical records, medical literature, and expert reports, coupled with the testimony presented at hearing, the special master finds that the totality of evidence demonstrates that petitioner's June 9, 1995 varicella vaccination caused her encephalomyeloneuritis. Petitioner proved by a preponderance of the evidence that the varicella vaccine was the cause in fact of her encephalomyeloneuritis.

Thus, petitioner is entitled to reasonable compensation. The special master hopes that the parties may reach an amicable settlement, and will convene a telephonic status conference soon to discuss damages.

IT IS SO ORDERED.

Margaret M. Sweeney
Special Master