

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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No. 10-850V

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PUBLISHED

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PAMELA ANN DILLON,

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Influenza Vaccine; Alleged Autoimmune Transverse Myelitis; Documented Diagnosis of Cavernoma; Weight of Record Evidence Preponderates Against a Finding of Injury as Claimed

Petitioner,

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v.

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SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

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Respondent.

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William E. Cochran, Jr., Black, McLaren, Jones, Ryland & Griffee, Memphis, TN, for petitioner.

Ryan Pyles, United States Department of Justice, Washington, DC, for respondent.

DECISION¹

¹ Because this decision contains a reasoned explanation for the undersigned’s action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, “the entire” decision will be available to the public. Id.

On December 10, 2010, Pamela Ann Dillon (petitioner or Ms. Dillon) filed a petition under the National Vaccine Injury Compensation Program (Vaccine Act)² alleging that the injuries she sustained were caused by the vaccine she received on October 1, 2008. Petition (Pet.) at 1. She specifically alleged that as a result of her receipt of the influenza vaccination, she suffered—and continues to suffer—the effects of an autoimmune transverse myelitis. Petition (Pet.) at 1-2; Petitioner’s Exhibit (Pet’r’s Ex.) 1 at 2. Among her identified complaints are severe back pain, constipation, moderate sensory loss below the waist, and radiating leg pain. Id.

After reviewing the petition and accompanying medical records, respondent recommended against compensation, asserting that petitioner’s injuries were not vaccine-related, but rather stemmed from the growth of—and associated bleed from—a vascular malformation located in her spinal cord (known as a cavernoma). Respondent’s Rule 4(c) at 4-5.

At the core of the parties’ dispute regarding entitlement is a disagreement regarding the nature of petitioner’s injury. Transverse myelitis is a broad term describing various injuries that may include an “autoimmune response or [response to a] viral infection” as well as an “inflammatory event secondary to [trauma, such as] a bleed in the spinal cord.” Tr. at 175; see also Tr. at 262-63. At issue here is whether the transverse myelitis petitioner suffered was primary, autoimmune, and vaccine-related or was secondary to the hemorrhage of her cavernoma and thus, unrelated to the flu vaccine.

For the reasons set forth in greater detail below, the undersigned finds that petitioner has failed to satisfy her burden of proving that she suffered a vaccine-related injury. Accordingly, her claim must be dismissed.

The undersigned begins with a brief procedural summary.

I. PROCEDURAL BACKGROUND

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, (codified as amended, 42 U.S.C.A. §§ 300aa-10 et. seq. (2006)). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

After respondent recommended against compensating this claim in the Rule 4 report, petitioner filed an expert report from Sidney A. Houff, M.D., her former treating neurologist. Pet'r's Ex. 12-26. She also filed more medical records. Id.

In turn, respondent filed an expert report prepared by Thomas Leist, M.D., Ph.D., an expert in neuroimmunology. Order at 1, Sept. 15, 2011. Respondent argued that petitioner's injury stemmed from a preexisting vascular malformation (specifically, a cavernoma) that hemorrhaged and caused—as a secondary effect—a transverse myelitis episode. Respondent's Exhibit (Resp't's Ex.) A at 8, 10; Respondent's Supplemental Rule 4(c) at 4-5.

Petitioner then filed expert reports from Lawrence Steinman, M.D., a neuroimmunologist, and Robert M. Kessler, M.D., a neuroradiologist, as well as additional medical records. Pet'r's Ex. 29-50. Petitioner's counsel communicated that Dr. Houff's availability to continue serving as an expert witness was uncertain due to his personal health issues.³ Pet'r's Status Report at 1, Aug. 15, 2012.

Respondent responded by filing a supplemental expert report from Dr. Leist and an expert report from Chip Truwit, M.D., a neuroradiologist, to address Dr. Kessler's report. Resp't's Ex.'s B, C, D.

After the filing of the parties' expert reports, a status conference was held to address petitioner's pending request for copies of her most current radiologic images. Order at 1, Aug. 18, 2012. On August 20, 2012, three days after the status conference, petitioner filed a compact disc containing the imaging which confirmed that the lesion she had removed surgically from her spinal cord was a cavernoma. Pet'r's Ex. 63 at 64.

A two day hearing was held in Nashville, Tennessee in August 2012. The parties' expert witnesses testified at the hearing and thereafter, the parties filed additional exhibits. Resp't's Ex.'s G, H, I, J;⁴ Pet'r's Ex.'s 67-71. The parties were afforded an

³ The undersigned afforded petitioner the opportunity to file a later supplemental opinion from Dr. Houff, if desired. Order at 2, Aug. 15, 2012. Petitioner did not do so.

⁴ Respondent filed two case studies referenced by Dr. Leist during the hearing that discuss cavernous malformations within the spinal cord. Dr. Leist indicated that the first article (filed as Resp't's Ex. G) reflects the results of a study conducted in China. Young-A Kim, M.D., et al., A Case of Spinal Cord Cavernoma Mimicking Transverse

opportunity to explore the possibility of an informal resolution. Order at 2, Nov. 27, 2012. Because their efforts were unsuccessful, the parties resumed the litigation by filing post-hearing briefs. The matter is now ripe for a ruling.

For context, the undersigned now reviews the facts of this case. The parties do not dispute the relevant facts. Rather, they dispute the medical significance of the facts.

A. Petitioner's Pertinent Medical History

1. Petitioner's pre-vaccination health

Petitioner was born in July 1957. Pet'r's Ex. 2 at 1. Her medical history is remarkable for depression, anxiety, kidney stones, obesity, sleep apnea, and a hysterectomy. Pet'r's Ex. 11 at 1. She had no noted neurologic problems before she received a trivalent influenza vaccine on October 1, 2008, the immunization of which she complains here. Pet'r's Ex. 1.

On February 14, 2006, more than two years before she received the subject vaccination, petitioner received a skin test for tuberculosis (known as a PPD test) and a flu vaccine; her medical records indicate that she had not experienced any problems with her previous immunizations. Pet'r's Ex. 2 at 2. Three months later, petitioner received a measles, mumps, and rubella (MMR) vaccination on May 11, 2006, with no reported side effects. Id.

Myelitis, 18 Dep't of Pediatrics & Neurosurgery, Asan Med. Ctr. Univ. of Usan Coll. of Med. 153 (May 2010). He indicated that the second article (filed as Resp't's Ex. H) reflects the results obtained from a pediatric study of cavernomas. Erwin M. J. Cornips, et al., Intramedullary cavernoma presenting with hematomyelia: report of two girls, 26 Child's Nervous Sys. 391 (2010).

Respondent also filed, as Exhibit I, the medical literature referenced by Dr. Leist addressing whether the time lapse between the onset of a patient's symptoms and the conduct of an MRI has any effect on the results of the imaging. B.G. Leypold, et al., The Early Evolution of Spinal Cord Lesions on MR Imaging following Traumatic Spinal Cord Injury, 29 Am. J. Neuroradiology 1012 (May 2008).

Exhibit J contains Dr. Truwit's response to Dr. Kessler's rebuttal expert report dated September 27, 2012.

More than two years later, on September 30, 2008, petitioner conferred with Eric Smith, a doctor of osteopathic medicine, to explore the possibility of gastric bypass surgery. Pet'r's Ex. 11 at 5. Dr. Smith noted that petitioner was suffering from hyperlipidemia,⁵ morbid obesity, and back pain. Id.

2. Petitioner's flu vaccine and the subsequent onset of her neurologic symptoms

On October 1, 2008, the day after conferring with Dr. Smith about her gastric bypass surgery, petitioner received the flu vaccine at issue here. Pet'r's Ex. 2 at 14. Two weeks later, on October 17, 2008, petitioner underwent a sleep study at St. Claire Regional Medical Center's Sleep Laboratory. The study revealed that she had moderate sleep apnea. Pet'r's Ex. 3 at 139. The consulting physician ordered a continuous positive air pressure (CPAP) machine to help petitioner breathe more easily while sleeping. Id.

On October 19, 2008, two days after undergoing the sleep study, petitioner sought treatment at the St. Claire's emergency room for complaints of severe back pain that had started a day earlier. Pet'r's Ex. 3 at 163. An abdominal ultrasound and an abdominal computed tomography (CT) scan⁶ were performed; the results were negative for kidney stones, but diffuse fatty gallstones were noted. Id. at 168-69. Among petitioner's recorded diagnoses were acute pain, lumbar strain, and a left ovarian cyst. Pet'r's Ex. 1; Pet'r's Ex. 3 at 161. After treatment with pain relievers, she was discharged. Pet'r's Ex. 3 at 161.

Two days later, on October 21, 2008, petitioner returned to St. Claire's emergency room complaining of ongoing back pain and the onset of radiating leg pain. Pet'r's Ex. 3

⁵ Hyperlipidemia is a general term for elevated concentrations of lipids in blood plasma. Dorland's Illustrated Medical Dictionary 891 (32nd ed. 2012).

⁶ A computerized tomography (CT) scan combines a series of X-ray views from different angles and computer processing to create cross-sectional images of the bones and soft tissues inside a subject's body. CT Scan, WebMD, <http://www.mayoclinic.com/health/ct-scan/MY00309> (last revised Mar. 23, 2012). A CT scan of the abdomen can assist in finding cysts, abscesses, infection, tumors, aneurysms, enlarged lymph nodes, foreign objects, bleeding in the belly, diverticulitis, inflammatory bowel disease, and appendicitis. Computed Tomography (CT) Scan of the Body, WebMD, <http://www.webmd.com/a-to-z-guides/computed-tomography-ct-scan-of-the-body> (last updated June 13, 2011).

at 177. She also reported constipation and moderate sensory loss in the length of her legs. Id. She had no fever. Tr. at 179. Petitioner presented with an abrupt onset of symptoms, which were neither systemic nor prodromal⁷ in nature. See Tr. at 177-79, 316; see also Tr. at 90. The attending emergency room physician recorded a clinical impression of “acute back pain with sensory deficit.” Id.

That same day, petitioner was transferred from St. Claire’s emergency room to the University of Kentucky Medical Center (UKMC). Id. At the time of her admission, petitioner was unable to walk without assistance, due to weakness. Pet’r’s Ex. 4 at 35.

A magnetic resonance image (MRI)⁸ was taken of petitioner’s spine on October 22, 2008, the day after petitioner’s admission. Pet’r’s Ex. 4 at 86. The MRI taken of her lumbosacral region showed degenerative disc changes in the L5-S1 disc. Id. at 79.

Another MRI revealed ascending lesions of white matter in the lumbothoracic spine; these findings were indicative of inflammation. Pet’r’s Ex. 4 at 35-36. This MRI also showed signal abnormality, and suggested a small, focal lesion within the distal thoracic spinal cord, centered at the T9/T10 disc space. Pet’r’s Ex. 4 at 36, 85-86. A hemosiderin deposit was detectable near the lesion; it appeared as a dark stain on the imaging. Tr. at 269. A hemosiderin deposit signals that blood was in the area. Tr. at 270-72; see Resp’t’s Ex. C at 4.

That same MRI also showed a signal enhancement at the T2 level. Pet’r’s Ex. 4 at 36, 85-86. This signal enhancement spanned an area of six vertebral segments. Id. Also discernible within the mid and distal portions of the thoracic spinal cord was nearly complete resolution of vaguely observable edema.⁹ Id. This particular finding was

⁷ Prodrromal symptoms are symptoms indicating the onset of a disease. Dorland’s Illustrated Medical Dictionary 1522 (32nd ed. 2012).

⁸ An MRI uses a magnetic field and pulses of radio wave energy to create pictures of the spine. Magnetic Resonance Imaging (MRI) of the Spine, WebMD, <http://www.webmd.com/brain/magnetic-resonance-imaging-mri-of-the-spine> (last updated May 16, 2011). Such imaging can assist in identifying changes in the spine and in other tissues. Id. It also can assist in the detection of infection or tumors. Id. MRIs may focus on particular segments of the spine, specifically, the neck (cervical), the upper back (thoracic), or the lower back (lumbosacral). Id.

⁹ Edema refers to the presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body, usually referring to subcutaneous tissues. Dorland’s Illustrated Medical Dictionary 593 (32nd ed. 2012).

deemed consistent with transverse myelitis. Id. Transverse myelitis is a neurologic disorder caused by inflammation in the spinal cord.¹⁰

Petitioner was examined by Kevin Nelson, M.D., a neurophysiologist, who found that her muscle strength had improved. Id. at 35-36, 188; Tr. 47-48. Her weakness however, persisted, and the reflexes in her lower extremities remained flat. Id. Petitioner received a high-dose treatment of intravenous steroids (methylprednisolone)¹¹ for three days, but she showed only modest improvement. Pet'r's Ex. 4 at 35-36, 118; Tr. 47-48.

A lumbar puncture study performed on October 24, 2008, three days after petitioner's hospital admission, showed an elevated red blood cell count in tubes one and four.¹² Pet'r's Ex. 4 at 89. This finding was not normal.

Due to the lack of any prior evidence of a hemorrhage in petitioner's spinal fluid—as detected by her treating physicians—no consideration appears to have been given to the possibility of a bleed within her spinal cord. Id.

Three days later, on October 27, 2008, petitioner had a neurology consult. Id. at 19. The examining neurologist opined that petitioner was suffering from a transverse myelitis episode, possibly secondary to the flu vaccine she had received three weeks before her hospital admission. Id.

¹⁰ The suffix “itis” in the term “myelitis” refers to inflammation. Myelitis refers to inflammation of the myelin fibers surrounding the spinal cord; and the term “transverse” describes the positioning of the detected inflammation across the width of the spinal cord. Transverse Myelitis Fact Sheet, Nat'l Inst. of Neurological Disorders & Stroke, http://www.ninds.nih.gov/disorders/transversemyelitis/detail_transversemyelitis.htm (last updated Oct. 15, 2012); Dorland's Illustrated Medical Dictionary 1218 (32nd ed. 2012).

¹¹ Methylprednisolone (also known by the brand names of Medrol and Solu-Medrol) is a synthetic glucocorticoid derived from progesterone. Dorland's Illustrated Medical Dictionary 1154 (32nd ed. 2012). Administered orally, it operates as an anti-inflammatory and immunosuppressant in a wide variety of disorders. Id.

¹² A normal red blood cell count for this procedure is 0. CSF cell count, MedlinePlus, <http://www.nlm.nih.gov/medlineplus/ency/article/003625.htm> (last updated Apr. 30, 2011). Petitioner's red blood cell (RBC) count was 240 in tube 1 and 2000 in tube 4. Pet'r's Ex. 4 at 89. Otherwise, her spinal fluid culture was unremarkable. Id.

Petitioner was discharged on October 29, 2008, after a ten day hospitalization. Pet'r's Ex. 4 at 19, 36. Her diagnosis was transverse myelitis. Id.

3. Petitioner's medical condition after her hospital discharge in October 2008

Petitioner spent the next two-month period, from October 29, 2008, to December 11, 2008, at Cardinal Hill Rehabilitation Hospital. Pet'r's Ex. 5 at 4. On discharge, she was able to groom and bathe herself and to function independently. Pet'r's Ex. 5 at 90-91.

In February 2009, two months after her release from the rehabilitation center, petitioner reported that her condition had improved, but she continued to require the use of a walker. Id. at 944-45. She also continued to have difficulty with her bowels, spasticity in her right leg, and numbness of her left hand. Id. Her problems with anxiety, obstructive sleep apnea, and obesity were ongoing. Id.

On April 28, 2009, petitioner conferred with Dreama Rucker, M.D., a family practitioner at the Morehead Clinic, to establish a course of routine patient care and management of her medical issues. Pet'r's Ex. 7 at 8.

Six weeks later, on June 9, 2009, petitioner returned to UKMC for a neurology consult. Pet'r's Ex. 4 at 397. Although her symptoms had improved, she still had not returned to her baseline condition. Id. at 397-98. She reported an onset of vision problems, id., which prompted an admission to the hospital for two days. Id. at 397-98, 404.

During that hospitalization, petitioner received another neurologic evaluation to determine whether she was suffering from transverse myelitis or neuromyelitis optica (also known as Devic's disease), a type of transverse myelitis further complicated by eye inflammation.¹³ A thoracic MRI taken of petitioner's spine revealed to petitioner's

¹³ Subjects with neuromyelitis optica (NMO) develop optic neuritis—which causes pain in the eye and vision loss—in addition to transverse myelitis—which causes weakness, numbness, sensory disturbances, loss of bladder and bowel control and, upon occasion, paralysis of the arms and legs. NMO occurs when myelin, the fatty sheath surrounding nerve fibers that protects the movement of nerve signals between cells, is damaged. For reasons that are not yet well-understood, NMO can occur as a result of an autoimmune attack on the myelin cells in the optic nerves and the spinal cord. NINDS

examining physician that the lesion of interest on her earlier MRIs was “most suggestive of a cavernous malformation with remote hemorrhage.” Pet’r’s Ex. 28 at 58. That MRI also revealed that the swelling detected on the earlier October 21, 2008 study had resolved.¹⁴ Pet’r’s Ex. 28 at 57. Id. A profile of petitioner’s cerebrospinal fluid showed elevated myelin basic protein levels, which can be an indicator of trauma, infection, stroke, or disease in the central nervous system. Pet’r’s Ex. 28 at 49. The test did not reveal any oligoclonal banding or an elevation in IgG index, either of which would be indicative of systemic inflammation.¹⁵ Id. Nor did petitioner test positive for Devic’s disease. Pet’r’s Ex. 4 at 509-11.

Between June 2009 and March 2010, petitioner returned to the Morehead Clinic on several occasions for various medical issues that were independent of her alleged vaccine-related injury.¹⁶ During an office visit in March of 2010, Dr. Rucker noted that petitioner still needed a cane to help her walk. Pet’r’s Ex. 7 at 5. She attributed the areas

Neuromyelitis Optica Information Page, Nat’l Inst. of Neurological Disorders & Stroke, http://www.ninds.nih.gov/disorders/neuromyelitis_optica/neuromyelitis_optica.htm (last updated May 14, 2010).

¹⁴ Other MRIs were taken as well. The MRI taken of petitioner’s cervical spine showed mild degenerative changes at C5/C6; the MRI taken of her lumbar region showed a small disc protrusion at L5-S1. Pet’r’s Ex. 28 at 43, 56.

¹⁵ Cerebrospinal fluid may be tested for the presence of oligoclonal banding. CSF oligoclonal banding, PubMed Health, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0004097/> (last reviewed Apr. 30, 2011). Oligoclonal bands are proteins (immunoglobulins). Id. Detection of these bands suggests that inflammation is present in the central nervous system. Id.

IgG antibodies are found in blood and lymph fluid and are the first type of antibody made in response to infection. Immunoglobulins, WebMD, <http://www.webmd.com/a-to-z-guides/immunoglobulins> (last revised July 29, 2010). IgG antibodies cause other immune system cells to destroy foreign substances. Id. The elevation of IgG levels found in the cerebrospinal fluid of patients with inflammatory diseases of the central nervous system is caused by the synthesis of IgG in the local central nervous system. Clinical Cerebrospinal Fluid (CSF) IgG Index, MayoClinic, <http://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8009> (last visited June 17, 2013).

¹⁶ Among the various health issues requiring close attention was petitioner’s nodular basal cell carcinoma. See Pet’r’s Ex. 7 at 5.

of persistent numbness between petitioner's waist and thighs to an earlier reported episode of post-vaccinal transverse myelitis.

Petitioner visited the clinic again in September 2010. Id. at 2. Among her various complaints was chronic constipation. Id.

Petitioner filed this vaccine claim three months later, on December 10, 2010. Pet. at 1.

Four months thereafter, petitioner sought follow-up for her neurologic symptoms at a consult with Dr. Houff. Pet'r's Ex. 59 at 83-84. Dr. Houff noted in a record dated April 12, 2011 that petitioner had experienced minimal improvement since June 2009 in the sensations affecting her legs. Id. He carried forward in his records—as part of petitioner's medical history—her earlier diagnosis of transverse myelitis. Pet'r's Ex. 59 at 83. Attributing petitioner's ongoing symptoms to the earlier episode of transverse myelitis, which occurred three weeks after she had received a flu vaccine, id., Dr. Houff prepared an expert report in support of her vaccine claim. Pet'r's Ex. 12 (Dr. Houff's reported dated June 26, 2011).

On May 10, 2011, one month after her visit to Dr. Houff, petitioner had another MRI taken of her thoracic spine. Pet'r's Ex. 28 at 21. That MRI showed a lesion at the T9/T10 disc base. Id. The evaluating physician noted: “[T]he size, configuration, and signal intensity characteristic of the lesion [has] remained stable over the past 2 years. There [also] remains speckled punctuate enhancement of the lesion and evidence of prior hemorrhage. The lack of interval change overall . . . favors the diagnosis of a vascular malformation or cavernous angioma.” Id. (emphasis added).

Almost one year later, on March 27, 2012, another MRI revealed that the lesion detected at the T9/T10 location had grown. Pet'r's Ex. 50 at 4-5. Notably, the lesion had grown approximately 200 times in volume since its initial detection in October 2008. Tr. at 149, 151-52. Petitioner consulted in June 2012 with Abdunnasser Alhajeri, M.D., a radiologist, concerning the lesion. Id. at 5. Dr. Alhajeri observed that petitioner's symptoms had “progressed over the last year and a half.” Id.

On that same day, Dr. Houff—the neurologist with whom petitioner first consulted nearly two and a half years after the onset of her neurologic symptoms—expressed

concern that petitioner might have developed an arteriovenous malformation¹⁷ of the spinal cord in addition to her earlier vaccine-related event. Pet'r's Ex. 55 at 4.

Petitioner eventually became confined to a wheelchair. Id. The lesion detected on her radiologic imaging was confirmed to be a cavernoma and was surgically resected on July 31, 2012. Pet'r's Ex. 63; Pet'r's Ex. 64 at 1.

The parties disagree about the condition from which petitioner was suffering when her neurologic symptoms first appeared in October 2008. Before considering the experts' respective positions, a brief discussion of the injuries at issue in this case follows.

B. The Injuries at Issue

1. Cavernoma

A cavernoma¹⁸ is a vascular tumor composed mainly of large, dilated blood vessels that often contain large amounts of blood. Dorland's Illustrated Medical Dictionary 831 (32nd ed. 2012). The blood vessels that comprise a cavernoma are thin-walled, and are different in size and diameter. Tr. at 176; see also Tr. at 21, 264.

Usually located in the skin or subcutaneous tissue, a cavernoma may also be found throughout the body in viscera such as the liver, spleen, pancreas or brain. Dorland's Illustrated Medical Dictionary 831 (32nd ed. 2012). The lesion often presents early in life, but not ordinarily at birth. Id. When the lesion is superficial, it is bright to dark red in color, but when the lesion is more deeply embedded, it has a blue color. Id.

A spinal cavernoma presents as "a lesion on the spinal cord" but it exists "separately" from the surface of the spinal cord. Tr. at 176. Over time, such a lesion

¹⁷ Arteriovenous malformations (AVMs) are masses of arteries and arterialized veins which disrupt normal blood flow by operating as high flow shunts for blood. Central Nervous System Vascular Malformations: A Patient's Guide, Neurovascular Ctr, Mass. Gen. Hosp., Harv. Med. School, <http://neurosurgery.mgh.harvard.edu/neurovascular/vascintr.htm#AVM> (last visited June 21, 2013). Compressed between the mass of blood vessels is brain tissue. Id. AVMs are distinguishable from other types of vascular malformations such as cavernomas, which are composed of large, blood-filled channels, or "caverns," immediately adjacent to each other and without interspersed brain tissue. Id.

¹⁸ A cavernoma may be referred to variously as a cavernous malformation or a cavernous hemangioma. Tr. at 22.

may grow large enough to cause the spinal cord surrounding it to expand. Tr. at 133. Because the walls of the blood vessels contained within a cavernoma are thin, growth of a cavernoma may lead to a bleed.

A cavernoma can remain asymptomatic for a long period of time. But once it begins to grow or to bleed, it can create “the same constellation of neurological problems ...[one] might see when there is inflammation in the spinal cord.” Tr. at 23-24 (Dr. Steinman); see also Tr. at 88; Resp’t’s Ex. G. It is undisputed that once a cavernoma becomes symptomatic, its clinical presentation is indistinguishable from that in a subject suffering from an episode of autoimmune transverse myelitis. See, e.g., Tr. at 23, 88, 219, 241; see also Pet’r’s Ex. 29 at 23; Resp’t’s Ex. G. Thus, clinical presentation alone does not determine whether an observed transverse myelitis is autoimmune-mediated or vascularly-mediated.

What causes a cavernoma to form is unclear, but some vascular malformations appear to have been formed as a result of genetic cues. Tr. at 176.

2. Transverse Myelitis

As mentioned earlier, myelitis generally refers to inflammation of the spinal cord and is often part of a more specifically defined disease process. Dorland’s Illustrated Medical Dictionary 1218 (32nd ed. 2012). In practice, however, the term also is used to refer to non-inflammatory lesions in the spinal cord. Id.

Myelitis can be caused by radiation, infection, or various viruses. Tr. at 117 (Dr. Kessler). It also can be caused by an immune-mediated response, whether in association with autoimmune disorders or vaccine-triggered reactions. Id. at 117-18.

Transverse myelitis is a form of myelitis in which the functional effect of a lesion spans the width of the entire cord at a given level (and is thus, transverse). Id. In its purest form, transverse myelitis is an inflammatory disease of the spinal cord. Tr. at 15 (Dr. Steinman). The inflammatory process may involve either a small segment of the spinal cord or several vertebral segments. Id. at 262 (Dr. Truwit).

Although transverse myelitis primarily involves inflammation of the spinal cord, it can involve inflammation of other parts of the nervous system and take on various forms. Tr. at 15 (Dr. Steinman). Idiopathic transverse myelitis is the presumed diagnosis when no specific cause for the condition can be determined, and such cases are not well-understood by the medical community. Tr. at 15, 72 (Dr. Steinman). The condition is described as acute when symptom onset is abrupt. Id. at 15-16. The condition is

described as chronic if acute relapses have occurred or the affected patient suffers long term sequelae from the initial acute attack. Id. In cases of autoimmune transverse myelitis, the condition is caused by an immune system attack on the spinal cord. Id. at 17. The term transverse myelitis also may describe a myelopathy, which is a dysfunction of the spinal cord. Tr. at 176 (Dr. Leist). Because the forms of transverse myelitis vary and the pathophysiology remains largely unknown, imprecise terminology often is used to describe the broad class of conditions that can be defined as transverse myelitis. Id. at 16-17.

A diagnosis of transverse myelitis is based on a combination of clinical symptoms and evidence of inflammation within the spinal cord—usually detected by either cerebrospinal fluid abnormalities or visible lesions on radiologic imaging. Resp’t’s Ex. G at 156. Increased T2 signals in the spinal cord and swelling over a long segment of the cord routinely—even if not uniformly—appear on spinal MRIs of subjects with inflammatory conditions, such as transverse myelitis. Tr. at 117 (Dr. Kessler). Spinal cord abnormalities alone, however, are not dispositive of transverse myelitis, and in a clinical setting, where there is a lack of specific disease markers, an absence of laboratory findings, and variability in the clinical presentation, making a diagnosis of transverse myelitis can be problematic. Resp’t’s Ex. G at 156.

C. The Opinions of the Parties’ Experts

Petitioner presented the opinions of Drs. Steinman and Kessler. Respondent presented the opinions of Drs. Leist and Truwit. All of the parties’ experts were well-qualified, and the undersigned accepted each expert as tendered.¹⁹

¹⁹ Petitioner offered, and the undersigned accepted, Dr. Steinman as an expert in neurology and immunology. See Tr. at 14-15. He received his medical degree from Harvard University. Pet’r’s Ex. 30 at 1; Tr. at 10. He completed residencies in pediatrics and adult neurology at Stanford University Hospital. Pet’r’s Ex. 30 at 1; Tr. at 11. He received postdoctoral training in chemical immunology from the Weizman Institute of Science in Israel. Pet’r’s Ex. 30 at 1; Tr. at 11. Dr. Steinman is board certified in psychiatry and neurology. Pet’r’s Ex. 30 at 2; Tr. at 10. He has served as a professor at the Weizman Institute of Science, as well as an assistant professor and associate professor at Stanford University in the Departments of Neurology, Pediatrics, and Genetics. Pet’r’s Ex. 30 at 1.

Dr. Steinman is currently a professor at Stanford University in the Department of Neurology, Pediatrics, and Genetics, and serves as Chair of the Interdepartmental

Program in Immunology. Pet'r's Ex. 30 at 1; Tr. at 12. He trains neurology residents, immunology doctoral candidates, and postdoctoral fellows. Tr. at 12. He also sees two to three patients per month in the neurology clinic. Tr. at 10, 60. Dr. Steinman was elected to the Institute of Medicine with the National Academy of Sciences USA, and he holds several vaccine-related patents. Pet'r's Ex. 30 at 2-3; Tr. at 14. He has published extensively on the subjects of neurology and immunology. Pet'r's Ex. 30 at 4-35; Tr. at 12.

Petitioner offered, and the undersigned accepted, Dr. Kessler as an expert in neuroradiology. See Tr. at 116. Dr. Kessler received his medical degree from Yale University. Pet'r's Ex. 45 at 1; Tr. at 112. He completed a residency in diagnostic radiology at Peter Bent Brigham Hospital and a fellowship in nuclear medicine at the Clinical Center for the National Institutes of Health. Pet'r's Ex. 45 at 1; Tr. at 112-13. He is board certified in diagnostic radiology and eligible for board certification in nuclear medicine. Pet'r's Ex. 45 at 1; Tr. at 113. He served as a Major for the United States Army Medical Corps and Chief for the Special Procedures Section of the Brooke Army Medical Center. Pet'r's Ex. 45 at 3; Tr. at 112. He also served as a staff physician in the Department of Nuclear Medicine and Project Officer for the Positron Tomography Program at the Clinical Center for the National Institutes of Health. Pet'r's Ex. 45 at 3; Tr. at 112-13.

Dr. Kessler has held positions as associate professor and full professor of Radiology and Psychology at Vanderbilt University School of Medicine. Pet'r's Ex. 45 at 3. He has also served as the School's Chief of Neuroscience Imaging for the Department of Radiology, Chief of the Positron Tomography Section, and Director of Positron Tomography Research. Pet'r's Ex. 45 at 3; Tr. at 113. He is currently the Roentgen Professor of Radiology at Vanderbilt University School of Medicine, where he engages in research, teaching, and clinical services. Pet'r's Ex. 45 at 3; Tr. at 112, 115. Over the span of his practice, he has reviewed thousands of MRI scans and patient studies for diagnostic and research purposes. Tr. at 115-16. He holds three patents, and he has published extensively on neurological and neuroradiological issues. Pet'r's Ex. 45 at 6-16.

Respondent offered, and the undersigned accepted, Dr. Leist as an expert in neurology and neuroimmunology. See Tr. at 172. Dr. Leist holds a doctoral degree in biochemistry from the University of Zurich. Resp't's Ex. D at 1; Tr. at 169. He received his medical degree from University of Miami. Resp't's Ex. D at 1; Tr. at 169-70. He completed his residency in neurology at Cornell Medical Center, Sloan Kettering Memorial Cancer Center. Resp't's Ex. D at 1; Tr. at 170. He completed a staff

fellowship in pathology at the University of Zurich and a fellowship in microbiology and immunology at the University of California at Los Angeles. Resp't's Ex. D at 1; Tr. at 170. He held a position as Senior Clinical Staff Associate with the National Institute of Neurological Disorders and Stroke at the National Institutes of Health. Resp't's Ex. D at 1; Tr. at 171. Dr. Leist also served as an instructor in the Department of Pediatrics at University of Miami. Resp't's Ex. D at 1. He is board certified in psychiatry and neurology. Resp't's Ex. D at 1; Tr. at 172.

The last twelve years of Dr. Leist's career have been spent at Thomas Jefferson University as an Assistant Professor of Neurology and Director of the Neuroimmunology Division within the Department of Neurology. Resp't's Ex. D at 1; Tr. at 170. In his practice, Dr. Leist sees patients with multiple sclerosis, lupus, neuromyelitis optica, and other autoimmune disorders. Tr. at 170. He described his current research which involves a comparison of subjects' immune responses, prior to treatment and during treatment. Tr. at 172.

Respondent offered, and the undersigned accepted, Dr. Truwit as an expert in neuroradiology. See Tr. at 257. Dr. Truwit received his medical degree from Georgetown University. Resp't's Ex. E at 2; Tr. at 252. He completed a residency in diagnostic radiology with special competence in nuclear medicine at the Brooke Army Medical Center while serving with the United States Army Medical Corps. Resp't's Ex. E at 2-3; Tr. at 252. He completed a fellowship in neuroradiology at the University of California, San Francisco. Resp't's Ex. E at 2; Tr. at 252. He is board certified by the National Board of Medical Examiners and the American Board of Radiology with a certificate of added qualifications in neuroradiology maintenance. Resp't's Ex. E at 3. While in the United States Army Medical Corps, he served as Chief of the Emergency Department at the Eighth Army Community Hospital in Seoul, Korea. Resp't's Ex. E at 4. Dr. Truwit also served as an Army physician and radiologist at Fitzsimons Army Medical Center, with a clinical appointment at the University of Colorado. Resp't's Ex. E at 4; Tr. at 253. He has held various associate professorship positions in radiology, neurology, and pediatrics, as well as positions as Director of Neuroradiology and Magnetic Resonance and Director of Neuroradiology at the University of Minnesota. Resp't's Ex. E at 4; Tr. at 253.

Dr. Truwit currently serves as a professor at the University of Minnesota and Chief of the Department of Radiology with the Hennepin County Medical Center. Resp't's Ex. E at 5; Tr. at 253. He is a member of the clinical advisory boards in computed tomography, angiography, picture archive and communication systems, and C-

1. Petitioner's Experts

Petitioner's two experts sought to establish that the onset of petitioner's neurologic symptoms in October 2008 was causally related to the flu vaccine she received several weeks earlier. Petitioner acknowledges that a cavernoma was likely present in her spinal cord, but she insists that it was asymptomatic at the time she sought treatment for the pain, weakness, and sensory disturbance in her legs, Tr. at 6-7, and thus, was not a causal factor.

Instead, petitioner argues that her post-vaccinal transverse myelitis produced sufficient inflammation to aggravate her cavernoma and provoke its growth. Tr. at 6. Alternatively, petitioner asserts that while suffering from a post-vaccinal transverse myelitis in October of 2008, she coincidentally developed a cavernoma that was asymptomatic initially, but later grew and bled. Tr. at 7.

Dr. Steinman, petitioner's expert neuroimmunologist, based his opinion of vaccine-related causation on the biologic mechanism of molecular mimicry. Relying on peer reviewed journals and his experience as an immunologist, he described the process as one by which the flu vaccine could trigger an immune response that targeted the myelin basic protein contained in the protective sheathing surrounding the nerve fibers in the body, Pet'r's Ex. 29 at 2, due to the structural similarity between components of the flu vaccine and the spinal cord. Pet'r's Ex. 29; Tr. at 25-26.

Addressing the abnormality that was detected at the T9/T10 level on petitioner's earliest MRI, Dr. Steinman attributed the abnormal finding to changes in the spinal cord caused by the inflammation associated with petitioner's transverse myelitis event. Pet'r's Ex. 29 at 17. Pointing to case reports in the medical literature, he averred that inflammation can cause a cavernoma to grow. Tr. at 33-34. But, he conceded that he

arm X-ray with Phillips Medical Systems. Resp't's Ex. E at 5. Dr. Truwit is also a member of the advisory board for several radiological imaging and health service boards. Resp't's Ex. E at 4-5. He holds thirty-two patents. Resp't's Ex. E at 5-7. His practice focuses on brain and spinal examinations, for which he reviews spinal MRIs on a daily basis. Tr. at 256-57. Dr. Truwit evaluates imaging for transverse myelitis cases and regularly diagnoses and sees cases of suspected or confirmed cavernoma cases. Tr. at 258.

was unaware of any specific paper indicating that transverse myelitis could provoke growth of a cavernoma in the spinal cord. Tr. at 34.

In Dr. Steinman's view, the strongest evidence in support of a finding that petitioner had suffered an autoimmune transverse myelitis event after her receipt of the flu vaccine was her October 2008 MRIs, Pet'r's Ex. 29 at 21, and her June 2009 cerebrospinal fluid test results—which showed elevated levels of myelin basic protein. Pet'r's Ex. 28 at 49. But, he conceded that elevated levels of myelin basic protein could result from a trauma. Tr. at 94, 100.

Dr. Steinman asserted that the finding of “speckled punctuate enhancement” on petitioner's October 2008 imaging was consistent with a post-vaccinal transverse myelitis. Pet'r's Ex. 29 at 22. He added that the myelin basic protein detected in petitioner's cerebrospinal fluid could be found in petitioner's spinal cord sheathing as well as in the flu vaccine petitioner received. Pet'r's Ex. 29 at 22; see also Pet'r's Ex. 12.

Also informing Dr. Steinman's opinion of causation was the timing of petitioner's symptom onset. He observed that the medically accepted time frame for the onset of a post-vaccinal transverse myelitis would be a few weeks, and he pointed out that petitioner's neurologic symptoms first appeared within that time frame. Tr. at 30. Persuaded by the vaccine-relatedness of petitioner's injury, Dr. Steinman insisted that petitioner's cavernoma was not a significant factor in the development of petitioner's injury. Tr. at 91-92.

Dr. Steinman cited the Brinar series of cases in an effort to explain how diagnostic confusion might arise when attempting to distinguish between inflammatory disorders—that include transverse myelitis—and those involving spinal cord tumors. Id. The authors of the Brinar case series described five cases in which the respective patient's medical history and clinical symptoms suggested that an inflammatory process was under way in the spinal cord; but, the patient's MRIs indicated that a lesion was present. Pet'r's Ex. 43 at 1. The authors described the most common clinical symptoms of spinal tumors. Pet'r's Ex. 43 at 5. These symptoms included local or radiating pain, spasms of the paravertebral muscles, motor weakness, sensory changes, and bladder dysfunction. Id. The authors noted that a more detailed patient history and a longer period of observing a patient's clinical course allowed for a more accurate diagnosis. Pet'r's Ex. 43 at 1. The symptoms accompanying spinal lesions, as described by the Brinar case series authors, and the conclusions drawn by the authors regarding how to achieve a more accurate

diagnosis certainly have application here, but the author's conclusions are not supportive of petitioner's claim in this case.

Petitioner's expert neuroradiologist, Dr. Kessler, sought to bolster petitioner's claims with radiologic evidence. He reviewed the MRI scans of petitioner's brain, orbits, and spine that were performed between October 21, 2008 and March 27, 2012. Pet'r's Ex. 44. He noted that degenerative changes were apparent in petitioner's lower back (at the L5-S1 disc level). Pet'r's Ex. 44 at 1-3 (referencing imaging taken on October 21, 2008, June 10, 2009, and May 10, 2011). He also noted that degenerative changes were detectable in petitioner's mid-shoulder area (at the C5-6 and C6-7 levels). Pet'r's Ex. 44 at 1-4 (citing petitioner's MRIs dated October 22, 2008, June 10, 2009, and March 27, 2012). Dr. Kessler remarked that increased T2 signals were apparent in petitioner's distal thoracic spinal cord imaging taken on October 21, 2008 and October 22, 2008. Pet'r's Ex. 44 at 4. He described these abnormal findings as consistent with transverse myelitis, *id.*, but he acknowledged that these findings were non-specific and could have been indicative of inflammatory swelling, demyelination, or a tumor. Tr. at 117-18.

By June 10, 2009, a lesion with focal areas of T2 signal hyperintensity had become identifiable on petitioner's imaging at the T9/T10 level. Pet'r's Ex. 44 at 2. A long segment T2 hyperintensity lesion extended from her T6-T12 regions. Tr. at 124. This lesion had increased considerably in size since the previous examination eight months prior. *Id.* The lesion—which had measured 1.5 mm on petitioner's October 22, 2008 MRI—subsequently measured 16 by 10 mm on petitioner's March 27, 2012 MRI. Pet'r's Ex. 44 at 5.

Although Dr. Kessler acknowledged that the detected lesion on the petitioner's imaging had the features of a cavernous angioma, Tr. at 145, he discounted the likelihood of a correlation between the amount of hemorrhage detected in petitioner's cerebrospinal fluid, the observed inflammation on her imaging and disclosed by her lumbar puncture studies, and the nature of her presenting symptoms. Tr. at 161.

Dr. Kessler recognized that transverse myelitis could occur in the context of a variety of disorders. But he asserted that a post-vaccinal transverse myelitis should be considered in this case due to the timing between the receipt of petitioner's flu vaccine and the radiologic findings associated with her symptom onset. Petitioner's imaging was suggestive of transverse myelitis. Pet'r's Ex. 44 at 4. Yet, Dr. Kessler allowed that a

finding of post-vaccinal transverse myelitis could not be established by the radiologic findings alone. Id.

2. Respondent's Experts

Respondent's experts asserted that the onset of petitioner's neurologic symptoms was not causally related to the flu vaccine she received on October 1, 2008. Instead, they averred that petitioner's symptoms resulted from the growth and hemorrhage of her cavernoma.

Although petitioner's treating physicians diagnosed her with a possible post-vaccinal transverse myelitis at the time of her initial symptom presentation, respondent contends that petitioner's early symptoms, her MRIs, and her laboratory test results provide much stronger support for a finding that her injury resulted from the hemorrhage of her cavernoma that, in turn, led to a secondary transverse myelitis.

Dr. Leist, respondent's expert neuroimmunologist, challenges petitioner's claim that she suffered an adverse reaction to the flu vaccine she received on October 1, 2008. Tr. at 173. He notes that petitioner previously had received two flu vaccines with no reported issues. Resp't's Ex. A at 6. He adds that the results of petitioner's imaging and testing, taken when her symptoms first manifested, established that she had a bleeding cavernoma. Resp't's Ex. A at 7.

Dr. Leist asserts that the relatively abrupt onset of petitioner's symptoms on October 18, 2008—first as pain and thereafter as weakness and as disturbing leg sensations (dysesthesia²⁰)—occurred most likely at the same time that petitioner's cavernoma began to bleed. Resp't's Ex. A at 7. Dr. Leist points to the faint enhancement on imaging that continued to be seen in 2008, 2009, and 2011 as evidence of petitioner's cavernoma and the residue from the associated bleed. Resp't's Ex. A at 7. As he explained, this radiologic imaging was not consistent with the expected course of an inflammatory, demyelinating lesion—which diminishes in appearance over time. Id. The lesion observed on petitioner's imaging at the T9/T10 level continued to grow and thus did not evolve in the manner that a lesion produced by demyelination or inflammation does. Resp't's Ex. B at 1.

²⁰ Dysesthesia is a distortion of any sense, especially that of touch; it is an unpleasant abnormal sensation produced by normal stimuli. Dorland's Illustrated Medical Dictionary 577 (32nd ed. 2012).

As additional support for his view that petitioner did not suffer an autoimmune transverse myelitis as a result of the flu vaccine she received, Dr. Leist observed that after her symptom onset, petitioner's neurologic problems did not change appreciably. Tr. 174. Nor did her neurologic symptoms respond well to her steroid treatment—as is expected with inflammatory or demyelinating conditions. Id.

Dr. Leist discussed the results of petitioner's cerebrospinal fluid testing. Resp't's Ex. B at 1. Testing of her cerebrospinal fluid showed a modest elevation in myelin basic protein. Id. Myelin basic protein is a non-specific marker of tissue injury in the central nervous system that can be detected by lumbar puncture study. Id. Dr. Leist further observed that if “massive inflammatory changes” had occurred as part of the vaccine-triggered autoimmune event she suffered, as petitioner claimed, the spinal fluid test results would have been expected to show an elevated level of inflammatory cells. Id. Such was not the case here. Id.

Dr. Leist challenged the diagnosis proposed by petitioner, persuaded that petitioner suffered from a non-vaccine related hemorrhage of a pre-existing vascular malformation in her spinal cord. Resp't's Ex. A at 8.

Petitioner's neuroradiologist, Dr. Truwit, testified that petitioner's radiologic imaging showed a vascular malformation in the distal aspect of her spinal cord, Tr. at 259-60, and her earliest imaging showed traces of hemosiderin as “speckled punctuate enhancement,” which is a residual signature of a bleed. Tr. at 272-73. Dr. Truwit asserted the thoracic MRI study performed on October 22, 2008, clearly showed that Ms. Dillon had a long-segment lesion of her mid and lower thoracic spinal cord that was characterized predominantly by cord swelling and hyperintensity of T2-weighted images. Resp't's Ex. C at 3. He explained that a high T2 signal could be caused by various events, such as trauma or a tumor. Tr. at 278. Dr. Truwit conceded that from a radiologic perspective, these early findings on imaging were compatible with transverse myelitis. Id. But he pointed out that another finding was visible on the October 22, 2008 study; it was of mixed focus, and was characterized by both hyperintensity and hypointensity at the T9/T10 disc level. Id. That particular finding, when considered with petitioner's subsequent studies, seems more likely than not to have been the initial presentation of a small vascular malformation. Id.

Dr. Truwit explained that the hemosiderin deposition in petitioner's spinal cord was more evident on the second MRI study performed in June 2009. Resp't's Ex. C at 5. On that imaging, the lesion was much more obvious, and the cord edema had resolved. Id. By the time of the third study in May 2011, however, the lesion had accumulated even more blood and had more focal cord swelling. Id.

Dr. Truwit asserted that the radiologic imaging and laboratory test results supported a finding that petitioner's myelitis was secondary to the bleed of her cavernoma. Resp't's Ex. C at 5. The finding of a red blood cell count in petitioner's cerebrospinal fluid test results could not be construed as normal, and a series of images revealed that the detected lesion was a cavernoma. Id.

Dr. Truwit posited that the timing of the appearance of petitioner's myelitis coincided with her cavernoma's first release of a small amount of intrathecal subarachnoid hemorrhage—that was detected, relatively contemporaneously, in her cerebrospinal fluid. Id. Giving further credence to his position was the bit of hemosiderin deposition on the T2-weighted image that likely led to the amount of cord edema observed on imaging—which was greater than would be expected otherwise for the type of cavernoma petitioner had. Id. Dr. Truwit observed that in his extensive professional experience, hemosiderin deposition does not occur in cases of autoimmune transverse myelitis. Resp't's Ex. C at 5.

Addressing the temporal relationship between petitioner's flu vaccination and the appearance of her thoracic cord lesion—about which petitioner's experts made much—Dr. Truwit stated that petitioner's claim that her vascular malformation developed in response to her vaccine-related transverse myelitis seemed to be “fitting the facts to the answer, and not the answer to the facts.” Resp't's Ex. C at 5.

Dr. Truwit could not identify a causal association between petitioner's cavernoma and the flu vaccine petitioner received in October 2008. Tr. at 261-62. Dr. Truwit asserted that the better explanation for petitioner's injury was a bleed from an atypical cavernous angioma, rather than a flu vaccine-related transverse myelitis. Resp't's Ex. C at 7.

After careful consideration of the parties' experts' testimony as it pertained to “the reliability of the medical underpinnings of petitioner's proposed causal sequence for a vaccine injury,” Doe 11 v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1357 (Fed.

Cir. 2010), the undersigned finds that respondent’s experts offered a more cohesive and convincing explanation for petitioner’s injury. In contrast, petitioner’s experts relied on selective components of the record to offer an earnest but strained—an ultimately, less persuasive—theory of causation.

Before analyzing the merits of petitioner’s claim, the undersigned turns to consider the legal standards to be applied.

II. STANDARDS OF ADJUDICATION

A. Elements of Petitioner’s Claim

If petitioner alleges an injury listed on the Vaccine Injury Table (“Table”) occurring within the correlative time frame set forth in the Table, petitioner’s vaccine claim is considered a Table claim, and a presumption of vaccine-causation attaches. See § 300aa-14; see also 42 C.F.R. § 100. If petitioner alleges an injury that is not listed on the Table, such as the immune-mediated transverse myelitis alleged in this case, the vaccine claim is considered a non-Table case, and no presumption of causation attaches. Id. Instead, petitioner must satisfy her burden of proof. See § 300aa-13(a)(1)(A).

In order to prevail on a non-Table vaccine claim, as has been asserted here, petitioner must allege: (1) that she “sustained, or had significantly aggravated any illness, disability, injury, or condition not set forth in the Vaccine Injury Table;” and (2) that the injury “was caused by a vaccine.” 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010) (quoting Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)).

As required by the Federal Circuit, petitioner must prove that the flu vaccine she received in October 2008 caused her alleged injury by preponderant evidence that shows: (1) a medical theory causally connecting the vaccine and her alleged injury; (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury; and (3) a showing of a proximate temporal relationship between the vaccine and her injury. Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005); 42 U.S.C. § 300aa-13(a)(1) (requiring proof by a preponderance of the evidence).

Because the causation theory must relate to the alleged injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner’s case—although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548–49 (Fed. Cir.1994); Moberly, 592 F.3d at 1322. To be clear, “the function of a special master is not to ‘diagnose’ vaccine-related injuries, but instead to determine ‘based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [claimed] injury.’” Andreu v. Health & Human Servs., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994)).

The preponderance of the evidence standard has been interpreted to mean that a fact is more likely than not. Moberly, 592 F.3d at 1322 n.2. A petitioner who satisfies this burden is entitled to compensation unless the government can prove, by a preponderance of the evidence, that the petitioner’s injury is “due to factors unrelated to the administration of the vaccine.” 42 U.S.C. § 300aa-13(a)(1)(B).

B. Establishing the nature of petitioner’s injury

When the parties dispute the nature of the injury at issue, the special master may first determine which injury is best supported by the evidence before applying the Althen test to determine whether the vaccine caused the injury. Broekelschen v. Sec’y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010); see also Locane v. Sec’y of Health & Human Servs., 685 F.3d 1375 (Fed. Cir. 2012); Lombardi v. Sec’y of Health & Human Servs., 656 F.3d 1343 (Fed. Cir. 2011). A special master’s findings regarding the nature of petitioner’s injury may be sufficient to resolve the case when the special master determines, from the record evidence, that the injury petitioner suffered was not the injury alleged in petitioner’s theory of causation. See Lombardi v. Sec’y of Health & Human Servs., 656 F.3d 1343 (Fed. Cir. 2011); Broekelschen v. Sec’y of Health & Human Servs., 618 F.3d 1339 (Fed. Cir. 2010). The Federal Circuit has provided that evidence of an injury other than the one alleged can be relevant—not only to the “factors unrelated” defense on which the government bears the burden of proof—but also to the showing petitioner must make, specifically, that the vaccine was a substantial factor in causing the claimed injury. Stone v. Sec’y of Health & Human Servs., 676 F.3d 1373, 1380 (2012).

C. Evaluating the presented evidence

Petitioner cannot establish entitlement to compensation under the Act based on the petitioner's claims alone. 42 U.S.C. § 300aa-13(a)(1). A vaccine claim must be supported either by the medical records or by the opinion of a competent physician. Id. In determining whether petitioner is entitled to compensation, a special master shall consider all material contained in the record, 42 U.S.C. § 300aa-13(b)(1), including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner's illness." 42 U.S.C. § 300aa-13(b)(1)(A) (emphasis added). Any such diagnosis, conclusion, judgment, test result, report, or summary, however, shall not be binding on the special master, but must be evaluated in the context of the entire record and the course of petitioner's injury, disability, illness, or condition, from symptom onset until the date of the special master's ruling. 42 U.S.C. § 300aa-13(b)(1).

1. Reliability of Medical Records

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally created contemporaneously to the medical events. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993) (citing United States v. U.S. Gypsum Co., 333 U.S. 364, 396 (1947)). The Federal Circuit's decision in Cucuras v. Secretary of Health & Human Services clearly supports the view that medical records are favored over oral testimony in circumstances when there is a conflict between the former and the latter, and when the prepared medical records are internally consistent and complete. Id.

2. The Experts' Opinion

The persuasiveness of the experts' testimony must be evaluated, and the testimony of one side's expert may be rejected when there is a reasonable basis for doing so. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

In the Vaccine Program, an expert's opinion may be evaluated according to the factors identified by the United States Supreme Court in Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). As recognized in Terran, the Daubert factors for analyzing the reliability of testimony are:

- (1) whether a theory or technique can be (and has been) tested; (2) whether

the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing Daubert, 509 U.S. at 592-95). After Terran, decisions issued by of the Court of Federal Claims have consistently cited to Daubert. E.g., De Bazan v. Sec’y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2000) (“A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness’s testimony regarding causation.”), rev’d on other grounds, 539 F.3d 1347 (Fed. Cir. 2008); Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006); Piscopo v. Sec’y of Health & Human Servs., 66 Fed. Cl. 49, 54 (2005).

When evaluating the reliability of an expert’s opinion, it is important to ascertain whether the information on which the doctor is relying is accurate because inaccuracies in the expert’s factual assumptions compromise the reliability of the view offered. See Perreira v. Sec’y of Health & Human Servs., 33 F.3d 1375, 1377 (Fed. Cir. 1994) (an expert opinion is no better than the soundness of the reasons supporting it).

Applying these standards to determine whether petitioner has established that she is entitled to compensation for her alleged vaccine-related injury of immune-mediated transverse myelitis, the undersigned finds that she has not, and thus, she cannot prevail on her claim. The undersigned’s reasoning is explained below in greater detail.

III. ANALYSIS

The evidence strongly militates in favor of a finding that Ms. Dillon suffered from a bleeding cavernoma, rather than an autoimmune transverse myelitis. Of particular interest are: (1) petitioner’s MRIs and lumbar puncture study results; (2) the absence of any indication that petitioner suffered either a significant inflammatory response or an autoimmune reaction; and (3) the focus of petitioner’s treating doctors on the temporal proximity between symptom onset and petitioner’s flu vaccine, rather than on important clinical information. The undersigned addresses each of these evidentiary factors in turn.

A. Petitioner’s MRIs and Lumbar Puncture Studies

The parties’ experts agreed that an acute bleed from a cavernoma could cause swelling (or edema) in the spinal cord that would register on an MRI as T2 signal

enhancement.²¹ See, e.g., Tr. at 137-38, 160-61, 219, 265. Petitioner’s MRI dated October 22, 2008 showed T2 signal enhancement extending from T6 to T12 with a lesion representing the cavernoma at the epicenter. Pet’r’s Ex. 4 at 86; Tr. at 276-77. Dr. Truwit noted that although hemosiderin was detected near the lesion—indicating that “blood [had been]. . . in the area,” the mere presence of hemosiderin provides no information regarding when the bleed occurred. Tr. at 270-72.

Dr. Kessler suggested that the hemosiderin on the October 22, 2008 MRI was possibly an “artifact” caused by movement during the formation of the image. Tr. at 129. Dr. Truwit dismissed that suggestion—noting that if it were artifact, “it would have to be [an] artifact on [petitioner’s] serial examinations.” Tr. at 301. Because the hemosiderin stain was observed repeatedly (and consistently) on petitioner’s imaging, Dr. Truwit reasoned that it could not be an artifact. Id.

While the hemosiderin on petitioner’s imaging does not pinpoint when the bleed occurred, the results of petitioner’s spinal tap taken on October 24, 2008 contained red blood cells, an abnormal finding indicating that blood had leached into the cerebrospinal fluid surrounding the spinal cord and was very likely present at the time petitioner’s painful symptoms began. Tr. at 273; 293.

Dr. Steinman argued that the red blood cells detected in petitioner’s spinal fluid were more likely due to a traumatic tap. Tr. at 45-47. While Dr. Truwit acknowledged this possibility, he discounted it as a “reasonable medical probability,” explaining that while a traumatic tap would show bleeding in the first tube, ordinarily the bleeding would subside—and not increase as it did in this case—in subsequent tubes. Tr. at 293-94, Pet’r’s Ex. 4 at 89. Trauma, associated with the physical lumbar puncture therefore, does not explain the presence of red blood cells in this context.²²

Petitioner’s imaging and testing provide strong evidence that her cavernoma had begun to bleed at the time her neurologic symptoms first presented.

²¹ Dr. Truwit explained that a bleed may not be accompanied by clinical symptoms in all circumstances. Tr. at 274, 292. Nor does swelling necessarily recur after an initial hemorrhage of a cavernoma. Id.

²² Dr. Steinman argued that autoimmune transverse myelitis could cause a hemorrhage in the spine, citing Petitioner’s Exhibit 52 (U.K. Misra, et. al., A clinical, MRI and neurophysiological study of acute transverse myelitis, J. Neurological Sci. 150 (1995)). Tr. at 141. However, as both Dr. Leist and Dr. Truwit pointed out in their testimony, it is unclear whether the authors of the Misra article focused on cases of autoimmune transverse myelitis only, or whether some of the cases involved vascular malformations. Tr. at 202-05, 281-83.

Nonetheless, petitioner's experts argued that her cavernoma could not account for her symptoms or the abnormalities seen on her October 22, 2008 MRI based on the size of her cavernoma and the extent of the observed swelling. Tr. at 36, 46-47, 82, 138.

Petitioner's argument that her cavernoma was too small to have caused extensive neurologic impairment is unavailing. See, e.g., Tr. at 36. Respondent's expert Dr. Leist explained, and petitioner's expert agreed, that "large lesions in the spinal cord [can occur] with very minimal disability, [and] . . . small lesions [can produce] very significant disability." Tr. at 207. Thus, a one-to-one correlation between the size of a lesion and its clinical significance cannot be assumed, Tr. at 156 (Dr. Kessler), and is not determinative.

After acknowledging that lesion size cannot predict the severity of a subject's symptoms, petitioner's experts argued that petitioner's cavernoma could not have been responsible for the extensive signal abnormality seen on her October 22, 2008 MRI. Tr. at 36, 138. Petitioner's experts reasoned that the local swelling associated with a cavernoma's bleed typically spans from "one to two segments." Tr. at 138. Petitioner's T2 signal abnormality, however, spanned over six vertebral segments. Id.; see also Tr. at 59, 303, 312.

Dr. Truwit conceded that the swelling observed in connection with petitioner's cavernoma was atypical. Tr. at 302-03. Respondent's experts and petitioner's expert neuroradiologist agreed that swelling typically peaks three to six days after the inciting event. Tr. at 221, 281. In petitioner's case, the critical MRI was conducted four days after her initial symptoms appeared, and such imaging was taken well within the time frame the experts had identified for edema to reach its peak. See Pet'r's Ex. 4 at 86; see also Resp't's Ex. I. Dr. Truwit explained that petitioner's cavernoma could have produced edema spanning six vertebral segments if the vascular malformation had restricted her veins—which, he speculated, had occurred in this case. Tr. at 261, 303-04. Dr. Leist observed that edema spanning six segments in association with a cavernoma is not inconceivable, and he noted that such extensive edema has been found in pediatric cases. Tr. at 222; see also Resp't's. Ex. H.

Respondent's experts asserted that an atypical, but confirmed cavernoma is the more likely explanation for petitioner's condition than is her claim of a coincidental autoimmune event for which there is little corroborating evidence. The undersigned is similarly persuaded on this record.

B. Evidence is lacking that petitioner experienced either a significant inflammatory response or an autoimmune reaction

Missing from this record is evidence pointing to the initiation of an autoimmune process or the onset of a massive inflammatory response. If petitioner's condition had been an autoimmune one, systemic or prodromal symptoms would have been expected prior to the onset of petitioner's condition. Tr. at 178-79; see also Tr. at 90. Such symptoms would include fever and a significantly elevated white blood cell count. Tr. at 182-83. Also, some sensory loss above and below the area of the lesion would have been expected to occur were an autoimmune process at work. Tr. at 196. Moreover, were an inflammatory process underway, an increase in protein in the cerebrospinal fluid would have been expected, Tr. at 185, and oligoclonal banding would likely have been observed on lumbar puncture testing. Tr. at 185, 192. But, there were no such indications here.

None of the labs or imaging established the presence of "massive inflammatory response." Tr. at 86. Nor did petitioner's cerebrospinal fluid testing in June 2009 disclose any inflammatory changes, oligoclonal banding, or elevation in IgG index. Pet'r's Ex. 28 at 49.

Petitioner's imaging and lab work consistently pointed to the existence of a bleeding cavernoma. But, petitioner's treating doctors seemed to have missed a number of relevant clinical details when petitioner first presented for treatment. In connection with this vaccine claim, petitioner's experts have discounted the details of petitioner's initial presentation for treatment that might have implicated her bleeding cavernoma as the causal trigger for her symptoms.

Dr. Steinman argued that the absence of these findings does not exclude the possibility that petitioner suffered an autoimmune transverse myelitis. Tr. at 73, 76. Dr. Leist conceded that Dr. Steinman's postulate was a remote possibility; however, he observed, the lack of supportive evidence for petitioner's claim does not compel an "inference of opposites." Tr. at 239. The undersigned agrees.

C. Ms. Dillon's treating physicians seem to have focused on a circumscribed set of facts and not on petitioner's clinical indicators as a whole

It appears that at the time of petitioner's symptom onset, her treating physicians were heavily influenced by the possibility that she had experienced a post-vaccinal event, largely based on the timing of her received vaccine and indications on her spinal imaging that were not inconsistent with transverse myelitis. This focus seems to have distracted petitioner's treaters from more fully examining the details of her presentation and the results of her testing. Even as evidence of her cavernoma became more pronounced, petitioner's treaters continued to carry forward in her medical records the initial assessment of a possible post-vaccinal transverse myelitis. While the opinions of treating physicians may be probative in vaccine proceedings, see Andreu, 569 F.3d at

1375, Capizzano, 440 F.3d at 1326, they are not “sacrosanct.” Snyder v. Sec’y of Health & Human Servs., 88 Fed. Cl. 706, 745 n.67 (Fed. Cl. 2009). Here, the record as a whole furnishes proof countering the early diagnostic impressions of petitioner’s treating doctors.

D. The record establishes that Ms. Dillon did not suffer from the injury for which she now seeks compensation under the Vaccine Program

As noted previously, special masters are required to evaluate the record as a whole. 42 U.S.C. § 300aa-13(a)(1). The record here—including the contemporaneous medical records containing the results of Ms. Dillon’s brain imaging, and laboratory testing, and the cogent testimony of respondents experts Drs. Leist and Truwit—significantly undercuts petitioner’s claim that she developed a primary autoimmune transverse myelitis either prior to or during her October 2008 hospitalization, and militates against a finding that her injuries were caused by a vaccine-related GBS event.

This determination precludes a finding of causation in petitioner’s favor. When the evidence does not support a finding that the vaccinee suffered from the injury for which petitioner seeks Program compensation, an Althen causation analysis may not be required. See Lombardi, 656 F.3d at 1356 (affirming special master’s decision foregoing Althen analysis after concluding petitioner did not suffer from any of his alleged injuries). Out of an abundance of caution, however, the undersigned evaluates petitioner’s theory under the Althen standard.

E. The Althen Analysis

1. Althen Prong One: Petitioner’s Medical Theory

Under Althen Prong One, petitioner must put forth a biologically plausible theory explaining how the received vaccine “can” cause the injury alleged. Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). To satisfy this prong, “a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” Broekelschen, 618 F.3d at 1345 (quoting Knudsen, 35 F.3d at 548-49); see also Moberly, 592 F.3d at 1324 (“[T]he special master is entitled to require some indicia of reliability to support the assertion of the expert witness.”).

The offered medical theory must be supported by either the vaccinee's medical records or the opinion of a competent physician. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Support for the offered medical theory must also include an explanation that "pertains specifically to the [claim made in] petitioner's case." Moberly, 592 F.3d at 1322; see Veryzer v. Sec'y of Health & Human Servs., No. 06-0522V, 2010 WL 2507791, at *24 (Fed. Cl. Spec. Mstr. 2010) (noting that the relevant inquiry is whether, based on facts known to medical science and logical inferences drawn by a qualified expert, the vaccine at issue is more than likely to have caused the alleged injury), aff'd, 100 Fed. Cl. 349 (2011), aff'd, 475 F. App'x 765 (Fed. Cir. 2012).

Petitioner's theory of causation need not be medically or scientifically certain, Knudsen, 35 F.3d at 548-49, but it must be informed by "sound and reliable medical or scientific explanation." Id. at 548; see also Veryzer v. Sec'y of Health & Human Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both 42 U.S.C. § 300aa-13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira, 33 F.3d at 1377 n.6 (Fed. Cir. 1994) (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980)) ("An expert opinion is no better than the soundness of the reasons supporting it.").

The undersigned does not evaluate whether petitioner put forth a biologically plausible theory explaining how the received flu vaccine could have caused an autoimmune transverse myelitis because petitioner failed to establish by preponderant evidence that Ms. Dillon developed an autoimmune transverse myelitis. The weight of the evidence points in favor of a finding that petitioner's transverse myelitis was secondary to the hemorrhage of her cavernoma, and petitioner did not put forth any evidence regarding whether the flu vaccine can cause cavernoma.

Petitioner does not prevail on Prong One.

2. Althen Prong Two: Logical Sequence of Cause and Effect

Under Althen Prong Two, petitioner must prove “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278. Under this prong, petitioner must show that the received vaccine “did” cause the alleged injury. Pafford, 451 F.3d at 1354.

Petitioner need not make a specific type of evidentiary showing. That is, petitioner is not required to offer “epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect” Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. See id. at 1325-26.

Here, the record evidence strongly militates against a finding that Ms. Dillon suffered from an autoimmune episode of transverse myelitis. Petitioner’s radiologic imaging and laboratory testing indicate that petitioner suffered a bleed from a barely perceptible cavernoma at the time she presented with her painful symptoms of back pain, incontinence, and leg discomfort. This hemorrhage produced edema in petitioner’s spinal cord which was construed as a transverse myelitis episode. But the episode was not primary and autoimmune—as petitioner urged—but was a secondary effect of the trauma caused by her hemorrhaging cavernoma.

Petitioner does not prevail on Prong Two.

3. Althen Prong Three: Timing

Under Althen Prong Three, petitioner must establish that Ms. Dillon’s injury occurred within a time frame that is medically appropriate for the alleged mechanism of harm. See Pafford, 451 F.3d at 1358 (“Evidence demonstrating petitioner’s injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the ‘but-for’ prong of the causation analysis.”). Petitioner may satisfy this prong by producing “preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” De Bazan, 539 F.3d at 1352.

Petitioner may discharge her burden by showing: (1) when the condition for which she seeks compensation first appeared after vaccination and (2) whether the period of symptom onset is “medically acceptable to infer causation.” Shapiro v. Sec’y of Health & Human Servs., No. 99-552V, 2011 WL 1897650, at *13 (Fed. Cl. Spec. Mstr. Apr. 27, 2011), aff’d in relevant part, vacated in non-relevant part, 101 Fed. Cl. 532, 536 (2011), aff’d 503 F. App’x 952 (2013) (per curiam). The appropriate temporal association will vary according to the particular medical theory advanced in the case. See Pafford, 451 F.3d at 1358.

The parties do not dispute the appropriateness of the timing between petitioner’s receipt of the flu vaccine and the onset of her injury—were her injury, in fact, an autoimmune episode of transverse myelitis. But petitioner failed to establish that she suffered from that particular injury. The weight of the record evidence points to a traumatic injury that was not vaccine-related and thus, critically weakens petitioner’s theory of causation. Although petitioner could prevail on Prong Three on the theory she put forward, she cannot prevail on her vaccine claim because she did not establish, by preponderant evidence, that she suffered the condition she has alleged.

F. Conclusion

For the foregoing reasons, petitioner’s claim for Program compensation must fail and the petition **SHALL BE DISMISSED**. The Clerk of Court shall enter judgment consistent with this decision.²³

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Chief Special Master

²³ Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties’ joint filing of notice renouncing the right to seek review.