

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

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REBECCA WHITNEY and  
RANDALL WHITNEY, parents of  
S.W., a minor,

Petitioners,

v.

SECRETARY OF HEALTH  
AND HUMAN SERVICES,

Respondent.

\* \* \* \* \*

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for  
Petitioners;

Lara A. Englund, U. S. Dep't of Justice, Washington, DC, for Respondent.

No. 10-809V

Special Master Christian J. Moran

Filed: May 8, 2015

Reissued: July 20, 2015

Entitlement; diphtheria-tetanus  
acellular pertussis (DTaP) vaccine;  
transverse myelitis; burden shifting;  
human herpesvirus (HHV-6).

### **PUBLISHED DECISION DENYING COMPENSATION<sup>1</sup>**

Rebecca and Randall Whitney allege that one of the vaccines given to their son, S.W., when he was approximately four-months old caused him to develop a severe neurologic problem, transverse myelitis. They seek compensation pursuant to the National Childhood Vaccine Injury Compensation Program, codified at 42 U.S.C. § 300aa-10 through 34 (2012).

Although the Whitneys have presented a plausible claim, S.W.'s treating doctors have not agreed with the allegation that the vaccinations caused S.W.'s transverse myelitis. Because the Federal Circuit has instructed special masters to consider the opinions of treating doctors with great care, the most persuasive

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<sup>1</sup> The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

evidence is against the Whitneys' claim. Thus, they are not entitled to compensation.

### **Facts**

S.W. was born on [redacted] 2007. Exhibit 1 at 1. He has an older sister and an older brother, who were 7 and 3 years old, respectively, when he was born. Exhibit 13 at 1. For approximately the first four months of life, S.W. was healthy and did not present any problems with development or illness to his pediatrician. See exhibit 13 at 1-7.

In mid-November 2007, S.W. had a mild upper respiratory infection. The rest of S.W.'s family had similar symptoms. Exhibit 2 at 264.<sup>2</sup> The Whitneys did not bring S.W. to his pediatrician for this illness. See exhibit 13. Evidence adduced from the records and at hearing established that S.W.'s illness was probably a manifestation of an infection with human herpesvirus 6 (HHV-6). Tr. 493.<sup>3</sup>

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<sup>2</sup> The medical records are not very precise about when S.W. had symptoms of an upper respiratory illness. A December 13, 2007 report states that he had a running nose and a cough "about one month ago." Exhibit 2 at 253. Another report, which was created on December 14, 2007, states that Ms. Whitney recalled an upper respiratory infection "about 4 weeks ago near Thanksgiving." Id. at 264.

The parties agreed that the precise date of S.W.'s illness around Thanksgiving is not a material fact. Pet'rs' Resp., filed Jan. 30, 2015, at 1-5; Resp't's Memorandum, filed Jan. 30, 2015, at 1.

<sup>3</sup> The finding that S.W. probably suffered from an HHV-6 infection around Thanksgiving 2007 is an inference drawn from several facts. First, S.W. is very unlikely to have become infected with HHV-6 before November 2007, because antibodies that he inherited from his mother protected him until the maternal antibodies faded. Tr. 356-60; see also exhibit A, tab 1 (Danielle M. Zerr et al., A Population-Based Study of Primary Human Herpesvirus 6 Infection, 352 N. Engl. J. Med. 768) at 772 (showing incidence of HHV-6 infections). Second, as discussed below, S.W. tested positive for HHV-6 on December 14, 2007. The specific values suggested that S.W. was in the convalescent stage of the HHV infection, meaning that he had recently been infected but was recovering from the infection. Tr. 495-501 (Dr. Wientzen); see also Tr. 339-42, 593-96 (Dr. Oleske: "the points [Dr. Wientzen] made about latent infection and convalescence in recovery phase, I would agree with"). Thus, it is probable --- although not certain --- that S.W.'s mild illness around Thanksgiving was actually HHV-6. See Tr. 363 (Dr. Oleske: "it's reasonable to say he acquired [the HHV-6 infection] somewhere around a month or two -- a month of age, when he had that . . . mild URI"), 493 (Dr. Wientzen: "I think he had an active HHV-6 infection at about Thanksgiving").

On November 26, 2007, S.W. saw his pediatrician for his four-month well baby visit. The notes associated with this visit are relatively sparse. They indicate that S.W. was not sleeping well, had normal elimination, and displayed a good temperament. Exhibit 13 at 5; exhibit 1 at 1. For other concerns, the pediatrician recorded none. Id. At this appointment, S.W. received a set of vaccinations: his second doses of the diphtheria-tetanus-acellular pertussis (“DTaP”), haemophilus influenzae B, inactivated polio virus, pneumococcal conjugate, and rotavirus vaccines. Id.

On approximately December 6, 2007, S.W. had “some congestion and upper respiratory symptoms. . . but no fevers. No nausea, vomiting, diarrhea.” Exhibit 2 at 261. Also around December 6, 2007, S.W. “appeared to be straining whenever he stoolled.” Exhibit 2 at 253. The testifying experts opined that the change in S.W.’s bowel habits indicated he was starting to have neurologic problems. Tr. 160 (Dr. Shafrir), 280 (Dr. Wiznitzer); see also Tr. 361 (Dr. Oleske).

On December 12, 2007, S.W.’s legs were weak. He did not sleep well that night. Exhibit 2 at 253; exhibit 14 (Ms. Whitney’s affidavit) at 2, ¶5.

S.W.’s problems continued into the next day, December 13, 2007. His mother brought him to the pediatrician’s office and reported that S.W. was not moving for two days and screaming when waking up or moving his legs. The doctor’s examination showed that S.W. had a decreased tone in his lower extremities, “some clonus,” and absent reflexes.<sup>4</sup> The doctor admitted S.W. to the hospital. Exhibit 1 at 46. The presence of clonus means that S.W. began suffering from neurologic problems 7-10 days earlier. Tr. 33, 65, 194.

In the emergency room, the doctor obtained a history similar to that presented above. The doctors obtained blood samples to conduct laboratory tests, consulted a neurologist, and performed a lumbar puncture. S.W. was sent to the pediatric intensive care unit. Exhibit 2 at 261. The cerebrospinal fluid showed inflammation in the spinal cord. Id. at 254; Tr. 96, 160.

Upon admission, Ms. Whitney provided another history which, although more detailed, was consistent with the previously provided histories. The doctors

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<sup>4</sup> The term “clonus” is defined as “alternative muscular contraction and relaxation in rapid succession,” and “a continuous rhythmic reflex tremor initiated by the spinal cord below an area of spinal cord injury, set in motion by reflex testing.” Dorland’s Illustrated Medical Dictionary 373 (32d ed. 2012).

ordered a series of MRIs and prescribed Rocephin. Exhibit 2 at 253-55. Rocephin could kill bacteria infecting S.W. Tr. 97, 161, 209.

Before S.W. had his MRIs, a neurologist, Steven DeRoos, saw him. Dr. DeRoos recorded another history of S.W.'s illness.<sup>5</sup> For social history, Dr. DeRoos stated "[n]o acute febrile illness recently." Dr. DeRoos examined S.W. His plan was to obtain the MRIs and a CT scan of the spine. Dr. DeRoos "agree[d] with the IV antibiotics until more information is known." Exhibit 2 at 267.

S.W. had four MRIs on December 13, 2007. The images for S.W.'s brain and lumbosacral spine were normal. However, the images for S.W.'s cervical spine and thoracic spine showed damage in his spine. Exhibit 2 at 249-52. The radiologist interpreting the images stated that the abnormal signaling may represent "an immune mediated disseminated myelitis, perhaps parainfectious in etiology." Exhibit 2 at 250.

On December 14, 2007, George Fogg, a specialist in pediatric infectious diseases, saw S.W. Dr. Fogg received another history and noted that S.W. "had his 4-month immunizations on 11/26/07, [which] included DTaP." Exhibit 2 at 264. Dr. Fogg stated that S.W.'s presentation was "consistent with acute disseminated encephalomyelitis (ADEM)." *Id.* at 265. With respect to potential causes, Dr. Fogg listed: "possible infectious triggers include viral (CMV, EBV, HSV, enterovirus and West Nile), bacterial (Campylobacter, and mycoplasma), post vaccination reaction, or autoimmune disease." *Id.* Dr. Fogg made 10 recommendations. *Id.* at 265-66. Significant requests include polymerase chain reaction (PCR) testing on S.W.'s blood for various organisms including HHV-6, and an "ANA screen for autoimmune causes." *Id.* Dr. Fogg stated that he "will report the possible post immunization adverse event to the vaccine adverse event reporting system (VAERS)." *Id.* Finally, Dr. Fogg also agreed with "the plans for high-dose steroid therapy as directed by pediatric neurology." *Id.*

An ANA test is helpful in detecting the presence of various autoimmune diseases. Kathleen Deska Pagana and Timothy J. Pagana, Mosby's Manual of Diagnostic and Laboratory Tests 90-93 (4th ed. 2010); Tr. 109, but see Tr. 270. S.W.'s ANA screen was negative (0.1 with an equivocal result being 1.0 – 1.4). Exhibit 2 at 239.

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<sup>5</sup> Dr. DeRoos's report stated that S.W. "had an MRI approximately 4 weeks ago." Exhibit 2 at 266. The reference to an "MRI" is almost certainly a typographical error and "URI," meaning upper respiratory infection, was probably intended.

The test that Dr. Fogg ordered for HHV-6 was conducted on plasma. The result showed 4,100 units. Exhibit 2 at 234.<sup>6</sup> The pediatric neurologists who cared for him in the hospital indicated that S.W. had “HHV 6 myelitis.” Exhibit 2 at 186 (report dated December 21, 2007); accord id. at 183 (report from pediatric service dated December 20, 2007). All the experts testified about these records. Tr. 118 (Dr. Shafrir), 163 and 271 (Dr. Wiznitzer), 435 (Dr. Oleske), 474 (Dr. Wientzen).

On December 18, 2007, S.W. transferred out of the pediatric intensive care unit. Exhibit 2 at 273. He remained in the same hospital until December 21, 2007, when he was transferred to a rehabilitation hospital, Mary Free Bed Hospital. Exhibit 2 at 271.<sup>7</sup> He stayed in the rehabilitation hospital until January 2, 2008. Exhibit 5 at 47.

S.W. had a follow-up appointment at a neurology clinic on February 13, 2008. A family nurse practitioner, Kim Shelanskey, described that an MRI showed an abnormal signal from the C2–C3 level to the upper thoracic spine. Ms. Shelanskey stated “[t]his was thought to be a form of myelopathy.” Continuing, she explained that “Infectious Disease was able to identify the HHV-6 virus as the causative agent.”<sup>8</sup> Ms. Shelanskey reported that S.W. was “making nice gains and continues to work with both occupational therapy and physical therapy.” Dr. DeRoos, the neurologist, agreed with this assessment. Exhibit 6 at 44-45; see also exhibit 5 at 330-33; Tr. 121. Unfortunately, as noted below, S.W.’s improvement was not complete.

S.W. saw a urologist, Brian Roelof, on February 19, 2008. In the context of presenting S.W.’s history, Dr. Roelof indicated that Ms. Whitney “states that they

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<sup>6</sup> The testifying doctors disputed whether S.W.’s treating doctors responded appropriately to the positive PCR test. Tr. 102 and 149-53 (Dr. Shafrir), 192-94, 210, and 257-58 (Dr. Wiznitzer), 325-27, 432-35, and 449 (Dr. Oleske). However, this issue is extraneous to determining whether the vaccines caused S.W.’s transverse myelitis.

<sup>7</sup> At the time of both transfers, doctors listed S.W.’s diagnosis as ADEM. However, another doctor (Adam Rush) disagreed with the diagnosis of ADEM because S.W.’s problem was limited to his spine and did not affect his brain. Exhibit 5 at 328. Both testifying neurologists have agreed with the diagnosis of transverse myelitis. See exhibit 16 at 7 (Dr. Shafrir: “[t]here is no ‘encephalo’ involvement”); Tr. 198 (Dr. Wiznitzer).

<sup>8</sup> Dr. Shafrir testified that the reports from the specialist in infectious diseases, Dr. Fogg, did not actually identify HHV-6 as the infectious agent. Dr. Fogg’s report listed several possible causes (exhibit 2 at 264-66), but he did not narrow down this list in a written report. Tr. 27-28, 272.

thought he had acute viral myelitis secondary to a virus or perhaps from his vaccinations.” Dr. Roelof did not otherwise comment on possible causes for his viral myelitis. Exhibit 4 at 17.

Adam Rush, the doctor who cared for S.W. during his rehabilitation in Mary Free Bed Hospital, saw S.W. on February 22, 2008. Mr. and Ms. Whitney informed him that S.W. was having a “dramatic return of strength and apparent sensation in his bilateral[] lower limbs.” S.W.’s parents also told Dr. Rush that they were “not planning at this time for him to receive any more immunizations.” Dr. Rush anticipated seeing S.W. back in six months.

Dr. Rush extensively commented upon S.W.’s missing of his scheduled six-month immunization. Dr. Rush wrote:

Finally, as regards immunization noncompliance, I failed today to address this issue with his parents, which I regret. It is incredibly important like any other child, he get his immunizations. I can only surmise at this point his parents are reluctant give him immunizations in the misguided belief that the immunizations were the cause of his myelitis. I do not have any reason to believe this is the case, nor do I believe literature would [bear] that out. He should get all his immunizations.

Exhibit 5 at 328; see also Tr. 123, 274.

When Dr. Rush next saw S.W., on June 4, 2008, he returned to “the issue of immunizations again with S.W.’s mother.” He recorded that Ms. Whitney “clearly feels very strongly at this point against resuming them now, though she did seem to leave the door open for his receiving his immunizations at some point in the future.”<sup>9</sup> Id. at 325-26.

S.W. returned to see Dr. DeRoos, his neurologist, on September 15, 2008. The Whitney’s reported that S.W. had had two spells over the last few weeks. Dr. DeRoos did not know whether they had any significance. Exhibit 5 at 319-20.

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<sup>9</sup> A note from 2012 indicated that Ms. Whitney was refusing vaccinations for S.W. Exhibit 24 at 177.

About 13 months after S.W. was hospitalized, he had a repeat set of MRIs performed. These were “unremarkable... with resolution of abnormal cord signal previously seen on the study of 12/13/2007.” Exhibit 6 at 53 (report dated January 12, 2009).

S.W. had a somatosensory evoked potential test on July 13, 2009. The result was abnormal, but S.W.’s axonal integrity remained. Exhibit 6 at 59.

On June 23, 2010, which was approximately two and one half years after S.W.’s episode of acute transverse myelitis, he saw Lawrence C. Vogel, a pediatrician. The appointment appears to be for routine follow-up, as the Whitneys did not complain about any recent health troubles for S.W. In the context of reviewing S.W.’s medical history, Dr. Vogel recounted events when he was almost five months old. Dr. Vogel stated “apparently herpes virus 6 [was] isolated in the cerebral spinal fluid but whether or not this was related to that or immunizations has never been clarified.”<sup>10</sup> Dr. Vogel also summarized the extent of S.W.’s current treatments and therapies. He concluded with recommendations for follow-up studies. Exhibit 8 at 2-4.

A licensed occupational therapist, Karen Gora, saw S.W. at Mary Free Bed Rehabilitation Hospital on July 2, 2010. The purpose was to evaluate S.W.’s mobility, seating, and ability to transfer. The ensuing letter of medical necessity begins with a caption that states S.W.’s diagnosis is “Paraplegia, Myelitis (Reaction to an Immunization at age 4 months).” Dr. Rush concurred with Ms. Goya’s recommendations. Exhibit 5 at 380-83.<sup>11</sup>

More recently, S.W. started school in fall 2013. He becomes fatigued easily while in school. Also, S.W. is having difficulty in learning (losing some of his sight words and not making progress in math). He has speech delays, uses a wheelchair or crutches, and wears diapers. Exhibit 22 at 3 (Dr. DeRoos’s report, dated Dec. 5, 2013).

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<sup>10</sup> Dr. Shafrir stated that Dr. Vogel’s history incorrectly locates the HHV-6 virus in S.W.’s cerebrospinal fluid. Tr. 148, 164-65. The actual source was plasma.

<sup>11</sup> Although this form is captioned “Reaction to an Immunization,” it is very unlikely that Dr. Rush changed his assessment of the cause of S.W. transverse myelitis. Both neurologists testified that in practice, neurologists spend little time reviewing the precise wording of a form. Tr. 126-28, 164-65, 274.

## **Procedural History**

The Whitneys began this case representing themselves, filing a pro se petition on November 22, 2010. They did not file any of the documents, such as medical records or affidavits, listed in 42 U.S.C. § 300aa-11(c)(2).

The case remained undeveloped until Mr. Ronald Homer became counsel of record. Through their attorney, in March 2011, the Whitneys requested authorization to subpoena medical records. They started filing medical records in August 2011. On March 20, 2012, the Whitneys filed an amended petition, reflecting the accumulation of information about S.W. The Whitneys alleged that the DTaP vaccine caused S.W. to suffer ADEM. Am. Pet. at 1, 15.

The Secretary reviewed this material and advised that the information did not support an award of compensation. The Secretary presented two reasons. First, the Secretary argued that the Whitneys did not submit either a medical record from a treating doctor saying that the vaccines caused S.W.'s neurological problem or a report from a specially retained expert opining about causation. Second, the Secretary also maintained that S.W.'s treating doctors "attributed his condition to an HHV-6 infection." Resp't's Rep. at 6 (citing exhibit 2 at 182, 186, 234). Thus, the Secretary maintained that compensation was not appropriate.

In the status conference held after the Secretary filed her report, the Whitneys stated that they planned to retain an expert. They were instructed to have their expert address whether HHV-6 caused S.W.'s problem. The Whitneys requested (and were granted) 60 days to obtain the expert's report. Order, issued June 13, 2012.

Approximately eight months later, the Whitneys filed a report from Yuval Shafrir, a pediatric neurologist. Dr. Shafrir summarized S.W.'s medical records, stated that S.W. suffered from transverse myelitis (not ADEM), concluded that the DTaP vaccine caused the transverse myelitis, and ruled out HHV-6 as the cause of the transverse myelitis. Exhibit 16. The Whitneys filed his curriculum vitae, and, as tabs to his report, 26 articles Dr. Shafrir cited.

The Secretary requested (and was granted) 90 days to respond. After a single (7 day) enlargement of time, the Secretary filed the reports, curricula vitae, and cited literature from two doctors, Raoul Wientzen and Max Wiznitzer.

Dr. Wientzen brought the perspective of specialist in pediatric infectious diseases. His report recounted S.W.'s history briefly, countered Dr. Shafrir's



opinion that the DTaP vaccine can cause transverse myelitis by discussing many of the articles Dr. Shafrir cited, and asserted that the HHV-6 infection caused S.W.'s transverse myelitis. Exhibit A.

Dr. Wiznitzer's report was similar to Dr. Wientzen's report. After a summary of the medical records that show S.W. suffered from transverse myelitis, Dr. Wiznitzer stated S.W.'s "transverse myelitis was caused by the acute infection that preceded its onset." Exhibit C at 7. He also argued that the proposition that the DTaP vaccine can cause transverse myelitis "is not supported." Id. at 8.

In the next status conference, the Whitneys stated that they were exploring retaining another expert to address the HHV-6 infection. During a status conference on August 22, 2013, the Whitneys disclosed that they retained James Oleske, a specialist in immunology and pediatric infectious diseases, to opine about HHV-6 infection.

Dr. Oleske's first report was approximately two pages. It mainly addressed the HHV-6 infection. Dr. Oleske stated that "I do not believe HHV-6 had any causal relationship to [S.W.'s] neurologic diagnosis." However, in passing, Dr. Oleske also asserted that S.W.'s "illness represented an adverse reaction to the second of his childhood immunizations that was administered seventeen days prior to the onset of his illness and subsequent disabilities." Exhibit 18 at 4.

The parties began to seek mutually convenient dates for a hearing. In conjunction with this process, the parties were ordered to file briefs before the hearing. Prehr's Order, issued Nov. 21, 2013. This order noted that petitioners had not disclosed any basis for Dr. Oleske's opinion that the vaccinations caused S.W.'s transverse myelitis. Id. at 5 n.3, 7 n.4. Thus, a status conference was held to discuss the scope of Dr. Oleske's anticipated testimony. The Whitneys stated that they would explore the topic with Dr. Oleske, and, if necessary, file another opinion.

The Whitneys filed a three-page supplemental report from Dr. Oleske (exhibit 20). Approximately one-third of Dr. Oleske's supplemental report is an extensive quotation taken, without attribution, from an article filed as exhibit 20, tab F. (Daniel Zagury et al., Toward a new generation of vaccines: the anti-cytokine therapeutic vaccines, 98(14) Proc. Nat'l Acad. Sci. USA 8024 (2001)). Dr. Oleske proposed that the vaccinations led to a production of cytokines and cytokines led to transverse myelitis. Dr. Oleske cited seven articles, of which Dr. Oleske co-authored five between 1977 and 1989. In a status conference, the

Whitneys represented that Dr. Oleske was primarily relying upon the 2001 article from the National Academy of Science. Order, issued Jan. 14, 2014.

Both parties filed briefs before the hearing. The parties' factual presentations showed that they agreed about the basic chronology of events. The parties also agreed that S.W. suffered from transverse myelitis. Compare Pet'rs' Prehr'g Br., filed Jan. 8, 2014, at 2-15, with Resp't's Prehr'g Br., filed Jan. 29, 2014, at 2-3.

The parties, however, differed in their assertions about the cause of S.W.'s transverse myelitis. The Whitneys stated that the vaccinations were the cause and they relied upon Dr. Shafrir and Dr. Oleske. The Secretary stated that HHV-6 was the cause and she relied upon Dr. Wientzen and Dr. Wiznitzer.<sup>12</sup>

The four doctors testified at the hearing, conducted in two separate sessions. On February 27, 2014, Dr. Shafrir and Dr. Wiznitzer testified. On March 7, 2014, Dr. Oleske and Dr. Wientzen testified.

Following the hearing, the parties filed an initial set of briefs. In response to an order, the parties also filed supplemental briefs. After the parties reported that they could not resolve the case despite a final attempt at settlement, they submitted the case for adjudication.

### **Standards for Adjudication**

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not

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<sup>12</sup> Neither party presented any evidence that the vaccinations acted in conjunction with the HHV-6.

entitled to compensation); see also Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty).

The elements of the Whitneys’ case are set forth in the often cited passage from the Federal Circuit’s decision in Althen: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

### **Analysis**

The three prongs of the Althen test are evaluated in separate sections below. The order of presentation begins with timing because that topic is easiest. The next issue is the theory and the last factor is the “logical sequence of cause and effect.” Following the three Althen prongs, there is a brief discussion of factors unrelated.

#### **A. Timing**

Although timing is the last prong in Althen, timing can be assessed with relatively few words at the beginning of the analysis. As part of their case-in-chief, the petitioners bear the burden of establishing that the onset of the disease occurred within an acceptable time. Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Here, the Whitneys meet their burden. S.W. received his immunization on November 26, 2007. Exhibit 1 at 1. He started developing neurologic problems between seven and ten days before his pediatric visit on December 13, 2007. Tr. 33, 65, 194. The experts on both sides agreed that this latency (approximately seven to ten days) was an appropriate amount of time for the vaccination to initiate a series of steps leading to transverse myelitis. Tr. 90 (Dr. Shafrir), 196 (Dr. Wiznitzer), 337 (Dr. Oleske), 575 (Dr. Wientzen).

The finding that the Whitneys established that S.W.’s transverse myelitis started within an appropriate time after his vaccination does not end the inquiry because “[t]emporal association is not sufficient, however, to establish causation in fact.” Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). The Whitneys must also establish two other prongs from Althen. See Hibbard v. Sec’y of Health & Human Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012)

(holding that special master did not err in resolving a case based upon the second prong of the Althen test); Paterek v. Sec’y of Health & Human Servs., 527 Fed. Appx. 875, 881 (Fed. Cir. 2013) (stating “[t]o resolve this appeal, we only need to address the second prong under Althen”).

## **B. Theory**

Pursuant to Althen, the Whitneys have the burden to present “a medical theory causally connecting the vaccination and the injury.” Althen, 418 F.3d at 1278. Here, the Whitneys’ experts, Dr. Shafrir and Dr. Oleske, attempt to connect the DTaP vaccine to what is known about transverse myelitis.

Very little is known about the cause of transverse myelitis. Dr. Oleske went so far as to say that the cause is not known. Tr. 409. One factor that contributes to the dearth of information about the etiology of transverse myelitis is the rarity of the disease. Tr. 14. Only about one person per million people suffers from transverse myelitis. Tr. 61, 185. Consistent with this frequency, the testifying neurologists have treated only a few patients with the disease. Tr. 14 (Dr. Shafrir: less than 5), 158 (Dr. Wiznitzer: less than 10).

In approximately two-thirds of transverse myelitis cases, an infection or immunization precedes the onset of spinal cord inflammation. Tr. 16, 510; exhibit 16, tab G (F.S. Pidcock et al., Acute transverse myelitis in childhood: center-based analysis of 47 cases, 68(18) Neurology 1474 (2007)) at 1476. In the remaining one-third of the cases, the doctors have not identified any potential causes. These cases are sometimes labeled idiopathic. Tr. 147, 584; see also Dorland’s at 912.

Due to the antecedent infection in many transverse myelitis cases, doctors have proposed two broad ideas. Doctors believe that an infectious agent (a bacterium or a virus) can invade the spinal cord, causing inflammation. Tr. 159 (Dr. Wiznitzer); see also Tr. 68, 149, 289 (Dr. Shafrir discussing whether HHV-6 caused “viral myelitis” in S.W.). For S.W., little evidence supports a direct invasion theory. Tr. 197-99 (Dr. Wiznitzer), 490 and 508 (Dr. Wientzen); Resp’t’s Mem., filed Jan. 30, 2015, at 2.

When an infection outside of the spinal cord precedes the onset of transverse myelitis, doctors believe that the infection leads to transverse myelitis via an autoimmune process. Tr. 10 (Dr. Shafrir), 217 (Dr. Wiznitzer), 500 (Dr. Wientzen). The term “autoimmune” means the body attacks itself. Tr. 509. The autoimmune process itself is largely not understood. Potential mechanisms include molecular mimicry, epitope spreading, and bystander activation. Tr. 16 (Dr.

Shafir, 217 and 282 (Dr. Wiznitzer); exhibit 16, tab D (N. Agmon-Levin et al., Transverse myelitis and vaccines: a multi-analysis, 18 *Lupus* 1198 (2009)) at 1201.

Assuming that one or more of these methods explain how an infection can cause transverse myelitis, the next question is whether vaccines can incite the same process. Dr. Wientzen testified: “I think all three of these pathophysiologic approaches would apply equally to vaccine as to infection.” Tr. 570.<sup>13</sup> Dr. Shafir and Dr. Oleske agreed. Tr. 16 and 64 (Dr. Shafir), 336 (Dr. Oleske). However Dr. Wiznitzer disagreed. Tr. 212, 236.

Given this evidence, it is relatively easy to find that the Whitneys have presented a plausible medical theory to explain how a vaccine can cause transverse myelitis. Whether this evidence rises to a preponderant level is a more difficult question.<sup>14</sup> For purposes of this decision, it is assumed that the petitioners meet their burden of proof for Althen prong 1. This assumption can be made because the evidence regarding prong 2 is decisive.

### **C. Logical Sequence of Cause and Effect**

Because the Whitneys have met their burden of proof regarding prong 3 and they are assumed to have met their burden of proof regarding prong 1, a critical issue to resolving this case is whether they have met their burden of proof regarding prong 2. The Federal Circuit has recognized that the second Althen prong may be crucial: “A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.” Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1327 (Fed. Cir. 2006). If the Whitneys establish all three Althen prongs, then the burden of proof would shift to the Secretary to establish a factor unrelated to the vaccinations caused the transverse myelitis. Althen, 418 F.3d at 1278.

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<sup>13</sup> Although Dr. Wientzen opined that the mechanisms by which HHV-6 could cause transverse myelitis are mechanisms by which the DTaP vaccine could cause transverse myelitis, Dr. Wientzen’s ultimate opinion was that “the vaccine had no relationship at all to S.W.’s transverse myelitis.” Tr. 472. Rather, Dr. Wientzen opined that HHV-6 or some other virus caused S.W.’s myelitis. Tr. 491, 502-03, 508.

<sup>14</sup> A plausible medical theory is not the same as a persuasive medical theory. Moberly, 592 F.3d at 1322.

The second Althen prong requires petitioners to present “a logical sequence of a cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278. The types of evidence relevant to this prong include the views of treating doctors, whose opinions are favored in the Vaccine Program. Capizzano, 440 F.3d at 1326; but see 42 U.S.C. § 300aa–13(b)(1); Snyder v. Sec’y of Health & Human Servs., 88 Fed. Cl. 706, 746 n.67 (2009).

In the context of prong two, the Whitneys cite: (1) five medical records of which two come from the summer 2010 or later, and (2) a single sentence from Dr. Shafrir’s testimony. Pet’rs’ Posthr’g Br., filed May 5, 2014, at 29-32; Pet’rs’ Reply, filed July 7, 2014, at 9-11. The Secretary maintains that the evidence does not support a finding in the Whitneys’ favor on prong 2. The Secretary dismisses the medical records that the Whitneys cite and emphasizes other medical records in which treating doctors linked S.W.’s transverse myelitis to his HHV-6 infection. The Secretary also relies upon the testimony of Dr. Wiznitzer and Dr. Wientzen. Resp’t’s Posthr’g Br., filed June 6, 2014, at 11-18.

## **1. Medical Records**

Quoting the Federal Circuit, the Whitneys argue that statements in medical records are “quite probative” for establishing the second prong of Althen. Pet’rs’ Posthr’g Br. at 31, quoting Capizzano, 440 F.3d at 1326. Consistent with this position, the Whitneys maintain that “opinions of treating physicians are absolutely sufficient to demonstrate a logical sequence of cause and effect between the vaccine and the injury.” Id.

The Secretary also quotes Capizzano. However, the Secretary also cites other authorities that recognize that statements from treating doctors may be “rebutted and found unreliable . . . based on the record as a whole.” Resp’t’s Posthr’g Br. at 12, citing 42 U.S.C. § 300aa–13(b)(1); Snyder, 88 Fed. Cl. at 746 n.67; Davis v. Sec’y of Health & Human Servs., No. 07-451V, 2010 WL 1444056, at \*14 (Fed. Cl. Spec. Mstr. Mar. 10, 2010), mot. for rev. denied, 94 Fed. Cl. 53 (2010), aff’d without op., 420 Fed. App’x 973 (Fed. Cir. 2011).

Here, of the five records the Whitneys cite, the three records created years after the transverse myelitis do not state that a vaccine caused S.W.’s transverse myelitis. The most recent record was created in 2011 and in that record, a pediatric orthopedist recorded that S.W. “has [a] history of spinal injury after vaccinations.” Exhibit 5 at 253. This simply states a chronology of events. It is not a statement of causation. See Cedillo v. Sec’y of Health & Human Servs., 617 F.3d 1328,

1347–48 (Fed. Cir. 2010); Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 136–37 (2011), aff'd per curiam without op., 463 Fed. Appx. 932 (Fed. Cir. 2012).

In another record, on June 23, 2010, Dr. Vogel noted that the vaccinations S.W. was due to receive after his set of immunizations at four months were being deferred “because of the issue [of a] potential relationship of transverse myelitis.” Exhibit 8 at 3. Dr. Vogel’s recognition of a “potential relationship,” however, does not advance the petitioners’ claim. See Paterek, 527 Fed. Appx. at 879 (stating that the testimony of a treating doctor that “causation was ‘not impossible’ fails to provide support for causation at all”).

In addition, the Whitneys cite to the form on which Dr. Rush endorsed S.W.’s need for a wheelchair. Exhibit 5 at 380-83 (July 16, 2010). However, as noted above, even the Whitneys’ own expert, Dr. Shafrir, did not accept this relatively ministerial act as an expression of Dr. Rush’s views on the role vaccinations played in S.W.’s illness. Tr. 126-28.

Thus, although the Whitneys have cited these records as supporting their position on causation, the words in the records actually do not assist the Whitneys in meeting their burden of proof. An additional reason for not crediting those three records is the date when they were created. These three records were created at least two years after S.W.’s transverse myelitis. As such, the doctor’s history reflects the impressions of S.W.’s parents who provided the narrative to S.W.’s doctors. See Tr. 164-65. A parent’s opinion about causation is not transformed into a medical opinion simply because a doctor recites the parent’s version in a medical record. See Moriarty v. Sec'y of Health & Human Servs., No. 03-2876V, 2014 WL 4387582, at \*15 (Fed. Cl. Spec. Mstr. Aug. 15, 2014), mot. for rev. denied, 2015 WL 738030 (Fed. Cl. Feb. 4, 2014), appeal docketed No. 15-5072 (Fed. Cir. Apr. 16, 2015).

A better source of information about a doctor’s opinion about the cause of an injury is usually the records created during the acute illness. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).<sup>15</sup> These records

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<sup>15</sup> Although doctors treating a patient’s acute illness often have valuable opinions about the cause of the condition, the doctors during the acute phase do not always have the best information. For example, events later in the patient’s life provide insights into the nature of the disease that were not available during the acute presentation. See Hunt v. Sec'y of Health & Human Servs., No. 12-232V, 2015 WL 1263356, at \*11 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) (a presentation of acute disseminated encephalomyelitis was later recognized as an initial manifestation of multiple sclerosis), mot. for rev. filed (Mar. 25, 2015). In addition, physicians

may contain a doctor's opinion about causation, largely independent of a historian's narrative.

The Whitneys cite two records from December 2007, both from Dr. Fogg. In a December 14, 2007 report, which was written before the discovery of HHV-6 in S.W.'s blood, Dr. Fogg identified a "post vaccination reaction" as one of many possible causes for S.W.'s transverse myelitis. Exhibit 2 at 264-66. The second Dr. Fogg report, which the Whitneys cited only in their reply brief, came a few days later. After testing showed the presence of HHV-6 in S.W.'s plasma, Dr. Fogg wrote "This [the HHV-6] or his immunizations could have been the trigger for his ADEM." Exhibit 2 at 166. Like Dr. Vogel's letter from more than three years later, a treating doctor's inclusion of a vaccine as a possible cause does not materially support the petitioners' argument.

In contrast to these weak pieces of evidence, the Secretary cites to other medical records in which treating doctors did not conclude that the vaccination caused S.W.'s transverse myelitis. Resp't's Posthr'g Br., filed June 4, 2014 at 13. On February 22, 2008, Dr. Rush considered and rejected the idea that the vaccines could have caused S.W.'s transverse myelitis. Instead, Dr. Rush recommended that S.W. "should get all his immunizations." Exhibit 5 at 328.

In the undersigned's experience, Dr. Rush's disagreement with the proposition that the vaccines caused his patient's transverse myelitis is remarkably strong and direct. His recommendation for additional vaccinations, which would include additional doses of the DTaP vaccine, further demonstrates his conviction that the vaccines did not harm S.W. See Andreu, 569 F.3d at 1376 (suggesting that a treating doctor's decision to withhold vaccinations may be evidence of a causation).<sup>16</sup> Significantly, in the Whitneys' reply, they failed to address Dr. Rush's recommendation at all. See Pet'rs' Reply Br., filed July 7, 2014, at 9-11. The Whitneys have not challenged Dr. Rush's ability to opine about causation. From the information available, it appears that Dr. Rush is an unbiased and

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who seen a patient later in the course of a disease may identify the cause of the disease after reviewing results of tests that were not conducted initially. See Barclay v. Sec'y of Health & Human Servs., No. 07-605V, 2014 WL 7891493, at \*8 (Fed. Cl. Spec. Mstr. Dec. 15, 2014) (Secretary's expert recommended genetic testing, which turned out positive for a mutation in the SCN1A gene), mot. for rev. filed (Jan. 14, 2015).

<sup>16</sup> Although Ms. Whitney did not accept Dr. Rush's recommendation, her belief that the vaccinations injured her son is not probative evidence that they did. See 42 U.S.C. § 300aa-13(a)(1).



qualified doctor who disagreed with the proposition that the vaccinations caused S.W.'s transverse myelitis. This opinion is valuable.

In addition to Dr. Rush's letter, other treating doctors specifically identified the HHV-6 virus as the cause of S.W.'s transverse myelitis. In pointing to the virus as the causative agent, the doctors were implicitly rejecting the vaccine as a cause. One example is the neurologist who treated S.W. in the hospital. This doctor made handwritten entries saying "HHV 6 myelitis" and "HHV-6 associated myelitis." Exhibit 2 at 173, 182, 186.<sup>17</sup>

A second example is Dr. DeRoos, who agreed with a parental report that said a specialist in infectious diseases identified the HHV-6 virus as causative. Exhibit 6 at 44-45. Despite a vigorous challenge from the Whitneys, this medical record retains some value as evidence that the treating doctors did not consider the vaccine to be causative. The Whitneys are correct that there is no medical record from Dr. Fogg or any other specialist in infectious disease identifying the HHV-6 virus as the cause for the myelitis. Thus, there is a degree of hearsay in the record from Dr. DeRoos. Nevertheless, the circumstantial evidence supports the accuracy of the report to Dr. DeRoos. First, Dr. Fogg included HHV-6 in his list of potential causes. Exhibit 2 at 166, 264-66. Second, Dr. Fogg knew about the positive test for HHV-6. Exhibit 2 at 234. Third, the neurologists, at a minimum, associated S.W.'s transverse myelitis with the HHV-6 virus. These foundational points are a basis for drawing the inference that Dr. Fogg, in fact, told the Whitneys that the HHV-6 virus caused their son's transverse myelitis orally.<sup>18</sup>

In addition to challenging the specific opinion from the infectious disease specialist that the HHV-6 virus caused S.W.'s transverse myelitis, the Whitneys presented a broader attack on the general proposition that HHV-6 virus can cause transverse myelitis. See Pet'rs' Postthr'g Br., filed May 5, 2014, at 34-39; Pet'rs' Reply Br., filed July 7, 2014, at 9-11; Pet'rs' Resp., filed Jan. 30, 2015, at 8-10. The Secretary responded with a robust defense of the theory that HHV-6 can cause

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<sup>17</sup> The statement "HHV-6 associated myelitis" is ambiguous as to whether the doctor was stating that the virus caused the myelitis or the virus simply preceded the myelitis. On the other hand, the statement "HHV 6 myelitis" more clearly expresses a causal (as opposed to simply temporal) relationship.

<sup>18</sup> When the undersigned asked whether information should be sought from S.W.'s treating doctors, the Whitneys declined. See Pet'rs' Resp., filed Jan. 30, 2015, at 5-6.

(and for S.W., did cause) transverse myelitis. Resp't's Posthr'g Br., filed June 4, 2014, at 14-20; Resp't's Mem., filed Jan. 30, 2015, at 2-4.

The potential trouble with the Whitneys' attack is that the arguments they raise against the lack of evidentiary support for the theory that HHV-6 can cause transverse myelitis are arguments that could undermine the theory that the vaccines can cause transverse myelitis.<sup>19</sup> In seeking to tear down the Secretary's home, the Whitneys risk destroying their own edifice.

Moreover, the Whitneys' fighting over whether HHV-6 can cause transverse myelitis overlooks Dr. Rush's report. Even if the Whitneys succeeded in entirely discrediting: (a) the handwritten statements from the neurologists whose reports the Whitneys did not address directly, (b) the implicit oral statement from an infectious disease specialist, and (c) the more formal statement from Ms. Shelanskey / Dr. DeRoos, Dr. Rush's report would remain. Dr. Rush discounted the vaccinations as a cause for myelitis without referring to the HHV-6 virus. Exhibit 5 at 328.

The Whitneys bear the burden of presenting affirmative evidence in support of causation.<sup>20</sup> Grant, 956 F.2d at 1149. At the end of the day, the Whitneys have not identified even one medical record in which a treating doctor expressed the opinion that a vaccination caused the transverse myelitis. The lack of evidence from treating doctors is a deficit in the Whitneys' case. See Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 550 (Fed. Cir. 1994) (when the evidence is in equipoise, the party with the burden of proof has failed to carry the burden of persuasion); In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Master Autism File, 2004 WL 1660351, at \*8 (Fed. Cl. Spec. Mstr. July 16, 2004) ("in legal factfinding if there is no evidence, the factual issue simply is resolved against the party having the 'burden of proof'"). The absence of affirmative evidence from treating physicians is especially significant because Dr. Rush's report constitutes evidence against the proposition. When there is no evidence in favor of the proposition and

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<sup>19</sup> For example, the Whitneys argued that "Dr. Wientzen indicated that there was no homology between HHV-6 and spinal cord components." Pet'rs' Posthr'g Br. at 38, citing Tr. 569. But, with respect to the DTaP vaccine, Dr. Shafrir stated the lack of "common homology . . . doesn't mean anything," and Dr. Oleske was not aware of any homology. Tr. 64, 415-17.

<sup>20</sup> "Affirmative evidence" means evidence in support of the proposition. "Affirmative evidence" does not mean scientifically certain evidence.

some un rebutted evidence against the proposition, the evidence must weigh against the proposition.<sup>21</sup>

## **2. Expert Testimony**

While the treating doctors, on a whole, do not assist the Whitneys in meeting their burden for prong two, the Whitneys may still prevail by presenting a persuasive case through their retained experts. See 42 U.S.C. § 300aa–13(a). However, the Whitneys’ evidence from Dr. Shafrir and Dr. Oleske was thin and not persuasive.

In their briefs regarding prong 2, the Whitneys cite one passage from Dr. Shafrir (and nothing from Dr. Oleske). After Dr. Shafrir expressed his opinion that the vaccinations “substantially contributed to” the transverse myelitis, he provided the basis for this opinion. He stated “the known relationship between vaccines in general and transverse myelitis, the previous case reports associating this particular vaccine . . . with transverse myelitis, and the time course and the lack of . . . any other stimulation as strong as the vaccine to explain this appearance of transverse myelitis.” Tr. 34.<sup>22</sup> Dr. Shafrir repeated this position later. Tr. 148.

Dr. Oleske’s reasoning was similar. When asked for the basis that the vaccinations caused S.W.’s transverse myelitis, Dr. Oleske indicated that an “immunological reaction that’s initially non-specific and related to things like cytokines can, in fact, cause unfortunately bystander damage to tissues. . . [And,] the timing of when he got the immunization as well and the development of transverse myelitis all fit into the temporal relationships we see when we immunize someone with multiple antigens.” Tr. 338. Although, in this passage, Dr. Oleske

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<sup>21</sup> In this case, the evidence from the treating doctors preponderates against the Whitneys. However, in other cases, the evidence from the treating doctors favors the petitioners. When the evidence from treating doctors supports a finding of causation, the parties typically resolve the case without the need for a formal adjudication by a special master.

<sup>22</sup> Although Dr. Shafrir opined that the vaccinations stimulated S.W.’s immune system more than the roughly concurrent infection with HHV-6, Dr. Wiznitzer testified that “the amount of antigen load from the immunization is trivial compared to what you get from the infectious illness.” Tr. 259. Dr. Shafrir, then, retreated from his assertion that the vaccines present a greater immunologic challenge. Tr. 297. The two immunologists differed on the question as to what presents a greater immunologic challenge, either a vaccination or an infection. Compare Tr. 398-407 (Dr. Oleske) with Tr. 564-67 (Dr. Wientzen).

did not specifically mention that he considered HHV-6 not to be the cause, in other portions of his testimony, Dr. Oleske actually did rule out HHV-6. Tr. 324-25.

The core of Dr. Shafrir's and Dr. Oleske's opinions for prong 2 is a series of three assertions: (1) the vaccine can cause the disease, (2) the timing is appropriate, and (3) the exclusion of other potential factors. Whether the evidence truly satisfies the first and third postulates is debatable. But, a flaw in the Whitneys' case does not depend upon whether they succeeded in establishing, by a preponderance of the evidence, that the DTaP vaccination can cause transverse myelitis or that HHV-6 does not cause transverse myelitis. Rather, even if these assertions were credited, the problem with the Whitneys' presentation is that the Federal Circuit "has previously rejected the same argument --- that proof that an injury could be caused by a vaccine and that the injury occurred within an appropriate period of time following the vaccination is sufficient to require an award of compensation unless the respondent can prove some other cause for the injury." Hibbard, 698 F.3d at 1365-66; (citing Moberly, 592 F.3d at 1323); Althen, 418 F.3d at 1278; see also Caves v. Sec'y of Health & Human Servs., No. 07-443V, 2010 WL 5557542, at \*21 (Fed. Cl. Spec. Mstr. Nov. 29, 2010) (citing Moberly), 592 F.3d at 1323, mot. for rev. denied, 100 Fed. Cl. 119, 135 (finding special master's determination on prong two was "not erroneous"), aff'd without op., 463 Fed. App'x 932 (Fed. Cir. 2012).

In Moberly and Althen, the two cases Hibbard cited, the Federal Circuit provided additional insights into the prong two analysis. Hibbard interpreted Moberly as establishing that "'temporal association between a vaccination and a seizure, together with the absence of any other identified cause for the ultimate neurological injury' is evidence of causation but does not by itself compel a finding of causation." Hibbard, 698 F.3d at 1366. So, too, in this case, Dr. Shafrir's opinion and Dr. Oleske's opinion constitute some evidence in favor of causation.

Hibbard also quoted Althen, 418 F.3d at 1278, for the proposition that "neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." Hibbard, 698 F.3d at 1366. This reference to needing something "more" might be satisfied in some cases with persuasive statements from treating doctors. But, as discussed in the preceding section, the Whitneys have not identified any treating doctor who stated the vaccines caused S.W.'s transverse myelitis. The treating doctors are actually against this proposition.

Consequently, when the record is considered as a whole, the Whitneys have not met their burden of proof for prong two.

#### **D. Factor Unrelated**

Because transverse myelitis is not listed on the Vaccine Injury Table, the petitioners must establish that the vaccinations were the cause-in-fact of S.W.'s transverse myelitis. They would meet this burden by establishing the three Althen prongs. Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1379 (Fed. Cir. 2012). However, for the reasons just explained, the Whitneys have not done so for prong two.

If the Whitneys had presented preponderant evidence on each Althen prong, then the burden would have shifted to the Secretary to present preponderant evidence that S.W.'s transverse myelitis was "due to factors unrelated" to the vaccinations. 42 U.S.C. § 300aa-13(a)(1)(B); accord Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1367 (Fed. Cir. 2013). But, in this case, the burden did not shift. See Doe 11 v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010).

The finding that the Whitneys did not meet their burden of establishing that the vaccinations caused S.W.'s transverse myelitis is a sufficient basis to deny compensation. The finding that the vaccine did not cause the injury "necessarily implies some other cause resulted in the injury." Bazan, 539 F.3d at 1353. Under the circumstances of this case, the Secretary is not required to establish what that other cause is. LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1341 (Fed. Cir. 2014) ("Additionally, it was not the government's burden to provide an alternative explanation").

#### **Conclusion**

Mr. and Ms. Whitney have presented a plausible case that the vaccinations caused S.W.'s transverse myelitis. Their sincere belief, however, conflicts with the opinions of the doctors who treated S.W., particularly Dr. Rush.

Congress reserved compensation in the Vaccine Program to those people who, among other elements, established that a vaccine caused the injury for which they seek compensation. The Whitneys have not made this showing. Therefore, they are not entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision.

**IT IS SO ORDERED.**

s/ Christian J. Moran  
Christian J. Moran  
Special Master