In the United States Court of Federal Claims

No. 10-809V

(Filed Under Seal: July 28, 2015)
(Reissued: August 12, 2015)

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REBECCA WHITNEY AND RANDALL WHITNEY, parents of S.W., a minor,	Vaccine case; dispute over *Althen* prong two – logical sequence of cause and effect between the vaccinations and the injury; remand
Petitioners,	
v.	
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Defendant.	
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Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, Massachusetts for petitioners. Representing petitioners at the hearing was Meredith Daniels, Conway, Homer & Chin-Caplan, P.C., Boston, Massachusetts.

Lara A. Englund, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for defendant. With her on the brief was Benjamin C. Mizer, Principal Deputy Assistant Attorney General, Civil Division, Rupa Bhattacharyya, Director, Torts Branch, Vincent J. Matanoski, Deputy Director, Torts Branch, and Voris E. Johnson, Jr., Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

OPINION AND ORDER[1]

LETTOW, Judge.

Petitioners, Rebecca and Randall Whitney, on behalf of their son, S.W., seek review of a decision by a special master filed May 8, 2015, denying them an award under the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 311, 100 Stat. 3743, 3755 (1986)

[1]In accord with the Rules of the Court of Federal Claims ("RCFC"), App. B ("Vaccine Rules"), Rule 18(b), this opinion and order was initially filed under seal. By rule, the parties were afforded fourteen days in which to propose redactions. No redactions were requested.

(codified, as amended, at 42 U.S.C. §§ 300aa-1 to -34) ("Vaccine Act"). The Whitneys allege that the injection of their son with diphtheria-tetanus-acellular-pertussis ("DTaP"), *Haemophilus influenzae* type b ("Hib"), inactivated polio ("IPV"), pneumococcal conjugate ("PCV"), and rotavirus vaccines, administered on November 26, 2007, caused him to develop transverse myelitis, a severe neurologic disorder. Pet'rs' Mem. in Support of Mot. for Review of the Special Master's May 8, 2015 Decision ("Pet'rs' Mem."), ECF No. 116.[2] The Secretary of Health and Human Services ("the government") acknowledges that S.W. suffered from an episode of transverse myelitis and continues to have adverse effects from that condition but argues that its cause is unrelated to administration of the vaccines. Response to Mot. for Review ("Resp't's Mem."), ECF No. 119.

Transverse myelitis is an "off-Table" vaccine injury for which petitioners must establish causation in fact by preponderant evidence. *See* 42 U.S.C. §§ 300aa-11(c)(1)(B), (C)(ii)(I), 300aa-13(a)(1); *see also Althen v. Secretary of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The special master, applying the causation framework set out in *Althen*, denied relief on the ground that the Whitneys failed to provide a logical sequence of cause and effect between the vaccinations and transverse myelitis. *See Whitney v. Secretary of Health & Human Servs.*, No. 10-809V, slip op. at 14 (Fed. Cl. Spec. Mstr. May 8, 2015) ("Entitlement Decision"). On review, the Whitneys aver that the special master's decision was arbitrary and capricious and his reasoning was contrary to relevant legal standards. The government responds that the special master's decision was in accordance with law and should not be set aside.

[2]Transverse myelitis is a neurological disorder "characterized by the sudden onset of rapidly progressive weakness of the lower extremities, accompanied by loss of sensation and sphincter control, and often preceded by a respiratory infection." John H. Menkes, *Textbook of Child Neurology* ("*Child Neurology*") 535 (Williams & Wilkins, 5th ed. 1995). For individuals with transverse myelitis, "[t]he spinal cord is generally softened, with the most striking changes occurring in the thoracolumbar region. . . . In the affected area, the spinal cord is often completely necrotic; all nervous elements are lost, replaced by a cellular infiltrate or by cavitation." *Id.* at 535-36; *see also* Tr. 159:11-17 (Test. of Dr. Max Wiznitzer, an expert witness called by the government). The transcript of the entitlement hearing before the special master held on February 27, 2014 and March 7, 2014 will be cited as "Tr. __."

Very little information exists about the etiology of transverse myelitis because the condition is rare. *See* Tr. 14:10-28 (Test. of Dr. Yuval Shafrir, an expert witness called by petitioners). Researchers believe that transverse myelitis is caused by either a "direct infection or by a parainfectious or postinfectious process." Tr. 159:18-20 (Wiznitzer) (a parainfectious process connotes a manifestation of an infectious disease caused by an immune response to an infectious agent); *see also* Child Neurology at 536 ("The condition can be caused by . . . autoimmune diseases, bacterial, viral, or spirochetal infections, and vascular malformations.").

BACKGROUND

A. *S.W.'s Medical History*

S.W. was born in July 2007. Pet'rs' Ex. 1, at 1 (Medical Records from Michigan Medical Pediatrics (June 8, 2011)).[3] During the first four months of his life, S.W. was healthy, and his pediatric records did not show any problems with development or illnesses. *See id.* Ex. 13, at 1-7 (Additional medical records from Michigan Medical Pediatrics). In mid-November of 2007, S.W. developed a mild upper respiratory infection, and other members of his family displayed similar symptoms. *Id.* Ex. 2, at 255 (History and Physical Report by Dr. Beatrice Guadalu Zepeda (Dec. 13, 2007)) & 264 (Consultation Report by Dr. George Fogg (Dec. 14, 2007)). His family did not take S.W. to a doctor, but tests conducted later indicated that he probably then was suffering from a human herpesvirus 6 ("HHV-6") infection. Entitlement Decision at 2 n.3; *see also* Tr. 493:15-24 (Test. of Dr. Raoul Weintzen, an expert who also testified on behalf of the government) ("I think he had an active HHV-6 infection at about Thanksgiving when, by history, he had the upper respiratory infection we read about in the medical record, the cold, runny nose, cough, and so on.").[4] On November 26, 2007, S.W. saw his doctor for his four-month pediatric well-child visit. Pet'rs' Ex. 13, at 5. At this appointment, S.W. received the DTaP, Hib, PCV, IPV, and rotavirus vaccines. *Id.* Ex. 10, at 1 (Medical Records from Dr. Donnie Reinhart (June 2, 2011)).

Around December 6, 2007, S.W. showed signs of "some congestion and upper respiratory symptoms," but "[n]o nausea, vomiting, [or] diarrhea." Pet'rs' Ex. 2, at 261 (Physician Report (Dec. 13, 2007)). He also "appeared to be straining whenever he stooled." *Id.* Ex. 2, at 253 (History and Physical Reports (Dec. 13, 2007)). Experts testifying for both parties testified that this condition indicated that S.W. may have developed neurologic problems at this time. *See* Tr. 160:10-19 (Wiznitzer), 280:6-14 (Test. of Dr. James Oleske, an expert who also testified on behalf of petitioners). A few days later, on December 12, 2007, S.W.'s mother noticed that his legs were shaking, and she stayed "up with him . . . that night, rocking and consoling him so he could get back to sleep." Pet'rs' Ex. 14, at ¶¶ 5-6 (Aff. of Rebecca Whitney (Mar. 19, 2012)). The next day, on December 13, 2007, S.W.'s mother took him to see the pediatrician, and she noted that S.W. had not been moving for two days and would scream when waking up or when moving his legs. *See id*. Exs. 1, at 46 (General Visit Report (Dec. 13, 2007)) & 14, at ¶ 8. S.W. was observed to have decreased muscle tone in his lower extremities, "some

[3]Documentary materials made part of the record by petitioners are cited as "Pet'rs' Ex. __, at __."

[4]HHV-6 is a "ubiquitous virus that is an etiologic agent of exanthema subitum[,] . . . a short lived disease of infants and young children." *Dorland's Illustrated Medical Dictionary* ("*Dorland's*") 664, 864 (Saunders Elsevier, 31st ed. 2007); *see also* Child Neurology at 428. "Most healthy adults carry the virus and are asymptomatic." *Dorland's* at 864.

clonus,"[5] and absent reflexes. *Id.* Ex. 1, at 46. Experts from the parties concurred that the presence of clonus indicated that S.W. had been suffering from neurological problems for seven to ten days. *See* Tr. 66:1-5 (Shafrir), 194:22 to 195:2 (Wiznitzer). Based on his symptoms, S.W. was admitted to the emergency room and sent to the pediatric intensive care unit. Pet'rs' Ex. 2, at 261. His admission record stated a history similar to that provided by the pediatrician who saw him. *See id.* Ex. 2, at 253-55. While S.W. was in the hospital, doctors took blood samples, consulted with a neurologist, and performed a lumbar puncture to remove a sample of cerebrospinal fluid. *Id.* Ex. 2, at 261. The latter sample showed inflammation in the spinal cord. *Id.* Ex. 2, at 254; *see also* Entitlement Decision at 3.

Doctors also ordered a series of MRIs and prescribed the antibiotic Rocephin to treat a possible bacterial infection. Pet'rs' Ex. 2, at 255; *see also* Tr. 97:8-25 (Shafrir). Prior to the MRIs, a neurologist, Dr. Steven DeRoos, examined S.W. and reported that S.W. had "[n]o acute febrile illness recently" and "agree[d] with the IV antibiotics until more information [wa]s known." *Id.* Ex. 2, at 267-68 (Consultation Report by Dr. DeRoos (Dec. 13, 2007)). On December 13, 2007, S.W. had four MRIs. *See id.* Ex. 2, at 249-52 (Magnetic Resonance Imaging Report (Dec. 13, 2007)). The images of the brain and lumbosacral spine were normal, but the images of the cervical spine and thoracic spine showed that "[a] form of myelopathy in the mid and lower cervical spinal cord exist[ed]." *Id.* at 250. According to the radiologist, Dr. Edward Bok, the results "suggest[ed] the likelihood that this represent[ed] an immune mediated disseminated myelitis, perhaps parainfectious in etiology." *Id.* Ex. 2, at 250.

The next day, on December 14, 2007, Dr. Fogg, a pediatric infectious disease specialist, evaluated S.W. and noted that the child "[wa]s a four-month old . . . responding to high-dose steroids" who received "DTaP, ITB, Hib, pneumococcal conjugate vaccine[s], and rotavirus vaccine" on November 26, 2007. Pet'rs' Ex. 2, at 264 (Consultation Report by Dr. Fogg (Dec. 14, 2007)). Dr. Fogg concluded that S.W.'s presentation of symptoms was "consistent with acute disseminated encephalomyelitis ([']ADEM[']))." *Id.* Ex. 2, at 265.[6] For "infectious triggers," Dr. Fogg listed "viral (CMV, EBV, HSV, enterovirus and West Nile), bacterial (*Campylobacter*, and mycoplasma), post vaccination reaction, or autoimmune disease" as possibilities. *Id.* He made several recommendations that included a request for a polymerase chain reaction ("PCR") test to detect several types of pathogens, including HHV-6, which may have been present in S.W.'s blood plasma. *Id.* Ex. 2, at 265-66. Finally, Dr. Fogg "*agree[d] with* the plans for *high-dose steroid therapy* as directed by pediatric neurology" and stated that

[5]The term "clonus" is defined as "alternate 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." *Dorland's* at 379.

[6]The term "encephalomyelitis" is defined as "inflammation involving both the brain and the spinal cord." *Dorland's* at 621. ADEM is "a manifestation of an autoimmune attack on the myelin of the central nervous system. . . . It occurs most commonly following an acute viral infection." *Id.*; *see also* Child Neurology at 521. Symptoms of ADEM include "fever, headache, vomiting, and drowsiness progressing to lethargy[,] and coma, seizures, and paralysis may also occur." *Dorland's* at 621.

he would "*report the possible post immunization adverse event to the [V]accine [A]dverse [E]vent [R]eporting [S]ystem [('VAERS')]*." *Id.* Ex. 2, at 266 (emphasis added).[7]

Following Dr. Fogg's assessment and the resulting testing, lab results indicated that S.W. had 4,100 copies of the HHV-6 per milliliter of plasma. Pet'rs' Ex. 2, at 234 (General Lab Reports (Dec. 14, 2007)). When "testing . . . show[ed] evidence of HHV-6 infection," Dr. Fogg wrote that "*[the HHV-6 virus] or his immunizations* could have been the trigger for his ADEM." *Id.* Ex. 2, at 166 (Progress Notes by Dr. Fogg (Dec. 17, 2007)) (emphasis added).[8] A pediatric neurologist who saw S.W. while he was in the hospital indicated that S.W. had "HHV[-]6 myelitis." *Id.* Ex. 2, at 186 (Rounding Report (Dec. 21, 2007));[9] *see also* Entitlement Decision at 5. S.W. remained in the hospital until December 21, 2007, when he was transferred to an inpatient rehabilitation hospital, Mary Free Bed Hospital. Pet'rs' Ex. 2, at 270-72 (Discharge Documentation (Dec. 21, 2007)). S.W. remained at Mary Free Bed Hospital until January 2, 2008. *Id.* Ex. 5, at 47-50 (Physician Discharge Summary (Jan. 2, 2008)).

On February 17, 2008, S.W. went to a neurology clinic for a follow-up appointment. *See* Pet'rs' Ex. 6, at 44 (Letter from Kim Shelanskey, family nurse practitioner, and signed by Dr. DeRoos, to Dr. Stephen McMahon (Feb. 17, 2008)). Ms. Shelanskey recited the following history of S.W.'s illness:

> [S.W.] is nearly 7-month-old male who was initially evaluated by Dr. Steven DeRoos during a hospitalization in December 2007 for transverse myelitis. At that time, [S.W.] presented with a 1-day history of decreased movement in his lower extremities. A full workup was completed in the hospital and included an MRI of the cervical spine which showed an abnormal signal running from the C2-C3 area in a rostrocaudal fashion to the upper thoracic spinal canal. *This was thought to be a form of myelopathy. Infectious Disease was able to identify the HHV-6 virus as the causative agent.*

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[7]"VAERS is a database maintained by the Center for Disease Control ('CDC') to compile information from reports about reactions to immunizations listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a)." *Analla v. Secretary of Health & Human Servs.*, 70 Fed. Cl. 552, 556 (2006).

[8]At this time, "doctors listed [S.W.]'s diagnosis as ADEM. However, another doctor (Dr. Adam Rush) disagreed with the diagnosis of ADEM because [S.W.]'s problem was limited to his spine and did not affect his brain." Entitlement Decision at 5 n.7 (citing Pet'rs' Ex. 5, at 328). During the Entitlement Hearing, testifying neurologists agreed with the diagnosis of transverse myelitis and not ADEM. *See, e.g.*, Tr. 198:4-12 (Wiznitzer) ("[S.W.] had . . . transverse myelitis."). The diagnosis of transverse myelitis is not in dispute.

[9]A neurologist also wrote "HHV-6 associated myelitis" in another medical note. Pet'rs' Ex. 2, at 182 (Runding Report (Dec. 20, 2007)).

Id. (emphasis added).[10] Ms. Shelanskey also noted that S.W. was "making nice gains and continues to work with both occupational therapy and physical therapy through Mary Free Bed [Hospital]." *Id.* Ex. 6, at 45. Dr. DeRoos, the neurologist "directly involved with formulating the plan [for S.W.'s care,] . . . agree[d] with [Ms. Shelanskey's] assessment." *Id.* Two days later, on February 19, 2008, S.W. saw a urologist, Dr. Brian Roelof, who noted that "[S.W.] seems to be improving." *Id.* Ex. 4, at 17 (Initial Visit Report by Dr. Roelof (Feb. 19, 2008)). S.W.'s mother informed Dr. Roelof that she "thought he had acute viral myelitis secondary to a virus or perhaps from his vaccinations." *See id.*

On February 22, 2008, S.W. had an appointment with a physiatrist,[11] Dr. Rush, who had previously cared for S.W. at Mary Free Bed Hospital. Mr. and Mrs. Whitney reported to Dr. Rush that S.W. was experiencing a "dramatic return of strength and apparent sensation in his bilateral[] lower limbs since [his last visit]." Pet'rs' Ex. 5, at 327 (Final Report by Dr. Rush (Mar. 4, 2008)). Mr. and Mrs. Whitney also informed Dr. Rush that they were "not planning at this time for him to receive any more immunizations." *Id.* Dr. Rush did not address the issue of "immunization noncompliance" with S.W.'s parents at this appointment, but noted in his report that:

> [*i*]*t is incredibly important that like any other child, [S.W.] get his immunizations*. I can only surmise at this point that his parents are reluctant to give him immunizations in the misguided belief that 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*.

Id. Ex. 5, at 328 (emphasis added). S.W. returned to see Dr. Rush a few months later, on June 4, 2008. S.W.'s mother reported to Dr. Rush that S.W. was suffering from the "occasional (approximately daily) spasms of the lower limbs . . . [and] shaking episodes," but they "[did] not seem to cause him any discomfort." *Id.* Ex. 5, at 325 (Final Report by Dr. Rush (June 13, 2008)). During this appointment, Dr. Rush "touch[ed] upon the issue of immunizations again with S.W.'s mother." *Id.* Ex. 5, at 326. According to Dr. Rush, Ms. Whitney felt "very strongly

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[10]Notably, the pediatric infectious disease specialist, Dr. Fogg, had *not* identified HHV-6 as *the* infectious agent, but rather listed HHV-6 along with S.W.'s immunizations as alternative causes, *see supra*, at 5; *see also* Tr. 122:8-13 (Shafrir).

[11]A physiatrist, or rehabilitation physician, is a medical doctor who has "completed training in the medical specialty of physical medicine and rehabilitation." American Academy of Physical Medicine and Rehabilitation, What is a Physiatrist?, *available at* https://www.aapmr.org/patients/aboutpmr/Pages/physiatrist.aspx. A physiatrist is responsible for "[d]iagnosing and treat[ing] pain." *Id.*; *see also Dorland's* at 1464 ("Physiatry [is] the branch of medicine that deals with the prevention, diagnosis, and treatment of disease or injury, and *the rehabilitation from resultant impairments and disabilities*.") (emphasis added).

at [that] point [in time] against resuming [vaccinations] now, though she did seem to leave the door open for [S.W.] receiving his immunizations at some point in the future." *Id.*

On September 15, 2008, S.W. had an appointment with his neurologist, Dr. DeRoos. Mr. and Mrs. Whitney were concerned that S.W. was experiencing seizures. Pet'rs' Ex. 5, at 319 (Letter from Amy Tolliver, signed by Dr. DeRoos, to Dr. McMahon (Sept. 15, 2008)). Dr. DeRoos concluded that the spells experienced by S.W. "could represent seizure[s]" and recommended "obtain[ing] a repeat MRI." *Id.* Ex. 5, at 320. The results from the repeat MRIs were "unremarkable . . . with resolution of abnormal cord signal previously seen on the study of 12/13/2007." *Id.* Ex. 6, at 53 (Magnetic Resonance Imaging Report (Jan. 12, 2009)).

On June 23, 2010, about two and a half years after S.W.'s onset of transverse myelitis, he was seen by a pediatrician, Dr. Lawrence Vogel, in a routine follow-up. Dr. Vogel summarized events from when S.W. was approximately five months old, stating that "[S.W.] developed irritability and constipation . . . about 2 to 2-1/2 weeks after receiving immunizations at the 4-month mark." Pet'rs' Ex. 8, at 2 (Outpatient History and Physical Report (June 27, 2010)). Dr. Vogel also recounted that "[S.W.]'s MRI was consistent with transverse myelitis" and that doctors had found "herpes virus 6 isolated in [S.W.'s plasma] but whether or not this was related to that or immunizations has never been clarified." *Id.* Finally, Dr. Vogel recorded that S.W.'s "[i]mmunizations were up-to-date as of [four] months, but because of the . . . potential relationship [to] transverse myelitis[,] immunizations are being deferred at the current time." *Id.* Ex. 8, at 3.

Shortly thereafter, on July 2, 2010, S.W. was seen by an occupational therapist, Karen Gora, "for an evaluation for independent manual mobility and advice for facilitating independent transfers." Pet'rs' Ex. 5, at 380 (Evaluation by Ms. Gora and signed by Dr. Rush (July 14, 2010)). In a "Letter of Medical Necessity" regarding S.W.'s orthopedic equipment needs, Ms. Gora listed S.W.'s diagnosis as "Paraplegia, Myelitis (*Reaction to an Immunization at age 4 months*)." *Id.* (emphasis added). Based on her evaluation, Ms. Gora recommended the use of orthopedic equipment, including a manual wheelchair and a custom seating system. *Id.* Ex. 5, at 382-83. Dr. Rush agreed with these recommendations. *Id.* Ex. 5, at 383.[12]

S.W. has remained in therapy, but he continues to experience sequelae of transverse myelitis. *See generally* Pet'rs' Exs. 5, 24 (Updated Medical Records from Shriners Hospital for Children), & 25 (Medical Records from Mary Free Bed Rehabilitation Hospital). The complications include "secondary spastic paraparesis,[13] neurogenic bladder and bowel," and sensory deficits in his legs. *Id.* Ex. 22, at 3 (Progress Notes (Dec. 5, 2013)). Since starting

[12]More recently, on June 5, 2012, S.W. was seen by Dr. Allen Bragdon for a fever and abdominal pain. Pet'rs' Ex. 26, at 178 (Physician Report by Dr. Bragdon). Dr. Bragdon reported that "[t]his is a 5-year-old child who unfortunately contacted transverse myelitis after immunization at [four] months old. . . . Immunizations are not up to date [because S.W.'s] [m]other opted not to do any further immunizations after the incident at 4 months old." *Id.*

[13]Paraparesis is the "partial paralysis of the lower limbs." *Dorland's* at 1400.

school, S.W. becomes easily fatigued and has difficulty learning. *Id.* He also has delays in his speech, uses a wheelchair or forearm crutches, and wears a diaper to school. *Id.* The transverse myelitis has left S.W. with severe disabilities. *See* Tr. 116:17-24 (Shafrir) ("[T]ransverse myelitis [is] a monophasic inflammatory disease that goes away . . . and in spite of the fact that it's a monophasic condition[] that goes away, [the patients] are left with very significant disabilit[ies]."); *see also* Pet'rs' Ex. 14 (Aff. of Mrs. Whitney), at ¶ 16 ("[S.W.] has had to endure intense physical therapy, countless medical tests, numerous doctor's appointments, long car rides, and time away from family in order to receive proper medical treatment . . . . [M]y child [has] face[d] such adversity at a young age.").

B. *Special Master's Decision*

The Whitneys filed their petition for compensation on November 22, 2010, alleging that S.W. "suffered a demyelinating neurological disorder" after receipt of his childhood vaccines. Pet'rs' Pet. for Vaccine Compensation ("Pet.") at 1, ECF No 1.[14] Hearings in this case were conducted by the special master in two sessions during February and March of 2014. At the hearings, the parties were in agreement both about the chronology of events and that S.W. suffered from transverse myelitis. *See* Entitlement Decision at 10. The parties disagreed sharply, however, as to the cause or causes of S.W.'s transverse myelitis. The Whitneys relied upon medical records, medical literature, and expert testimony of Dr. Yuval Shafrir and Dr. James Oleske to show that S.W.'s vaccine inoculations caused his transverse myelitis. *See* Pet'rs' Post-Hearing Br., ECF No. 103.[15] The government disagreed with the Whitneys' theory of causation, alleging that the treating physician's statements and expert testimony cited by petitioners were unpersuasive and failed to eliminate HHV-6 as the cause of S.W.'s condition. *See* Resp't's Post-Hearing Br., ECF No. 104. To support its arguments, the government offered

[14]The Whitneys initially filed this case *pro se*, but subsequently they retained counsel. Entitlement Decision at 8.

[15]Dr. Yuval Shafrir is board-certified in clinical neurophysiology and has a special qualification in child neurology. Tr. 11:22-24 (Shafrir); *see also* Curriculum Vitae, Yuval Shafrir M.D., ECF No. 52-3. Besides a private medical practice, he currently serves as Assistant Professor, Department of Pediatrics, University of Maryland School of Medicine, Baltimore, Maryland, and Assistant Professor in Neurology and Pediatrics, United Services University of the Health Sciences, F. Edwards Herbert School of Medicine, Bethesda, Maryland. Curriculum Vitae, Yuval Shafrir, M.D.

Dr. James Oleske is board-certified in pediatrics as well as allergy, immunology, and pediatric infectious diseases. Tr. 317:12-13 (Oleske); *see also* Curriculum Vitae, James M. Oleske, M.D., MPH, ECF No. 70-3. Dr. Oleske is François-Xavier Bagnoud Endowed Chair Professor of Pediatrics, University of Medicine and Dentistry of New Jersey, Newark, New Jersey. Curriculum Vitae, James M. Oleske, M.D., MPH.

testimony from Dr. Max Wiznitzer and Dr. Raoul Weintzen and emphasized medical records discussing S.W.'s HHV-6 infection. *Id.*[16]

The special master issued a decision denying compensation on May 8, 2015. Entitlement Decision at 22. The special master concluded that the Whitneys had failed to prove that the vaccines administered to S.W. on November 26, 2007 caused his transverse myelitis. *Id.* In so holding, the special master applied the three-prong test set forth in *Althen*, 418 F.3d 1274, which requires that a petitioner

> show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1278.

The special master concluded that the Whitneys had carried their burden with respect to prongs 1 and 3 of the *Althen* framework. Entitlement Decision at 11-13. However, upon analyzing the second prong of *Althen*, *i.e.*, relating to a logical sequence of cause and effect, the special master determined that although the Whitneys "ha[d] presented a plausible case that the vaccinations caused S.W.'s transverse myelitis, [this] belief . . . conflict[ed] with the opinions of the doctors who treated [S.W.]." *Id.* at 22. As he put it, "the Whitneys have not identified even one medical record in which a treating doctor expressed the opinion that a vaccination caused the transverse myelitis." *Id.* at 18-19. Additionally, according to the special master, the opinions from Dr. Shafrir and Dr. Oleske were "thin and not persuasive" and failed to amount to "something 'more'" needed to meet the burden of showing actual causation. *Id.* at 19-21 (citing *Hibbard v. Secretary of Health & Human Servs.*, 698 F.3d 1355, 1358 (Fed. Cir. 2012)). After discounting the medical records and expert testimony offered by the Whitneys, the special master gave credence to the report written by Ms. Shelanskey and signed by Dr. DeRoos, stating:

> Dr. DeRoos . . . agreed with a parental report that said a specialist in infectious diseases identified the HHV-6 virus as causative. . . . The Whitneys are correct that there is no medical record from Dr. Fogg or any other specialist in infectious disease identifying

[16]Dr. Max Wiznitzer is board-certified in pediatrics and neurodevelopmental disabilities with a special qualification in child neurology. Tr. 155:8-11 (Wiznitzer); *see also* Curriculum Vitae, Max Wiznitzer, M.D., ECF No. 57-6. Besides work at Rainbow Babies and Children's Hospital, Cleveland, Ohio, he serves as Associate Professor of Pediatrics, Neurology, and International Health, Case Western Reserve University, Cleveland, Ohio. Curriculum Vitae, Max Wiznitzer, M.D.

Dr. Raoul Weintzen is board-certified in pediatrics. Tr. 466:7 (Weintzen); *see also* Curriculum Vitae, Raoul L. Weintzen, Jr., M.D., ECF No. 57-2. Dr. Weintzen serves as Professor, Department of Pediatrics, Georgetown University School of Medicine, Washington, D.C. Curriculum Vitae, Raoul L. Weintzen, M.D.

> 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.

Id. at 17 (citing Pet'rs' Ex. 6, at 44-45). Also, the special master inferred that Dr. Fogg had spoken to the Whitneys to inform them that their son's transverse myelitis was caused by the HHV-6 virus. *Id.* at 17-19 (citing Pet'rs' Ex. 2, at 166, 234, & 264-66). The special master ultimately concluded that "when the record is considered as a whole, the Whitneys have not met their burden of proof for prong two." *Id.* at 21.

The Whitneys' motion for review, filed on June 8, 2015, has been fully briefed, and a hearing on the motion was held on July 22, 2015. *See* Hr'g Tr. on Pet'rs' Mot. to Review (July 22, 2015).[17] The case is now ready for disposition.

STANDARDS FOR REVIEW

Pursuant to the Vaccine Act, in reviewing a special master's decision, the court may take any one of the following three actions:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion[s] of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2).

In reviewing the special master's decision, determinations of law are reviewed *de novo*, *Andreu ex rel. Andreu v. Secretary of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278), and findings of fact are reviewed for clear error, *id.*; *see also Paluck v. Secretary of Health & Human Servs.*, 786 F.3d 1373, 1378 (Fed. Cir. 2015) ("[W]e review findings of fact under the arbitrary and capricious standard.") (citing *Griglock v. Secretary of Health & Human Servs.*, 687 F.3d 1371, 1374 (Fed. Cir. 2012)); *Broekelschen v. Secretary of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (same) (citing *Capizzano v. Secretary of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006)). Nevertheless, "a deferential standard of review 'is not a rubber stamp.'" *Paluck v. Secretary of Health & Human Servs.*, 113 Fed. Cl. 210, 224 (2013), *aff'd*, 786 F.3d 1373 (Fed. Cir. 2015)

[17]Further citations to the transcript of the hearing on the Whitneys' Motion to Review will be cited as "Hr'g Tr. __."

(quoting *Porter v. Secretary of Health & Human Servs.*, 663 F.3d 1242, 1255-56 (Fed. Cir. 2011) (O'Malley, J., concurring in part and dissenting in part)). The special master must "consider[] the relevant evidence of in the record as a whole, draw[] plausible inferences and articulate[] a rational basis for the decision." *Hines ex rel. Sevier v. Secretary of the Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); *see also* 42 U.S.C. § 300aa-13(b)(1) ("[T]he special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court."). And, while the special master need not address every individual piece of evidence presented in the case, *see Doe v. Secretary of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010), the special master may not dismiss contrary evidence to the extent that it appears that he "simply failed to consider genuinely the evidentiary record before him," *Campbell v. Secretary of Health & Human Servs.*, 97 Fed. Cl. 650, 668 (2011); *see also Hirmiz v. Secretary of Health & Human Servs.*, 119 Fed. Cl. 209, 216 (2014), *appeal pending*, No. 2015-5043 (Fed. Cir.).

ANALYSIS

Congress adopted the Vaccine Act to "establish a [f]ederal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3 (2d Sess. 1986), *reprinted in* 1986 U.S.C.C.A.N. 6334, 6334. A Vaccine Injury Table was originally established to provide an expeditious means of compensating children and others who suffer vaccine related injuries. *Loving ex rel. Loving v. Secretary of Dep't of Health & Human Servs.*, 86 Fed. Cl. 135, 141 (2009).[18] For "Table injuries," causation is conclusively presumed if a petitioner's vaccine and subsequent injury, or significantly aggravated condition, are listed on the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(i); *see also Hirmiz*, 119 Fed. Cl. at 216. For "off-Table injuries," *i.e.*, injuries or significantly aggravated conditions not found on the Vaccine Injury Table, the petitioner must prove causation in fact by preponderant evidence. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), -13(a)(1)(A); *see also Hirmiz*, 119 Fed. Cl. at 216.

Causation in fact is demonstrated by a petitioner who satisfies each of the three *Althen* factors by preponderant evidence. *Althen*, 418 F.3d at 1278 (quoted *supra*, at 9). The Federal Circuit has emphasized that "[a] persuasive medical theory is demonstrated by proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the logical sequence being supported by reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Id.* (citation and internal quotations omitted); *see also Paluck ex rel. Paluck v. Secretary of Health & Human Servs.*, 104 Fed. Cl. 457, 470 (2012) ("[A] reliable theory of causation must be shown to be applicable to the facts of the particular case at hand."). For each *Althen* prong, "[e]vidence . . . may overlap with and be used to satisfy another prong." *Hopkins ex rel. Hopkins v. Secretary of Dep't of Health &*

[18] First put in place via statutory enactment, 42 U.S.C. § 300aa-14(a), the Vaccine Injury Table has been periodically revised pursuant to notice-and-comment rulemaking under the statutory authority of 42 U.S.C. § 300aa-14(c). The current version of the Vaccine Injury Table, as amended, is set forth at 42 C.F.R. § 100.3.

Human Servs., 84 Fed. Cl. 517, 523 (2008). After a *prima facie* case of causation has been made by the petitioner, "the burden shifts to the government to prove by a preponderance of the evidence that the petitioner's injury is due to factors unrelated to the administration of the vaccine . . . ." *de Bazan v. Secretary of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citation and internal quotation omitted).

The Federal Circuit has repeatedly cautioned that preponderant proof of causation need not be shown with scientific certainty but rather by a demonstration that the vaccine more likely than not caused the injury. *See Althen*, 418 F.3d at 1280 ("[T]he purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."); *see also Moberly ex rel. Moberly v. Secretary of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) ("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.'") (quoting *Knudsen ex rel. Knudsen v. Secretary of Dep't of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994)); *Andreu*, 569 F.3d at 1378 ("Requiring 'epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act.'") (alteration in original) (quoting *Capizzano*, 440 F.3d at 1325-26).[19] Therefore, a finding of causation in fact in vaccine cases can be "based on epidemiological evidence and the clinical picture . . . without detailed medical and scientific exposition on the biological mechanisms." *Knudsen*, 35 F.3d at 549 (citing *Jay v. Secretary of the Dep't of Health & Human Servs.*, 998 F.2d 979, 984 (Fed. Cir. 1993)). Nonetheless, this standard for proving causation is not to be confused with a standard requiring only "possible" or "plausible" causation. *See Moberly*, 592 F.3d at 1322.

In proving causation, the special master is "entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324 (citing *Terran v. Secretary of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (in turn citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993))). In addition, the special master may consider medical literature or epidemiological evidence in reaching an informed judgment as to whether a particular vaccine inoculation caused a subsequent injury or significantly aggravated condition. *See LaLonde v. Secretary of Health & Human Servs.*, 746 F.3d 1334, 1339-40 (Fed. Cir. 2014).

Here, S.W.'s transverse myelitis is not listed on the Vaccine Injury Table. Therefore, the Whitneys must prove causation by preponderant evidence under the three-prong test set forth in *Althen*. To this day, it has not been established with scientific certainty whether a vaccine, virus, or other infectious agent caused S.W.'s transverse myelitis. *See supra*, at 7. Accordingly, indirect and circumstantial evidence of cause and effect is quite important to this case. And, while the present dispute concerns only the special master's application of the second prong of

[19]The requirement for preponderant evidence originates from the Vaccine Act itself: "Compensation shall be awarded . . . to a petitioner . . . [who] has demonstrated by a preponderance of the evidence the matters required in the petition by [42 U.S.C. § 300aa-11(c)(1)]." 42 U.S.C. § 300aa-13(a)(1); *see also Althen*, 418 F.3d at 1279 & n.6.

the *Althen* framework, the evidence related to the first and third prongs is pertinent to an analysis of the issues raised with regard to prong two.

I. *Althen*'s First Prong: A Theory Connecting Vaccine and Injury

With regard to *Althen*'s first prong, the special master assumed that the Whitneys had met their burden of proof because they had presented a plausible medical theory to explain how vaccinations can cause transverse myelitis. The special master's conclusion regarding prong one is adequately supported by both the facts and the record. Through expert testimony and medical literature, the Whitneys have demonstrated a biologically persuasive medical theory connecting S.W.'s vaccinations, particularly the DTaP vaccine, to transverse myelitis.

Dr. Shafrir explained that there are "different pathophysiologic mechanism[s] of how [transverse myelitis] occur[s]" and that "[w]e see an immune stimulation, other infection, or immunizations, and this creates an autoimmune reaction, which can be of different pathways." Tr. 16:10-16 (Shafrir).[20] To explain the potential immunological pathways by which vaccinations may induce autoimmunity and trigger the onset of transverse myelitis, Dr. Shafrir pointed to a scientific article that discussed "[t]he mechanisms by which vaccines may induce [transverse myelitis]." Pet'rs' Ex. 16, at Tab D (N. Agmon-Levin, S. Kivity, M. Szyper-Kravitz, & Y. Shoenfeld, *Transverse myelitis and vaccines: a multi-analysis*, 18 Lupus 1198-04 (2008) ("Agmon-Levin study")). The Agmon-Levin study outlined three pathways:

> The host's response to a vaccine, originally generated to produce protective immunity, is similar to its response to an infectious invasion. Therefore, it is reasonable to assume that as infectious agents can induce autoimmunity, so can the recombinant or live attenuated antigens used for vaccination. Several mechanisms by which an infectious antigen may induce autoimmunity have been defined.
>
> - *Molecular mimicry* between infectious antigens and self antigens is the most common mechanism.
> - *Epitope spreading*, whereby invading antigens accelerate an ongoing autoimmune process by local activation of antigen presenting cells and over processing of antigens is another mechanism.
> - Infectious agents, may induce autoimmunity via *polyclonal activation* of B lymphocytes *or bystander activation* which enhances cytokine production and further induce the expansion of auto reactive T-cells. The latter mechanism may be associated with post-infectious TM [transverse myelitis,] as IL-6 [inflammatory

[20] An autoimmune reaction is "characterized by a specific humoral or cell-mediated immune response against constituents of the body's own tissues (self antigens or autoantigens)." *Dorland's* at 183.

> marker] levels were found to be markedly elevated in the [cerebrospinal fluid] of TM patients.

Id. (emphasis in original); *see also* Tr. 23:21 to 24:16 (Shafrir).[21]

Building upon Dr. Shafrir's testimony, Dr. Oleske provided an immunological explanation as to how a vaccine can induce transverse myelitis. *See* Tr. 333:3 to 335:23 (Oleske) (testifying that vaccines can cause transverse myelitis through a cytokine response and stating that "[S.W.], unfortunately, was one of those rare individuals . . . [whose] . . . immunological response[] caused the transverse myelitis"). Dr. Oleske opined that "the multiple bacterial and viral antigens of childhood vaccines, most often with an adjuvant used to stimulate an immune and cytokine response, can be an extrinsic factor in adverse reactions to childhood immunizations such as the [t]ransverse [m]yelitis . . . experienced by S.W." Pet'rs' Ex. 20, at 1 (Supplemental Medical Expert Report of Dr. James Oleske (Jan. 7, 2014)). According to Dr. Oleske, his theory was consistent with the bystander activation theory outlined in the Agmon-Levin study. Tr. 337:4 (Oleske).

Notably also, several scientific publications identify the onset of transverse myelitis after vaccinations. In a case series from the Johns Hopkins University Hospital and Kennedy Krieger Institute, researchers collected clinical data from 47 patients between January 2000 and February 2004 who met the criteria for acute or remote transverse myelitis and were under the age of 18. Pet'rs' Ex. 16, at Tab G (F.S. Pidcock, C. Krishnan, T.O. Crawford, C.F. Salorio, M. Trovato, & D.A. Kerr, *Acute transverse myelitis in childhood: Center-based analysis of 47 cases*, 68 Neurology 1474-80 (May 1, 2007) ("Johns Hopkins Case Series").[22] In 28% of those cases (13 out of 47 children), the patient had received vaccinations or an allergy shot within 30 days of the first symptom of transverse myelitis. *Id.* at 1476. The immunizations that were administered included, *inter alia*, polio, hepatitis B, diphtheria-tetanus-pertussis, and *Haemophilus influenzae*. *Id.*; *see also* Pet'rs' Ex. 16, at 18 (Medical Expert Report of Yuval Shafrir, M.D. (Feb. 22, 2013)). In two cases, the patient had received a combination of three immunizations. Johns Hopkins Case Series at 1476. Antecedent immunizations and illness were documented in eight cases. *Id.* Because 28% of patients reported an immunization 30 days prior to the onset of symptoms, the authors addressed a "potential causal link" between vaccinations and transverse myelitis, commenting that "the large fraction of younger children affected, the current recommended vaccination schedule for children, and the lack of any single vaccine association within this group all undermine a potential cause link between vaccination and [acute transverse

[21]Dr. Wiznitzer, "who appears regularly for the [g]overnment in Vaccine Act cases," *Santini v. Secretary of Health & Human Servs.*, __ Fed. Cl. __, __, No. 06-725V, 2015 WL 4077254, at *6 (Fed. Cl. June 30, 2015), opined that molecular mimicry, epitope spreading, and bystander activation "have a basis in reality," Tr. 218:19-24 (Wiznitzer), "[w]hen it comes to an infection, [but] not to a vaccine," Tr. 237:14-18 (Wiznitzer).

[22]The eligible patients for the case series had been evaluated at the Johns Hopkins Transverse Myelitis Center ("JHTMC"). Johns Hopkins Case Series at 1475. The JHTMC is "dedicated to the diagnosis, clinical management and research of transverse myelitis." Johns Hopkins Medicine, The Transverse Myelitis Center, *available at* http://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/transverse_myelitis/.

myelitis.]". *Id.* at 1479. According to Dr. Shafrir, the authors' comment was "unfounded" because their data are "statistically significant." Pet'rs' Ex. 16, at 18; *see also* Tr. 42:25, 41:6-7 ("We're talking about a quarter of the series, which is a . . . very high number."). Dr. Shafrir testified that the researchers may have been "shocked by the number" and were concerned about the "hot potato" that is vaccine politics. Tr. 41:4-5, 43:1 (Shafrir). Other case studies have also documented transverse myelitis after vaccinations containing tetanus, diphtheria, and acellular or cellular pertussis. *See, e.g.*, Pet'rs' Ex. 16, at Tab J (RMS Riel-Romero, *Acute transverse myelitis in a 7-month-old boy after diphtheria-tetanus-pertussis immunization*, 44 Spinal Cord 688-91 (2006)), Tab K (Naser U.A.M.A. Abdul-Ghaffar & K.N. Achar, *Brown-Sequard Syndrome following Diphtheria and Tetanus Vaccines*, 74 Trop. Doct. 74-75 (1994)), & Tab M (E. Whittle & N.R. Robertson, *Transverse myelitis after diphtheria, tetanus, and polio immunization*, Br. Med. J. 1450 (June 4, 1977)).

Even though the foregoing case studies and the Johns Hopkins Case Series are not definitive "proof of causality," Tr. 54:18-19 (Shafrir); *see also* Tr. 168:6 to 168:22 (Wiznitzer), the John Hopkins Case Series and other case studies demonstrate an "association" between vaccines and the disorder. Pet'rs' Ex. 16, at 20. Given the detailed explanation of the mechanisms through which vaccines can cause transverse myelitis and the circumstantial evidence from the case reports, Dr. Shafrir concluded that S.W.'s immunizations were "by far the most likely cause for [S.W.'s] transverse myelitis." Tr. 34:3-4 (Shafrir); *see also* Pet'rs' Ex. 16, at 21 ("[I]t is much more likely than not that [S.W.]'s transverse myelitis was a result of an immune process triggered by the vaccination."). Dr. Oleske agreed. Tr. 337:23-24 (Oleske) (testifying that S.W.'s vaccinations "more likely than not caused his transverse myelitis").[23]

The persuasiveness of this conclusion is bolstered by the admission of the government's expert, Dr. Weintzen. When asked about the immune-mediated mechanisms delineated in the Agmon-Levin study, Dr. Weintzen answered that "*all three of these pathophysiologic approaches would apply equally to vaccine as to infection*." Tr. 570:2-4 (Weintzen) (emphasis added); *see also* Tr. 510:17-20 (Weintzen) ("[A]ssuming vaccines do cause [transverse myelitis] . . . I think there would be no reason to assume that the immune mechanisms would be different."). Although Dr. Weintzen ultimately believed that HHV-6 or another virus caused S.W.'s transverse myelitis, Tr. 502:21 to 503:12 (Weintzen), he acknowledged a "hypothetical, theoretical possibility that if you studied enough people, maybe you could find that, in fact, the immune response to a vaccine can do what infections can do," Tr. 572:11-14 (Weintzen).[24] In

[23]Given the rarity of the disorder in children (about one in a million), "the ability to perform a prospective epidemiological study, which ideally would follow all the patients who were immunized and see which of them will develop transverse myelitis, is practically impossible." Tr. 22:3-6 (Shafrir). "You [would] have to review . . . three [to] four million patients." Tr. 22:6-8 (Shafrir).

[24]Dr. Weintzen testified that a circumstance in which he would tell a family that a DTaP vaccine caused transverse myelitis was if "a neurosurgeon went in and biopsied the spinal cord and a pathologist found pertussis antigen, or tetanus toxoid, or diphtheria toxoid, adherent to components of his bone marrow." Tr. 585:6-19 (Weintzen). Although Dr. Weintzen in effect would have required a showing of causation equivalent to "scientific certainty," such a

this respect, Dr. Weintzen joined Drs. Shafrir and Oleske in disagreeing with Dr. Wiznitzer's opinion that infections but not vaccines could cause transverse myelitis. *See supra*, at 14 n.21.

Applying the pertinent evidentiary standard to the foregoing facts, the Whitneys have established a persuasive "medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278.

II. *Althen*'s Third Prong: A Proximate Temporal Relationship

For the third prong of *Althen*, the special master found that the latency period between the vaccinations and S.W.'s transverse myelitis was appropriate for the appearance of the disorder. Entitlement Decision at 11-12. The court concurs.

S.W. received the DTaP, Hep B, Hib, PCV, IPV, and rotavirus vaccinations on November 26, 2007, and seventeen days later, on December 13, 2007, he was hospitalized for neurological problems. *See supra*, at 3. All four experts who testified at the entitlement hearings agreed that S.W. had been experiencing symptoms of his transverse myelitis as early as seven to ten days before this initial hospitalization. Tr. 65:12-24 (Shafrir) (testifying that S.W.'s first symptom of transverse myelitis was most likely constipation, which reportedly began ten days before his admission to the hospital); Tr. 279:22 to 280:14 (Wiznitzer) (agreeing that S.W. had some symptoms of transverse myelitis seven to ten days before hospitalization); Tr. 362:1-3 (Oleske) ("[At] seven to [ten] days, . . . there were probably early symptoms of the onset of the transverse myelitis."); Tr. 576:10-11 (Weintzen) ("I think the vaccine would be about ten days before the onset of his constipation."). Experts for both parties also testified that the temporal relationship between the vaccinations and the manifestation of S.W.'s transverse myelitis was medically appropriate. *See, e.g.*, Tr. 33:1-7 (Shafrir) (testifying that the onset of S.W.'s transverse myelitis was at an appropriate time for causation); Tr. 576:2-6 (Weintzen) ("Both the vaccine and the respiratory infection at about Thanksgiving fall in perfect timing for what you would expect for an immune system event to have been begun by that antigenic stimulation, on either . . . side of the equation."); *see also* Entitlement Decision at 11-12. The medical literature provided by the Whitneys supports the testimony of the parties' experts. *See, e.g.*, Pet'rs' Ex. 16, at J (transverse myelitis documented in child who was given DTaP vaccine seventeen days before he was admitted to hospital, and child was suffering from constipation prior to admission).

In these circumstances, the Whitneys have established that S.W.'s transverse myelitis began within an appropriate time after the administration of his vaccinations. *See Althen*, 418 F.3d at 1278.

III. *Althen*'s Second Prong: A Logical Sequence of Cause and Effect

The Whitneys raise objections to the special master's conclusion that they failed to demonstrate a logical sequence of cause and effect between S.W.'s vaccinations and the

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heightened burden of proof in vaccine cases has been rejected by the courts. *See, e.g.*, *Moberly*, 592 F.3d at 1322.

transverse myelitis. *See* Pet'rs' Mem. at 15-39. Their objections can be grouped into three categories, namely (1) the support or lack of support for certain inferences drawn by the special master, (2) the identification of a vaccine cause, or not, by treating physicians, and (3) the implications of the treatment plan adopted for S.W. after the onset of transverse myelitis.

A. *Inferences*

As an initial matter, the Whitneys aver that the special master drew wholly impermissible inferences from the factual record to support his conclusion that they failed to meet their burden of proof for prong two. Pet'rs' Mem. at 15-18. At onset of symptoms in December 2007, the principal treating physician was Dr. Fogg, a pediatric infectious disease specialist. *See* Hr'g Tr. 6:23 to 7:3 (discussing Dr. Fogg's role as an infectious disease specialist); *see also* Hr'g Tr. 22:23 to 23:1 ("Dr. Fogg was the infectious disease specialist who was consulted to try to figure out what was leading to [S.W.'s condition] or whether there was an infectious disease."). The special master in his decision inferred that Dr. Fogg disclosed to the Whitneys that the HHV-6 virus was the causative agent of their son's transverse myelitis. Entitlement Decision at 18 ("Dr. Fogg, in fact, told the Whitneys that the HHV-6 virus caused their son's transverse myelitis orally."). No direct evidence supported the special master's factual conclusion.

Dr. Fogg initially listed as possible triggers viral, bacterial, post-vaccination, and autoimmune causes for S.W.'s condition. Pet'rs' Ex. 2, at 265. He ordered a polymerase chain reaction test to detect pathogens in S.W.'s plasma, *id*. at 265-66, and that test showed evidence of an HHV-6 infection, *id*. at 234. Thereafter, he wrote that "[the HHV-6 virus] or his immunizations could have been the trigger for his ADEM." *Id*. at 166. That circumstantial evidence does not support the special master's inference. *See* Hr'g Tr. 14:2-4 ("[T]here is no record where Dr. Fogg explicitly says the HHV-6 vaccine was the cause of S.W.'s transverse myelitis."). Other circumstantial evidence points to a contrary conclusion. In February 2008, two months after S.W.'s hospitalization, S.W. saw a urologist, Dr. Roelof, who took a history from Ms. Whitney. Dr. Roelof reported that Ms. Whitney "state[d] that they thought [S.W.] had acute viral myelitis secondary to a virus or perhaps from his vaccination. Pet'rs' Ex. 4, at 17. And, notably, the Whitneys steadfastly refused to allow S.W. to have further vaccinations, a situation that a rehabilitation specialist, Dr. Rush, found to be problematic because, as he put it, they were acting "in the misguided belief that immunizations were the cause of [S.W.'s] myelitis." *Id*. Ex. 5, at 328. The Whitneys' belief had some basis, and nothing in the record indicates that they were given medical advice to the contrary, from Dr. Fogg or any other treating physician at the hospital. *See* Hr'g Tr. 27:18-20 ("[A]t some point the parents reached their own conclusion that the vaccine was the cause.").

In short, the special master's inference about what Dr. Fogg might have told the Whitneys about causation is wholly unreasonable and lacks credible support in the medical records. *See Paluck*, 786 F.3d at 1384-85 (finding that it was arbitrary and capricious for the special master to make an inference that the treating physician had referred the petitioners to a neurologist simply because he was "frustrated" with the petitioners).

B. *Medical Records from S.W.'s Treating Physicians*

The Whitneys contend that the special master incorrectly weighed certain medical reports and statements from S.W.'s treating physicians. Pet'rs' Mem. at 17-26. Essentially, the Whitneys aver that the special master improperly discounted statements by treating physicians that pointed to vaccine causation.

1. *Medical reports from Dr. Fogg on December 14 & 17, 2007.*

Dr. Fogg identified S.W.'s immunizations as a potential cause of his condition. On December 14, 2007, one day after S.W. was admitted to the hospital, Dr. Fogg stated "that the patient had his 4-month immunizations on 11/26/07. . . . *Possible infectious triggers include* viral[,] . . . bacterial[,] . . . *post vaccination reaction*, or autoimmune disease . . . . *I will report the possible post immunization adverse event to [VAERS]*." Pet'rs' Ex. 2, at 264-66 (emphasis added). Three days later, Dr. Fogg stated that "*[the HHV-6 virus] or his immunizations* could have been the trigger . . . ." *Id.* Ex. 2, at 166 (emphasis added). The special master considered these medical records to be "weak pieces of evidence." Entitlement Decision at 16.[25] He concluded that "a treating doctor's inclusion of a vaccine as a possible cause [did] not materially support the petitioners' argument." *Id.*

The Whitneys contend that the special master had no reasonable justification in discounting the significance of Dr. Fogg's medical notes. Pet'rs' Mem. at 19-20. To support their argument, the Whitneys rely on the Federal Circuit's recent decision in *Paluck*, 786 F.3d 1373. In *Paluck*, the court of appeals held that petitioners "were entitled to rely on the statements from [their child's] physicians that his condition *could* be due to a 'toxic . . . event' as evidence supporting a causal nexus between [his] vaccinations and his subsequent neurological regression." 786 F.3d at 1385 (emphasis added). The government counters that the circumstances here are different from those in *Paluck* because the special master in this case did not disregard any probative medical statements. Resp't's Mem. at 7-8. The government argues that in this instance, the evidence was insubstantial because Dr. Fogg listed "post vaccination reaction" as a "possible" cause, not a probable or likely one. *Id.* at 8. The government therefore contends that the special master's application to this record evidence was "perfectly reasonable." *Id.*

The government's argument is not persuasive. Dr. Fogg was most directly responsible for diagnosing S.W.'s condition at onset and making recommendations for testing and for S.W.'s treatment immediately upon the child's admission to the hospital. *See* Pet'rs' Mem. Ex. 2, at 264-66; *see also* Hr'g Tr. 6:23 to 7:3. Dr. Fogg was in the "best position to determine whether a logical sequence of cause and effect show[ed] that the vaccination was the reason for the injury." *Andreu*, 569 F.3d at 1375 (citations and internal quotations omitted); *see also Moberly*, 592 F.3d

[25]The special master's treatment of these medical records is inconsistent. While classifying the evidence as "weak," he also relied on the same records as "foundational points" for drawing the inference that Dr. Fogg informed the Whitneys that the HHV-6 virus caused their son's transverse myelitis. *See supra*, at 17.

at 1323.[26] While Dr. Fogg initially used the word "possible" when describing vaccine causation, he coupled his initial diagnosis with the annotation that he would report this possibility to VAERS. Pet'rs' Mem. Ex. 2, at 265-6. The willingness of an infectious disease specialist to file a VAERS report at the onset of a child's symptoms is relevant evidence of causation. The special master erred by neglecting to consider this probative piece of evidence. *Cf. Dobrydnev v. Secretary of Health & Human Servs.*, 566 Fed. Appx. 976, 984 (Fed. Cir. 2014), *reh'g denied*, (Aug. 20, 2014), *cert. denied*, 135 S. Ct. 1560 (2015) (finding that the special master was not required to give weight to a VAERS report filed 30 months after a vaccination when the pediatrician who filed the report "[was] not an expert in [the] field," and had "explicitly defer[red] to the expert whose opinion ha[d] been rejected").[27]

2. *Medical report from Dr. Rush on February 22, 2008.*

In a report from February 22, 2008, two months after the onset of S.W.'s condition, Dr. Rush recommended that S.W. receive additional vaccinations. Dr. Rush indicated that he did "not have any reason to believe . . . [that] immunizations were the cause of [S.W.'s] myelitis . . . nor d[id] [he] believe literature would [bear] that out." Pet'rs' Mem. Ex. 5, at 328. The special master described this statement as "remarkably strong and direct" evidence and stated that Dr. Rush's "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.]." Entitlement Decision at 17. The special master further noted that the Whitneys had not challenged Dr. Rush's qualifications to opine about causation and concluded that Dr. Rush was "an unbiased and qualified doctor" since he "discounted the vaccinations as a cause for myelitis without referring to the HHV-6 virus." *Id.* at 17-18.

The Whitneys challenge the special master's assessment of Dr. Rush's commentary for two main reasons. Pet'rs' Mem. at 18 n.25. First, the Whitneys suggest that Dr. Rush was not

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[26]In addition to Dr. Fogg, S.W. was seen during his hospitalization by at least one neurologist. A neurologist made a handwritten sequacious annotation: "HHV-6 associated myelitis." Pet'rs' Ex. 2, at 182. The special master considered that this note by a neurologist was "ambiguous as to whether the doctor was stating that the virus caused the myelitis or the virus simply preceded the myelitis." Entitlement Decision at 17 n.17. However, he considered the doctor's later comment, "HHV[-]6 myelitis," to be an indication of "a causal (as opposed to simply temporal) relationship." *Id.*; *see also* Pet'rs' Ex. 2, at 182, 186.

[27]Relatedly, the Whitneys dispute the special master's conclusion that they failed to "identif[y] *even one* medical record in which a treating doctor expressed the opinion that a vaccination caused the transverse myelitis." Entitlement Decision at 18-19 (emphasis added). The special master's determination is captious and untenable with respect to the evidence in the record as a whole. *See* 42 U.S.C. § 300aa-13(a)(1). Certainly Dr. Fogg's consideration that S.W.'s vaccinations may have been a cause of his transverse myelitis and his decision to report the adverse event to VAERS counts as "one medical record" expressing an opinion in support of vaccine causation. *See* Pet'rs' Ex. 2, at 166, 264-66; *see also* Pet'rs' Mem. at 30 (citing a total of six medical records from S.W.'s treating physicians that support a nexus between S.W.'s vaccinations and subsequent transverse myelitis).

qualified to render an opinion on causation. Dr. Rush is a medical doctor who specializes in rehabilitation, *see supra*, at 6 n.11. He neither examined S.W. upon his admission to the hospital nor was he involved in diagnosing S.W.'s condition or determining his initial treatment. Rather, as a physiatrist, his services were aimed at the amelioration of symptoms and complications of the disorder. *See* Pet'rs' Ex. 5, at 325-29. His remarks about vaccine causation are far less credible than the annotations made by Dr. Fogg, the infectious disease specialist who initially treated S.W., or the opinions of the neurologists who testified as experts at the Entitlement Hearing. That said, the Whitneys' expert neurologist, Dr. Shafrir, described Dr. Rush's report as "extensive and thoughtful." *Id.* Ex. 16, at 11. In addition, Dr. Rush correctly reasoned that S.W. met the criteria for transverse myelitis, not ADEM. *Id.* Ex. 5, at 328 ("Please note that I do not technically agree with the diagnosis of ADEM."). Second, the Whitneys suggest that Dr. Rush's assessment was flawed due to his pro-vaccination point of view. Pet'rs' Mem. at 18 n.25. As shown in the medical report, Dr. Rush regretted his failure to address the issue of vaccination when he met with S.W.'s parents because it was "*incredibly important* that like any other child, [S.W.] get his immunizations." Pet'rs' Ex. 5, at 328 (emphasis added). Dr. Rush's notes are relevant evidence to be considered as part of the record as a whole, evaluated in light of his medical background and focus and his evident emphasis on vaccinations notwithstanding contraindications. *See* 42 U.S.C. § 300aa-13(a)(1).

3. *Medical reports signed by Dr. DeRoos on February 17, 2008 and Dr. Rush on July 14, 2010.*

A report was prepared by a nurse practitioner, Ms. Shelanskey, on February 17, 2008, about two months after S.W.'s admission to the hospital. Pet'rs' Ex. 6, at 44. The report addressed S.W.'s past history, discussed exam findings, and provided an assessment. *Id.* The report noted that an infectious disease specialist, not named, had identified the HHV-6 virus as the cause of S.W.'s condition. *Id.* ("Infectious Disease was able to identify the HHV-6 virus as the causative agent."). A neurologist, Dr. DeRoos, signed the report indicating that he agreed with the nurse practitioner's assessment. *Id.* The special master acknowledged that there was "a degree of hearsay" in this statement; there was no record evidence that an infectious disease specialist had established that a virus triggered S.W.'s transverse myelitis. Entitlement Decision at 17. Regarding this report, Dr. Shafrir testified that "obviously[] the statement . . . is incorrect [because Dr. Fogg] said either the vaccination or the HHV-6 [virus was the causative agent], after the diagnosis of HHV-6 was known already." Tr. 122:11-13 (Shafrir); *see also* Tr. 163:14-17 (Wiznitzer) ("Yes, they did [consider the vaccines as a potential cause]. It was in the initial notes that were there, that was a question that was raised."); Tr. 329:6-11 (Oleske) (testifying that Dr. Fogg never identified the sole cause of S.W.'s disorder and that the medical workup "would not have allowed [the doctors] to come up with a sole cause."). The special master entirely overlooked expert testimony on this point. Instead, he found that the post-hospitalization Shelanskey-DeRoos report had "some value as evidence that the treating doctors did not consider the vaccine to be causative." Entitlement Decision at 17-18.[28]

[28]The special master improperly applied the same circumstantial evidence to credit this record as he did to infer that Dr. Fogg had spoken with the Whitneys to inform them that the

A report drafted by an occupational therapist, Ms. Gora, on July 14, 2010 evaluated S.W.'s mobility, seating, and ability of transfer, and it included the therapist's recommendation that S.W. begin using a particular type of wheelchair. Pet'rs' Ex. 5, at 380-83. Important to this dispute, the first page of the document listed S.W.'s diagnosis as a "Reaction to an Immunization," and the last page was signed by Dr. Rush, who "concur[red]" with the occupational therapist's recommendation. *Id.* Ex. 5, at 380, 383. Although Dr. Rush signed this report that identified S.W.'s condition as vaccine-induced, the special master did not afford this piece of evidence any importance because it came over two years after Dr. Rush's rehabilitative assessment in February 2008, and it was "very unlikely that Dr. Rush changed his assessment of the cause of [S.W.'s] transverse myelitis." Entitlement Decision at 7 n.11; *see also id*. at 15. To support this conclusion, the special master relied on the Whitneys' own expert, Dr. Shafrir, who "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." Entitlement Decision at 15 (citing Tr. 126 to 128 (Shafrir)). Indeed, Dr. Shafrir testified that he did not "think that we should look at [this document] as a determination of a diagnosis" because its purpose was to "get the child a wheelchair." Tr. at 127:12-15 (Shafrir). Similarly, the government's expert, Dr. Wiznitzer, testified that he suspected that Dr. Rush "[did]n't even look at the first page [of the report]," but simply signed the document because S.W. needed the wheelchair "irrespective of what the diagnosis [wa]s." Tr. 164:21 to 165:9 (Wiznitzer).

The Whitneys fault the special master for crediting the post-hospitalization Shelanskey-DeRoos report while "wholly discount[ing]" the later Gora-Rush report. Pet'rs' Mem. at 21-26. The Whitneys argue that "if the special master purports to use expert testimony to discount medical records helpful to petitioners, he should do so for all records in question." *Id.* at 26. And, indeed, the special master credited the Shelanskey-DeRoos report despite the "level of hearsay" within the report, which hearsay was contraindicated by other portions of the medical record, while relying on expert testimony to discredit the Gora-Rush report that supported the Whitneys' theory of vaccine causation. Entitlement Decision at 15-17. The Whitneys claim that "[i]t is clear that the special master desired a certain result, and misconstrued the evidence in order to reach that result." Pet'rs' Mem. at 26. There are indicia that the special master did what the Whitneys claim, but the dispute over the special master's treatment of the Shelanskey-DeRoos and the Gora-Rush reports focuses on records generated in both instances after diagnosis and testing, and this in a sense constitutes an argument over evidence secondary to the treating physicians' contemporaneous notes.

C. *S.W.'s Treatment Plan*

The medical records reveal that S.W. was initially treated with high-dose steroids, not anti-viral drugs. Pet'rs' Ex. 2, at 264 & 266. The Whitneys argue that S.W.'s treatment course of steroids is salient evidence that "[S.W.] was experiencing an inflammatory, immune-mediated process." Pet'rs' Mem. at 26-28. They contend that the special master abused his discretion by failing to consider this treatment plan as evidence in support of vaccine causation. *Id.*

HHV-6 virus triggered S.W.'s condition. *See supra*, at 17; *see also* Entitlement Decision at 17-18.

Contrary to the Whitneys' contention, the special master did consider S.W.'s treatment plan, acknowledging that there was a dispute among the testifying experts "whether [S.W.'s] doctors responded appropriately to the [HHV-6] positive PCR test." Entitlement Decision at 5 n.6. He concluded that "this issue is extraneous to determining whether the vaccines caused [S.W.]'s transverse myelitis," reasoning that, as Dr. Weintzen testified, steroid therapy is a proper treatment for either an immune-mediated reaction to vaccines or an immune-mediated reaction to a prior infection with the HHV-6 virus. *Id.*; *see* Tr. 501:10 to 502:20 (Weintzen) (discussing steroid treatment to prevent nerve tissue damage in the spinal cord by minimizing an immune response); *see also* Resp't's Mem. at 13-14. When S.W. was admitted to the hospital, he was in the "convalescent phase" of the HHV-6 infection. *See* Tr. 499:25, 501:19 to 502:12 (Weintzen) (indicating that the HHV-6 infection was convalescing based on the number of copies of viral DNA found in S.W.'s plasma). In essence, there were viral particles in S.W.'s blood, but his immune system had responded to the infection. Tr. 494:15-24, 593:24 to 594:2 (Weintzen) ("[S.W.] was in the recovery stage of his HHV-6 [infection] clearly."); *see also* Hr'g Tr. 31:12-14 ("[H]is immune system had kicked in and was starting to fight off the virus.").[29] Dr. Weintzen testified that he would not have ordered anti-viral drugs at that point in time because S.W.'s "immune system [had] already responded" to clear the virus. Tr. 578:4-12 (Weintzen). However, a powerful anti-inflammatory medication, such as steroid therapy, would suppress an immune-mediated reaction and prevent injury to S.W.'s spinal cord, regardless of the trigger.

The Whitneys disregard Dr. Weintzen's testimony and rely on the testimony of Dr. Wiznitzer, who opined "that if [S.W.] had a *direct viral myelitis* with HHV-6, [he] would worsen before he got better if he did not receive the anti[-]viral medication." Pet'rs' Mem. at 27 (emphasis added) (citing Tr. 281:23 to 282:1 (Wiznitzer)). The Whitneys further rely on the testimony of Dr. Oleske, who testified that treatment of high-dose steroids is an "indication that the treating physicians and specialists that were seeing [S.W.] certainly didn't consider this an active HHV-6 infection, otherwise they would have treated him with anti[-]viral drugs and been cautious with high-dose steroids." Tr. 325:14-21 (Oleske). As discussed above, the steroid treatment only proves that S.W.'s doctors thought he was having an immune-mediated reaction. It "says nothing about what triggered it." Resp't's Mem. at 16; *see also* Hr'g Tr. 18:2-7 (conceding that it was "correct" that the steroid treatment was ambiguous as to cause).

As a result, the testimony about treatment is not particularly helpful either to prove or disprove a vaccine cause. Among other things, the HHV-6 virus did not directly invade S.W.'s spinal cord, thereby causing inflammation. Entitlement Decision at 12-13 ("[L]ittle evidence supports a direct invasion theory"); *see also* Tr. 501:23 to 502:1 (Weintzen) ([I]t's not active . . . virus growing in the spinal cord, it's the immune response that somehow as an innocent bystander hurt[s] an organ of the body, in this case the spinal cord."). Rather, as discussed

[29]In the case of HHV-6, "before the immune response [is triggered]," the virus initially has an "unrestricted capability of growing." Tr. 500:7-9 (Weintzen). The convalescent phase refers to the later stage of the infection when the "immune response [has] mature[d] more," thus inhibiting viral replication "so that . . . over time the concentration of virus in blood drops." Tr. 500:13-18 (Weintzen).

supra, either a post-vaccination event or the HHV-6 virus led to S.W.'s transverse myelitis by triggering autoimmunity. *See* Entitlement Decision at 13; *see also* Agmon-Levin study (outlining three pathways that induce autoimmunity). Accordingly, "it was reasonable for the [s]pecial [m]aster to conclude that he could not draw any inferences about causation from [S.W.]'s treatment." Resp't's Mem. at 14.

IV. Synopsis

With regard to prongs 1 and 3 of the *Althen* framework, the special master properly weighed the evidence of record and made determinations in accord with law. Petitioners prevailed on those prongs. When analyzing the second prong of *Althen*, however, the special master made findings and conclusions that were contrary to the evidence of record and thus were arbitrary, capricious, and an abuse of discretion. The special master drew the unsupported and impermissible inference that Dr. Fogg informed the Whitneys that only the HHV-6 virus, and not the vaccinations, triggered their son's transverse myelitis. The special master also committed error when he discounted the diagnostic medical reports by Dr. Fogg and stated that the Whitneys had not produced even one medical record to support a nexus between S.W.'s transverse myelitis and the administration of the vaccines. Finally, the special master acted arbitrarily and capriciously by overly crediting the post-hospitalization Shelanskey-DeRoos report that contained hearsay not otherwise supported by the medical records, while discrediting the Gora-Rush report. The special master nonetheless was on a solid footing in determining that evidence regarding S.W.'s steroid therapy was not particularly helpful on the issue of causation.

CONCLUSION

For the reasons stated, the Whitneys' motion for review is GRANTED, the special master's decision of May 8, 2015 denying compensation is VACATED, and the case is REMANDED to the special master for further proceedings. The court sets aside the findings of the special master as to prong 2 of *Althen*, but makes no affirmative findings of its own.

In this instance, the respective burdens of proof and persuasion to be borne by the parties may become critical to the outcome. There is the distinct possibility that the Whitneys have, or will establish on remand, a *prima facie* case of causation under the Vaccine Act. The government can overcome the *prima facie* case by showing by preponderant evidence that S.W.'s condition "is due to factors unrelated to the administration of the vaccine." *Deribeaux ex rel. Deribeaux v. Secretary of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013); *see also de Bazan*, 539 F.3d at 1352. It therefore may be incumbent upon the special master explicitly to consider whether the Whitneys have made a *prima facie* showing, and, if so, then whether the government can by a preponderance of the evidence demonstrate that S.W.'s transverse myelitis was caused by the HHV-6 infection, a factor unrelated to vaccination. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A)-(B).

This may well be a case in which it is appropriate to obtain testimony from Dr. Fogg and other physicians who treated S.W. upon hospitalization, to gain a better understanding of the

most relevant medical records.[30] Correlatively, one or both of S.W.'s parents might testify as to what, if anything, Dr. Fogg told them at the time of his diagnosis.

It is so ORDERED.

s/ Charles F. Lettow
Charles F. Lettow
Judge

[30]The Federal Circuit has commented that

> [i]n most instances, however, it is both inadvisable and unnecessary to subpoena the testimony of treating physicians. It would not be in the public interest for the specter of a subpoena to provide physicians with a disincentive to treat a vaccine-injured patient or to cause them to be less than forthright in creating medical records assessing the relationship between a vaccine and a patient's injury. The submitted documentary evidence can, under most circumstances, provide adequate insight into the medical opinions of treating physicians, and there is little need to subject them to cross-examination in federal court.

Andreu, 569 F.3d at 1383 (citing *Cucuras v. Secretary of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993)). This appears to be the exceptional case. The special master apparently considered that possibility in asking the parties "whether information[, *i.e.*, testimony,] should be sought from [S.W.'s] treating doctors." Entitlement Decision at 18 n.18.