In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 24, 2020

For Publication

ROBERT NIZIOL *on behalf of* S.N., *a minor child*,	*	No. 15-1446V
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Measles, Mumps, Rubella ("MMR") Vaccine; Hepatitis A ("HAV") Vaccine; Influenza ("flu") Vaccine; Prevnar 13 Vaccine; Herpes Simplex Virus ("HSV") Encephalitis
Respondent.	*	

Diana L. Stadelnikas, Maglio Christopher and Toale, PA, Sarasota, FL, for Petitioner.
Voris E. Johnson, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

On December 1, 2015, Robert Niziol ("Petitioner") filed a petition for compensation on behalf of S.N., a minor child, pursuant to the National Vaccine Injury Compensation Program ("Program" or "Act"). Pet. at 1, ECF No. 1; 42 U.S.C. § 300aa-10 to -34 (2012). Petitioner alleges that the measles, mumps, rubella ("MMR") vaccine S.N. received on November 29, 2012, and the Hepatitis A virus ("HAV"), influenza ("flu"), and Prevnar 13 vaccines S.N. received on December 12, 2012, caused her to develop encephalitis. Pet. at 1.[2]

After carefully analyzing and weighing all the evidence and testimony presented in this case in accordance with the applicable legal standards, I find that Petitioner has not met his legal burden. Petitioner has failed to provide preponderant evidence that the MMR vaccine S.N.

[1] This decision shall be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, I find that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] Although the petition alleges that S.N. received the HAV, flu, and Prevnar 13 vaccines on December 12, 2012, the medical records reveal that S.N. received these vaccinations on December 6, 2012. *See* Pet'r's Ex. 1; Pet'r's Ex. 6 at 40.

received on November 29, 2012, or the HAV, flu, and Prevnar 13 vaccines she received on December 6, 2012, caused her to develop encephalitis. Accordingly, Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed his petition on December 1, 2015. Pet. at 1. Over the next four months, Petitioner filed twelve exhibits in support of his petition, consisting of medical records and an affidavit. *See* Pet'r's Exs. 1–12, ECF Nos. 11-1–11-8, 12–13. The parties filed a joint statement of completion on April 26, 2016. *See* ECF No. 15.

Respondent filed his Rule 4(c) report on June 24, 2016, in which he recommended that compensation be denied. Resp't's Report at 1, ECF No 16. Petitioner was ordered to file an expert report and supporting medical literature by September 30, 2016. Non-PDF Order, docketed July 11, 2016. Over the next seven months, Petitioner filed three motions for extensions of time, which were granted, extending this deadline until January 30, 2017. ECF Nos. 20–22; Non-PDF Orders, docketed Sept. 30, 2016, Dec. 2, 2016, Feb. 1, 2017. On March 1, 2017 and March 3, 2017, Petitioner filed expert reports authored by Vera Byers, M.D., Ph.D., and Marcel Kinsbourne, M.D., along with eighteen pieces of supporting medical literature. Pet'r's Exs. 13–34, ECF Nos. 24-2–24-10, 25-2, 26-2–26-6, 27-2–27-8. On May 24, 2017, Respondent filed an expert report authored by Michael Silverman, M.D., Ph.D., and five pieces of supporting medical literature. Resp't's Ex. A, ECF No. 30-1; Resp't's Ex. A, Tabs 1–5, ECF Nos. 30-2–30-6.

On June 20, 2017, an entitlement hearing was scheduled for June 18–19, 2018, ECF No. 32. This case was reassigned to me on July 3, 2017. ECF No. 34. On July 6, 2017, I issued an order cancelling the June 2018 entitlement hearing. ECF No. 35. Per the parties' request, I rescheduled the entitlement hearing for September 12–13, 2018. ECF No. 38.

On September 7, 2017, Petitioner filed a second expert report authored by Dr. Byers and two pieces of supporting medical literature. Pet'r's Exs. 35–37, ECF Nos. 43-2, 44-2–44-3. Respondent filed a supplemental expert report authored by Dr. Silverman and four pieces of supporting medical literature on October 10, 2017. Resp't's Ex. C, ECF No. 46-1; Resp't's Ex. C, Tabs 1–4, ECF Nos. 46-2–46-5.

On August 9, 2018, Petitioner filed a status report indicating that Drs. Byers and Kinsbourne were unavailable for the September 12–13, 2018 entitlement hearing. ECF No. 52. I held a status conference with the parties on August 13, 2018, and rescheduled the entitlement hearing for November 15–16, 2018. ECF No. 54.

I held an entitlement hearing with the parties on November 15, 2018. *See* Min. Entry, docketed Nov. 19, 2018. The parties filed post hearing briefs on March 4, 2019, April 16, 2019, and April 30, 2019. *See* Pet'r's Post-Hr'g Br., ECF No. 65; Resp't's Responsive Post-Hr'g Br., ECF No. 66; Pet'r's Reply Post-Hr'g Br., ECF No. 67. Neither party has filed any additional evidence. *See* docket. This matter is now ripe for consideration.

II. Factual Background

A. Medical Records

S.N. was born on May 25, 2011, at Columbia University Medical Center. Pet'r's Ex. 2 at 23. Her AGPAR[3] scores were nine and nine at one and five minutes, respectively. *Id.* On May 26, 2011, S.N. was assessed as "[s]table, doing well, [and] tolerating [by mouth] feeds." *Id.* S.N.'s mother "was counseled on [the Hepatitis B] vaccine but refuse[d] to [have it] administered [to S.N.] at [that] time." *Id.*

S.N.'s primary care physician ("PCP"), Robert Jawetz, M.D., assessed S.N. as having "routine" development at her one-, three-, six-, nine-, and twelve-month well-baby visits. Pet'r's Ex. 6 at 48, 53, 55, 59, 63. S.N. presented to Dr. Jawetz for her eighteen-month well-baby visit on November 29, 2012, which he again assessed as "routine." *Id.* at 42. Dr. Jawetz noted that S.N. was able to speak approximately "[ten] words, point[] to pictures, [and] point[] to body parts." *Id.* He also wrote that S.N. was able to "run[], throw[] objects, walk[] upstairs with help[,] . . . [and construct a three-four] cube tower." *Id.* S.N. received the MMR vaccine at issue at this visit. *Id.* at 43. On December 6, 2012, S.N. returned to Dr. Jawetz's office for an immunization visit, during which she received the HAV, flu, and Prevnar 13 vaccines. *Id.* Petitioner did not report any concerns during this visit. *See id.*

On December 16, 2012, S.N. was transported to the emergency department at The Valley Hospital because of "seizure activity." Pet'r's Ex. 12 at 836. S.N.'s mother reported to emergency responders that S.N. "was ill, febrile, and 'was not herself' yesterday." *Id.* S.N.'s mother also reported that S.N. "had not been eating or drinking well starting yesterday[,]" and she had "vomit[ted] overnight." *Id.* At approximately 4:00 AM that morning, S.N. "woke up . . . and was 'talking' to [her] mom when she started to have some unusual body movements." *Id.* Emergency responders noted that S.N. was "hot to [the] touch" and was "displaying jerking/twitching muscle movements on [the] left side of [her] body . . . ." *Id.* at 837. Emergency responders administered two 1 milligram doses of Ativan[4] to stop the seizure activity, but S.N. continued to seize upon arrival at the emergency department. *See id.* At the emergency room, doctors administered IV Ativan, which stopped S.N.'s seizure activity. *Id.* at 947. The medical records state that S.N.'s seizure activity "lasted at least [one-half-]hour and probably longer." Pet'r's Ex. 3 at 2.

[3] An APGAR score is "a numerical expression of the condition of a newborn infant . . . being the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, reflex irritability, and color." *Dorland's Illustrated Medical Dictionary* 1682 (32nd ed. 2012) [hereinafter *Dorland's*].

[4] Ativan is the "trademark for preparations of lorazepam." *Dorland's* at 173. Lorazepam is "a benzodiazepine with anxiolytic and sedative effects . . . used . . . intravenously to control status epilepticus . . . ." *Id.* at 1074. A benzodiazepine is "any of a group of compounds having a common molecule structure and acting similarly as depressants of the central nervous system, their actions including . . . anticonvulsant . . .effects." *Id.* at 209.

Upon admission to the hospital, S.N. had a consultation with Peter Heilbroner, M.D. Pet'r's Ex. 12 at 947. Dr. Heilbroner noted that S.N.'s temperature was one-hundred-and-one degrees, and that she was "somewhat lethargic but easily arouse[d]." *Id.* He wrote that S.N. was "not vocalizing at an age-appropriate level." *Id.* He noted that a head computed tomography ("CT")[5] test was negative, and S.N.'s "white blood cell count [was] elevated at 25,000." *Id.* A lumbar puncture ("LP")[6] revealed "somewhat bloody" cerebral spinal fluid ("CSF")[7] with 5,000 red blood cells compared to eighty white blood cells, which Dr. Heilbroner wrote was "a somewhat elevated white to red [blood cell count] ratio[]." *Id.* Dr. Heilbroner's impression was that S.N. had "an acute infection" with "prolonged associated seizure activity." *Id.* He raised "[t]he possibility of encephalitis" but noted that "this event also could have been either a febrile seizure or a fever induced seizure." *Id.* at 948. He admitted S.N. to the pediatric intensive care unit ("PICU") and ordered "herpes [polymerase chain reaction ("PCR")] test[8] and titers for [Epstein-Barr virus],[9] West Nile[10] and [cytomegalovirus ("CMV")][,][11]" and prescribed "ceftriaxone[,][12] . . . acyclovir[13] to cover possible herpes encephalitis[,][14] . . . and Keppra[15] prophylactically." *Id.* All initial tests returned negative. *See id.* at 961.

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[5] A computed tomography test is a "tomography in which the emergent x-ray beam is measured by a scintillation counter; the electronic impulses are recorded digitally and then are processed by a computer for reconstruction display." *Dorland's* at 1935. It is also known as a CT scan. *Id.* Tomography is "the recording of internal body images by means of the tomograph . . .." *Id.* A tomograph is "an apparatus for moving an x-ray source in one direction as the film is moved in the opposite direction, thus showing in detail a predetermined plane of tissue while blurring or eliminating detail in other planes." *Id.*

[6] A lumbar puncture is "the withdrawal of fluid from the subarachnoid space in the lumbar region, usually between the third and fourth lumbar vertebrae, for diagnostic or therapeutic purposes." *Dorland's* at 1556.

[7] Cerebrospinal fluid is "[t]he fluid that flows in and around the hollow spaces of the brain and spinal cord, and between two of the meninges (the thin layers of tissue that cover and protect the brain and spinal cord)." Cerebrospinal Fluid, National Dictionary of Cancer Terms, National Cancer Institute (last visited Apr. 22, 2020), retrieved from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cerebrospinal-fluid.

[8] A polymerase chain reaction test is "a type of rapid nucleic acid amplification of specific DNA or RNA sequences, allowing small quantities of short sequences to be analyzed without cloning . . . ." *Dorland's* at 1601. This test "is used in the diagnosis of infectious diseases through identification of microbial pathogens in clinical material . . . ." *Stedman's Medical Dictionary* 1647 (28th ed. 2006).

[9] The Epstein-Barr virus is "a virus of the genus *Lymphocryptovirus* that causes infectious mononucleosis and is associated with Burkitt lymphoma and nasopharyngeal carcinoma." *Dorland's* at 2061.

[10] The West Nile virus is "a virus of the genus *Flavivirus* . . . [that] causes West Nile encephalitis and is transmitted by *Culex* mosquitos, with wild birds serving as a reservoir. It occurs . . . sometimes in the eastern, southern, and midwestern United States." *Dorland's* at 2065.

[11] Cytomegalovirus refers to "any virus of the subfamily Betaherpesvirinae, highly host-specific herpesviruses that infect humans, monkeys, or rodents, with the production of unique large cells bearing intranuclear inclusions." *Dorland's* at 466.

[12] Ceftriaxone sodium is "a semisynthetic, β-lactamase-resistant, broad-spectrum, third-generation cephalosporin effective against a wide range of gram-positive and gram-negative bacteria; administered intravenously or intramuscularly." *Dorland's* at 312.

[13] Acyclovir is "a synthetic acyclic purine nucleoside with selective antiviral activity against herpes simplex virus[,] . . . administered orally or topically.´ *Dorland's* at 24. Acyclovir sodium is "the monosodium salt of acyclovir, used intravenously in the treatment of herpes simplex . . . in immunocompromised patients . . . ." *Id.*

On December 18, 2012, Yaron Harel, M.D., drafted an addendum to S.N.'s medical record after he "discussed with [another PICU physician S.N.'s] mom's question regarding the possibility of MMR immunization [two] weeks prior to current illness causing viral encephalitis . . .." *Id.* at 962. Dr. Harel wrote that "[i]n order for attenuated viruses (in MMR) to be able to cause viral encephalitis, a T cell immune deficiency must exist." *Id.* Dr. Harel therefore ordered a T cell study and repeat testing of S.N.'s CSF. *Id.* These tests were conducted on December 19, 2012, and revealed the following T cell and B cell deficiencies: CD3, CD4, CD8, and CD16+CD56. *Id.* at 1122–23.

S.N. also underwent a brain magnetic resonance imaging ("MRI") with and without contrast on December 18, 2012. *Id.* at 937. The impression was that "[t]he constellation of findings, while not entirely specific, is consistent with encephalitis (most likely herpetic) in this clinical context." *Id.* at 937. On December 19, 2012, S.N. underwent repeat testing with the Mayo Clinic, which detected herpes simplex virus I DNA in her CSF. *Id.* at 1118.

Over the next four days, S.N. remained afebrile and showed steady neurologic improvement while continuing Keppra and IV Acyclovir. *Id.* at 981. However, beginning on December 24, 2012, S.N. "was less arousable and . . . vomited several times." *Id.* Drs. Harel and Heilbroner ordered a CT scan of S.N.'s head, which revealed a "[r]ather large acute right cerebral parenchymal hematoma,[16] particularly involving the medial temporal lobe, with moderate edema[17] and considerable mass effect." *Id.* Dr. Harel started S.N. on IV Mannitol[18] and ordered an emergency right hemicraniectomy,[19] which was successful. *Id.* A repeat head CT conducted post-surgery showed a "[l]arge right cerebral parenchymal hematoma with extensive right hemispheric edema resulting in persistent mass effect effacing the right lateral ventricle and displacing the temporal lobe medially. There has been expansion of the right cerebral hemisphere through the craniotomy defect." *Id.* S.N. was transferred back to the PICU for further care. *Id.*

Over the next eight days, S.N. made a steady "clinical and radiographic improvement . . ., though she ha[d] residual [right] sided hemi-paresis." *Id.* at 1080. S.N.'s final brain MRI, conducted on December 30, 2012, showed "improvement of edema and hemorrhage . . . ." S.N.

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[14] Herpes encephalitis is "the most common form of acute encephalitis, caused by a herpesvirus and characterized by hemorrhagic necrosis of parts of the temporal and frontal lobes. Onset is over several days and involves fever, headache, seizures, and often coma, frequently ending in death." *Dorland's* at 612.

[15] Keppra is the "trademark for a preparation of levetiracetam." *Dorland's* at 978. Levetiracetam is "an anticonvulsant administered orally as an adjunct in the treatment of partial and myoclonic seizures and idiopathic generalized epilepsy." *Id.* at 1031.

[16] A parenchymatous hematoma is "a mass of blood within the brain tissue itself, usually from an artery or vein within the brain." *Dorland's* at 832.

[17] Edema is "the presence of abnormally large amounts of fluid in the intracellular tissue spaces of the body, usually referring to subcutaneous tissues." *Dorland's* at 593.

[18] Mannitol is "an osmotic diuretic used . . . to reduce cerebral edema or elevated intracranial or intraocular pressure." *Dorland's* at 1104.

[19] A hemicraniectomy is the "exposure of half the brain by sectioning the vault of the skull from front to back near the median line and forcing the entire side outward." *Dorland's* at 835.

"remain[ed] seizure free on Keppra," and her "mental status essentially [returned to] . . . baseline." *Id.* Repeat T cell and B cell testing conducted on January 2, 2013, showed low levels of CD3, CD4, CD8, CD9, and CD16+CD56. *Id.* at 1122. On January 3, 2013, S.N. was transferred to Blythedale Children's hospital for inpatient rehabilitation. *Id.* at 1081.

While undergoing inpatient rehabilitation, a repeat LP performed on January 3, 2013, was negative for herpes simplex I DNA, and S.N. completed her course of IV Acyclovir on January 6, 2013. Pet'r's Ex. 10 at 5. By discharge on January 11, 2013, S.N. was able to "[t]olerate[] standing on stander, [and] walk[ing] for 100 feet with one hand-held assistance." *Id.* at 52. She had also regained "more spontaneous movement in her left side" and "more spontaneous speech." *Id.* She was discharged home with a plan to "continue [physical therapy ("PT")], [occupational therapy ("OT"),] and [speech therapy ("ST")] in [an] outpatient setting . . .." *Id.*

On January 23, 2013, S.N. suffered a leakage from her cranial wound and presented to neurosurgeon Richard Anderson, M.D. Pet'r's Ex. 5 at 17. On examination, Dr. Anderson found that S.N. had "wound leakage and a subgaleal collection that when tapped indicated infection." *Id.* Therefore, Dr. Anderson decided to "perform an exploratory cranial wound debridement[20] and revision[,]" which was successful. *Id.* Cultures taken during the operation revealed "Serratia,"[21] and Dr. Anderson prescribed IV meropenem[22] and discharged S.N. home. *Id.* at 13.

S.N. had another follow-up with Dr. Anderson on February 5, 2013. *Id.* Since the surgery on January 23, 2013, S.N. had not experienced "wound healing issues such as further leakage or persistent fevers" nor "had any signs or symptoms of elevated intracranial pressure such as persistent vomiting, progressive lethargy, or eye movement abnormalities." *Id.* Additionally, S.N.'s "left hemiparesis . . . [was] dramatically improving." *Id.* at 14. Dr. Anderson wanted S.N.'s parents to "see Dr. Foca [for a] follow[-]up after the antibiotics are stopped in order to get clearance for replacement of [S.N.'s] autologous bone flap which[,] . . . [was] in the freezer at Valley Hospital." *Id.* S.N. underwent a successful replacement of her autologous bone flap on February 27, 2013. *Id.* at 15.

On April 23, 2016, S.N. presented to a pediatric neurologist, Jennifer Cope, M.D., for a follow-up. Pet'r's Ex. 3 at 43. Dr. Cope wrote that S.N. was "home with her family and thriving." *Id.* S.N. was "energetic and underst[ood] everything said to her. She [was] speaking in [one] or [two] word phrases and [could] follow directions." *Id.* While she was "slight clumsy with" her left hand, S.N. "use[d] her left arm for everything." *Id.* Dr. Cope wrote that S.N. was still "receiv[ing] OT, but was discharged from PT." *Id.* Dr. Cope also noted that S.N. was still

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[20] A debridement is "the removal of foreign material and devitalized or contaminated tissue from or adjacent to a traumatic or infected lesion until surrounding healthy tissue is exposed." *Dorland's* at 473.

[21] Serratia is a "a genus of gram-negative, facultatively anerobic bacteria of the family Enterobacteriaceae, consisting of motile, peritrichously flagellated rods, sometimes capsulated . . . . Many species are opportunistic pathogens, causing infections of the endocardium, blood, wounds, and urinary and respiratory tracts in immunocompromised patients." *Dorland's* at 1699.

[22] Meropenem is "a broad-spectrum antibiotic of the carbapenem group, similar to the imipenem in structure and activity and used in the treatment of intra-abdominal infections and bacterial meningitis." *Dorland's* at 1137.

"taking Keppra 200 mg twice a day, and [had] had no clinical seizures since her initial presentation." *Id.* Dr. Cope also ordered an EEG, which was normal. *Id.* at 42.

S.N. had her two-year well-child visit with Dr. Jawetz on July 1, 2013. Pet'r's Ex. 6 at 30. Dr. Jawetz noted that while S.N. spoke approximately "[thirty] words," she did not speak in phrases and therefore was receiving ST. *Id.* Dr. Jawetz also wrote that S.N. was still receiving "OT for weakness of her left hand." *Id.* Upon examination, Dr. Jawetz noted that there was "resorption of [seventy-five percent] of [S.N.'s] right hemicranium." *Id.* He assessed the visit as "routine," and planned to follow-up with S.N. in six months. *Id.* at 31.

On July 18, 2013, S.N. presented for an initial visit with Edward Smith, M.D., a neurosurgeon at Boston Children's Hospital, because, "over the past couple of months[,] [S.N.'s mother] ha[d] noticed what feels to be resorption of the bone where there are increasing areas of soft spots by palpation and perhaps a little bit of fluid under the skin." Pet'r's Ex. 9 at 502. Dr. Smith's examination revealed "some mild drift, weakness on the left arm and particularly in the left hand with a little bit of grasping weakness[,]" and while S.N. "[ran] around the office[,] she appear[ed] to favor the left leg a little bit . . . ." *Id.* Dr. Smith noted that S.N. had "a little bit of bogginess to the right scalp region" and "multiple areas of what appear to be soft and palpable defects in the bone" on S.N.'s "trauma flap." *Id.* Dr. Smith ordered "a CAT scan to see the true extent of any bony decompression or problems in order to more effectively assess what is going on." *Id.* The CAT scan revealed a "[l]arge surgical defect in the right parietal bone[, which] is likely the result of the prior craniectomy to relieve swelling[,]" and an "[e]ncephalomalacia in the right temporal lobe consistent with an old infarction." *Id.* at 495.

S.N. attended her two-and-a-half-year well-child visit with Dr. Jawetz on December 4, 2013. Pet'r's Ex. 6 at 28. Dr. Jawetz assessed the visit as "routine." *Id.* He noted that S.N. was still receiving OT and ST. *Id.* On examination, Dr. Jawetz found a "large[,] fist[-]sized defect in right temporal bone[,]" and planned for S.N. to "[follow-up with] neurosurgery and neurology . . . to reconstruct [her] skull and for long term control of [herpes simplex virus]." *Id.* at 29.

On December 9, 2013, S.N. presented to John Meara, M.D., D.M.D., a plastic surgeon at Boston Children's Hospital, "to discuss possible reconstruction" of her "right temporal bone." Pet'r's Ex. 9 at 487. Dr. Meara "reviewed [S.N.'s previous] . . . CT scan and [noted that] there is a very large area which is unossified with several bone islands in . . . the right temporal parietal region." *Id.* On examination, Dr. Meara found that S.N.'s "right temporoparietal region is soft to palpation." *Id.* Dr. Meara indicated a desire to discuss S.N.'s case with Dr. Smith before determining on how to proceed. *Id.*

S.N. underwent an exchange cranioplasty with Drs. Meara and Smith on April 29, 2014. *Id.* at 461. Drs. Meara and Smith "recommended [this procedure] in order to place solid cortical bone in the defect and to utilize particulate bone for the donor site where there is good dura and periosteum. *Id.* The were no complications during the procedure, *see id.*, and S.N. was discharged home on May 3, 2014, *id.* at 57.

S.N. presented to Dr. Jawetz for her three-year well-child visit on May 28, 2014. Pet'r's Ex. 6 at 24. Dr. Jawetz expressed uncertainty regarding whether S.N. "[could] balance on one

foot[,]" and wrote that S.N. "never [rides her] tricycle." *Id.* He noted that S.N. could "[draw[] a circle and a cross, [but does not] use scissors . . .." *Id.* Dr. Jawetz indicated that S.N. was still receiving PT and OT but that, because her "[l]anguage skills are much improved, [she] no longer requires ST," despite her skills being "perhaps mildly delayed." *Id.*

S.N. had a follow-up visit with Dr. Meara on August 4, 2014. Pet'r's Ex. 9 at 7. Dr. Meara wrote that S.N.'s "incision line is healing well. There [was] no fluid collection[]." *Id.* On examination, Dr. Meara found that "all of the areas [of S.N.'s scalp] [felt] firm and [Dr. Meara] [did] not feel a large soft spot." *Id.* Dr. Meara felt S.N. was "healing quite well[,]" and he planned to follow-up in six months. *Id.* S.N. presented for another follow-up with Dr. Meara on March 2, 2015. *Id.* at 2. Dr. Meara wrote that S.N.'s "overall head shape [was] quite good[,]" and she had "firm bone in the left and right parietal regions." *Id.* Dr. Meara did find "a small [one centimeter] soft spot on the right in the occipital parietal region and one also on the right in the postauricular mastoid region." *Id.* However, he wrote that he was "very pleased with the initial healing of both the donor site and the recipient site." *Id.* He planned to follow-up with S.N. in one year. *Id.*

On July 8, 2015, S.N. presented to Dr. Jawetz for her four-year physical. Pet'r's Ex. 6 at 11. Dr. Jawetz wrote that S.N. had been discharged from PT, but was still receiving ST because her language skills, while improved, were "still a few months behind."[23] *Id.* S.N.'s had normal physical, hearing, and vision tests at this visit. *Id.*

S.N.'s last relevant medical records are from a visit with Dr. Jawetz on September 25, 2015, to obtain medical clearance for a dental procedure. *Id.* at 9. S.N. had a normal neurological exam, with Dr. Jawetz noting that she had "normal strength, tone and reflexes." *Id.* at 10. S.N. also had normal physical, hearing, and vision tests at this visit. *Id.* at 9.

B. Fact Testimony

During the entitlement hearing, Anna Niziol, S.N.'s mother, testified as to her recollection of what happened to S.N. pre- and post-MMR vaccination. Ms. Niziol testified that S.N. "was a relatively healthy, normally developing child prior to" receiving the MMR vaccine on November 29, 2012. Tr. 12:4–5. Ms. Niziol stated that S.N. was "up-to-date with all well visits and . . . vaccinations." Tr. 12:10–11. However, Ms. Niziol explained that "one thing that [she] always care[d] about [was that S.N.] . . . [did] not get a massive amount of vaccinations [at] one [time]." Tr. 12:16–18. Therefore, while she consented to S.N. receiving the MMR vaccine on November 29, 2012, Ms. Niziol "[did not] feel comfortable [with S.N. receiving additional vaccinations, so she] split [the vaccinations] between two visits." Tr. 13:8–9.

Ms. Niziol explained that after the MMR vaccination at issue, her mother "took care of S.N." Tr. 13:22–23. Ms. Niziol testified that she and her family were "originally from Poland," and her mother "would travel back and forth for many, many years to be with [Ms. Niziol's] children and to help [Ms. Niziol] out." Tr. 14:5–7. Ms. Niziol stated that S.N. received the

[23] The record is not clear as to when S.N. ended ST because, on a few occasions, her treater indicated that she may not require continued ST. Despite these notations, it appears S.N. continued to receive ST until at least July of 2015. *Compare* Pet'r's Ex. 6 at 24 *with* Pet'r's Ex. 6 at 11.

MMR vaccination "pretty much a week before [her mother] was leaving" to return to Poland. Tr. 14:7–8. After S.N. received the MMR vaccination, Ms. Niziol explained that her mother noticed "that S.N. was becoming a little more clingy towards her and [S.N.] wanted to be carried more[,]" which Ms. Niziol's mother "kind of associated with [S.N.] . . . probably . . . [sensing] that" she was about to return to Poland. Tr. 14:12–15. In addition, Ms. Niziol stated that her mother "noticed . . . that [S.N. had] . . . moments of staring. But at that time, [Ms. Niziol and her mother] didn't pay too much attention to it because" Ms. Niziol also experiences staring spells. Tr. 14:16–20. Ms. Niziol estimated that these behaviors began on approximately December 10, 2012. Tr. 15:11–12.

Ms. Niziol testified that, the day after her mother returned to Poland, she "went shopping and S.N. had . . . episodes of throwing up." Tr. 16:15–16. Ms. Niziol stated that these vomiting episodes "concerned[her] because they were not typical . . . infections like [with]. . . a stomach flu." Tr. 16:17–18. Rather, Ms. Niziol explained that S.N. would experience "episodes of being energetic and then a minute later, start throwing up and being very lethargic . . .." Tr. 16:19–21. Later that evening, Ms. Niziol testified that S.N. "developed [a] fever . . . [and] was basically . . . almost not responsive . . . [because] she was really, really sick." Tr. 17:1–4.

Ms. Niziol explained that at approximately 1:00 AM the next morning, S.N. "was lying on [Mr. Niziol,] and she was like twitching." Tr. 17:23–24. Ms. Niziol "woke up and [S.N.] had . . . open eyes, but she had absolutely no reaction and . . . was twitching with one side of her body." Tr. 18:1–3. Ms. Niziol stated that she "called the ambulance and they came and tried to give her medication to stop the seizures, . . . but they were not successful . . . until [S.N. arrived at] the [emergency room]." Tr. 18:6–10. At the emergency room, Ms. Niziol explained that doctors "intubated [S.N.] and tried to stop the seizures" by giving S.N. "a massive amount of medications . . .." Tr. 18:18–19; Tr. 19:7.

Once S.N. was "settled," Ms. Niziol testified that doctors "transferred [S.N.] to the [PICU]." Tr. 19:12–14. In the PICU, Ms. Niziol stated that the original treatment plan was that S.N. would "get the anti-viral medications for [twenty-one] days." Tr. 22:20. Ms. Niziol explained that she and her husband would "stay in the hospital with S.N." during the treatment because the medication needed to be administered in the hospital due to S.N.'s age. Tr. 22:22–23:1. However, Ms. Niziol recalled that, during S.N.'s treatment, she noticed "that [S.N.'s] condition was actually deteriorating instead of improving . . . ." Tr. 23:2–5. Ms. Niziol stated that she mentioned this to doctors, but was told "that with herpes encephalitis, it's not like with another typical sickness. Sometimes [there isn't] this straight-up recovery; there are good and there are bad days." Tr. 23:6–10. Ms. Niziol continued, "[the doctors] did not think that there was anything additionally that was going on with S.N." Tr. 23:10–11.

Ms. Niziol explained that S.N.'s "condition deteriorated" beginning "the night before Christmas Eve," and S.N. "started throwing up, very similarly . . . [to what occurred before] she was admitted to the hospital." Tr. 23:17–19. At that point, Ms. Niziol stated that doctors "did a CT scan and . . . found out[] that [S.N.] ha[d] a pretty extensive hemorrhaging in her brain and in terms of swelling of [her] brain." Tr. 23:22–25. Ms. Niziol explained that doctors then "contacted Dr. Anderson . . . to come and basically do an emergency surgery for S.N. . . . [Dr.

Anderson had to] remove [S.N.'s] skull or half of her skull [to] basically . . . let the swelling -- the swelling go and just open up." Tr. 24:1–7.

Ms. Niziol further explained that, after the surgery, "S.N. was discharged . . . [on] January 3rd[] and . . . was transferred to the inpatient rehabilitation center . . . ." Tr. 25:1–3. Upon arrival, S.N. was "not walking . . . [or] talking . . . ." Tr. 25:11. Ms. Niziol stated that S.N. was discharged home after approximately a week in the rehabilitation center. Tr. 25:23–25.

Ms. Niziol noted, however, that on the day of discharge, S.N. "developed a fever[,]" which Ms. Niziol remembered to be "definitely around [one-hundred-and-one]." Tr. 16:4–5, 15. Ms. Niziol explained that she took S.N. "to the emergency room[,]" and doctors "checked [S.N.] into the hospital." Tr. 26:23–24. Ms. Niziol stated that doctors "thought that [S.N.] had maybe developed another viral infection . . ., and they let us go home." Tr. 26:25–27:2. Ms. Niziol explained that, because S.N.'s fever persisted for several days, doctors "check[ed S.N.'s] [c-reactive protein ("CRP") test,][24] . . . which was extremely, extremely elevated[,]" an indication that "there [was] some infection . . . in her body." Tr. 27:11–21. Ms. Niziol stated that doctors admitted S.N. to the hospital and "tested her for [clostridium difficile ("C. Diff."),]"[25] which returned positive on a repeat test. Tr. 27:25–28:10. Therefore, Ms. Niziol stated that doctors "treat[ed S.N.] for C. diff," although S.N.'s "fever came back and . . . [was] also pretty high." Tr. 29:3–6.

Ms. Niziol explained that, at this point, she "[saw] that, in the wound on the top of [S.N.'s] head, there was some liquid . . . leaking from it." Tr. 29:9–10. Ms. Niziol stated that the leaking became so voluminous that her husband's "shirt, everything, was basically wet from the leakage of the fluid." Tr. 29:22–23. She testified that doctors then performed an operation to clean S.N.'s wound and to "check what kind of bacteria got into her head." Tr. 29:24–30:2. After this surgery, Ms. Niziol stated that doctors prescribed S.N. another twenty-one day course of antibiotics. Tr. 30:7–11.

Ms. Niziol testified that, in February of 2013, S.N. had surgery to replace the bone flap on her skull, which Dr. Anderson removed in December of 2012. Tr. 31:7–8. However, Ms. Niziol noted that, "by August, . . . [ninety-five] percent of the bone [doctors] had [replaced had] completely [reabsorbed]." Tr. 31:13–16. Ms. Niziol described S.N.'s development at this time as "definitely delayed[,]" and noted that S.N. "struggled . . . with the left side of her body." Tr. 31:17–32:7. Ms. Niziol explained that S.N. "had weakness with the [left] hand. She had weakness with the [left] leg. And . . . S.N. . . . actually developed a little bit of depression . . . ."

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[24] A c-reactive protein test "measures the level of c-reactive protein ("CRP") in [the] blood. CRP is a protein made by [the] liver. It[is] sent into [the] bloodstream in response to inflammation." C-Reactive Protein (CRP) Test, Medline Plus (last visited Mar. 24, 2020), https://medlineplus.gov/lab-tests/c-reactive-protein-crp-test/.

[25] Clostridium difficile is "a species [of bacteria] that is part of the normal colon flora in infants and some adults; it produces a toxin that can cause pseudomembranous enterocolitis in patients receiving antibiotic therapy." *Dorland's* at 374. Pseudomembranous enterocolitis is "an acute type [of inflammation involving both the small intestine and the colon] with formation of pseudomembranous plaques that overlie superficial ulcerations and pass out in the feces; it may result from . . . aftereffects of antibiotic therapy." *Id.* at 625.

Tr. 32:9–14. Ms. Niziol also stated that S.N.'s "speech was significantly delayed for a two-year-old child." Tr. 32:23–24.

At the time of the hearing, Ms. Niziol explained that while S.N. had recovered somewhat, "there's two probably upcoming surgeries [S.N.] is going to have." Tr. 34:3–4. She explained that the first "is to fill the missing soft spots [on S.N.'s skull,] because even though the surgery was pretty successful with covering [her skull], there's still some soft spots [on S.N.'s] head . . . ." Tr. 34:4–6. She explained that the second surgery was needed, because "the part [on S.N.'s head] that was cut multiple times [during her prior surgeries was] just not healing." Tr. 34:14–15. Therefore, S.N. needed a procedure where doctors "have to put the balloons under her skin and basically expand her skin to graft that skin over." Tr. 34:21–23. Ms. Niziol explained that, due to the difficult recovery, S.N. "needs to be mature enough to make this decision, otherwise, she won't be able emotionally to go through this process . . . ." Tr. 34:23–25. Ms. Niziol stated that S.N. still "definitely has a weakness on the left side in terms of the hand." Tr. 35:6–7. Ms. Niziol described S.N. as "very much behind her peers" in terms of development and schooling. Tr. 35:8–9; Tr. 36:1–2.

Ms. Niziol testified that doctors did not "indicate to [her] what the cause of [S.N.'s] encephalitis was . . . ." Tr. 21:14–16. Ms. Niziol stated that, "because of the . . . [timing], . . . [she] asked [doctors] . . . if there was any possibility that MMR or any vaccinations that [S.N.] received two weeks prior could cause this[,] and nobody wanted to really discuss [that] . . . ." Tr. 21:19–24. Ms. Niziol also denied that any doctor had diagnosed S.N. with sepsis or septic shock. Tr. 24:15–22.

On cross-examination Ms. Niziol stated that, when she asked about the vaccinations, she "specifically was concerned about MMR[,] . . . because [the] MMR vaccination itself always caused a lot of concerns for [her] . . . ." Tr. 38:19–39:1. She explained that "[she] did not give [her other children] the combination of MMR; [she] gave them the separate – all three vaccinations separate, not as one dose." Tr. 39:1–4.

Under my questioning, Ms. Niziol explained that she gave S.N. the full MMR dose, because she "had no option." Tr. 41:15–22. Ms. Niziol stated that she "called Merck and . . . asked them if there was any way [she could] buy [the individual vaccines] . . . ." Tr. 41:23–24. Merck replied that "they do not offer that[,]" because "there is absolutely no proof that [the combined MMR vaccine] cause[s] anything." Tr. 42:1–5. Ms. Niziol explained that she allowed S.N. to receive the combined vaccine, because her "other children didn't have these issues[.]" Tr. 44:10–13.

III. Experts

A. Expert backgrounds

1. Petitioner's Expert, Marcel Kinsbourne, M.D.

Dr. Kinsbourne submitted one expert report and testified at the entitlement hearing. Pet'r's Ex. 23; Tr. 129–87. Dr. Kinsbourne received his medical degree from Oxford University

in 1963, and holds medical licenses in North Carolina, Massachusetts, and Virginia. Pet'r's Ex. 24 at 1–2. He has been board-certified in pediatrics since 1968. *Id.* at 2. He has held numerous academic positions throughout his career, including professorships in psychology, neurology, and pediatrics. *Id.* at 2–3. While he no longer practices in a clinical setting, Dr. Kinsbourne's clinical experience includes serving as a senior staff physician at the Hospital for Sick Children in Toronto, Ontario, and as a clinical associate in neurology at Massachusetts General Hospital in Boston, Massachusetts. *Id.* His curriculum vitae lists over four-hundred and twenty-five articles of which he is a credited author, as well as nine books. *Id.* at 7–39. He currently serves on numerous editorial boards and is a member of various professional societies. *Id.* at 4–6.

At Petitioner's request, and without objection from Respondent, I entered Dr. Kinsbourne as an expert in pediatric neurology. Tr. 132:1–6.

2. Petitioner's Expert, Vera Byers, M.D., Ph.D.

Dr. Byers submitted two expert reports and testified at the entitlement hearing. Pet'r's Exs. 13, 35; Tr. 45–128. Dr. Byers received her Ph.D. in immunology from the University of California at Los Angeles in 1969 and her medical degree from the University of California at San Francisco in 1981. Pet'r's Ex. 14 at 5. She completed her residency at the University of California at San Francisco in 1984 and became board-certified in internal medicine the same year. *Id.*

Over the course of her career, Dr. Byers has held numerous academic and research positions, including serving as an adjunct professor of immunodermatology at the University of California at San Francisco from 1976–2008. *See id.* at 1–5. She also has clinical experience, including seeing "patients with a wide range of autoimmune disease[s] and treat[ing] them with biologics." Pet'r's Ex. 13 at 2. She currently serves as the President of Immunology, Inc., where her responsibilities include "[d]esign[ing] Phase I, II, [and] III clinical trials in autoimmune disease[s] and cancer[s]," and "present[ing] data at national and international scientific meetings and grand rounds." Pet'r's Ex. 14 at 1–2. Dr. Byers also has "[o]ver [three hundred] articles and abstracts published in peer[-]reviewed medical journals . . . ." *Id.* at 1. She currently "serves on the editorial board[s] of two leading cancer journals (Cancer Immunology and Immunotherapy), and [on National Institute of Health] review panels in tumor immunology." *Id.* She has "worked in the Vaccine Court for many years," and testified in the Vaccine Program "many times [over] the past [fifteen] years." *Id.*; Tr. 48:19–21.

On cross-examination, Dr. Byers clarified her training and experience regarding continuing education and legal practice. She testified that her clinical practice is in the context of litigation, but that she also publishes based on "consultation with an epidemiologist who has access to . . . all of the hospital medical records in California." Tr. 82:3–7. Dr. Byers also testified that she attends immunology meetings, known as FOCIS, to complete her continuing education. These meetings "look at the immunologic consequences of different kinds of autoimmune diseases and immunodeficiencies." Tr. 84:1–2. Dr. Byers was unable to completely identify FOCIS but stated that they cover all topics; "what they're trying to do is look all aspects of immunology. . . in cancer and allergy, immunology and hepatology or whatever . . . [in] one place." Tr. 84:18–23.

At Petitioner's request, and without objection from Respondent, Dr. Byers testified as an expert in clinical immunology. Tr. 48:22–49:2.

3. Respondent's Expert, Michael Silverman, M.D., Ph.D.

Dr. Silverman submitted two expert reports and testified at the hearing. Resp't's Exs. A, C; Tr. 187–224. Dr. Silverman received his medical and doctoral degrees in immunology from the University of Pennsylvania School of Medicine in 2007. Resp't's Ex. B at 1, ECF No. 30-7. He became board-certified in pediatrics in 2012 and in pediatric infectious diseases in 2013. *Id.* at 2. He is currently licensed to practice medicine in Pennsylvania. *Id.*

Dr. Silverman held the position of instructor of pediatrics at Harvard Medical School from 2013–16 and currently serves as assistant professor of pediatrics at the University of Pennsylvania School of Medicine. *Id.* at 1. His clinical experiences include serving as the attending infectious disease physician at numerous hospitals, including Boston Children's Hospital and the Dana Farber Cancer Institute. *Id.* He currently serves as "an attending physician in pediatric infectious diseases" at the University of Pennsylvania School of Medicine. Tr. 188:4–6. His responsibilities include "a combination of research and clinical work." Tr. 188:15–16. As part of his clinical responsibilities, Dr. Silverman "do[es] inpatient consultations for the immunocompromised population at the Children's Hospital of Philadelphia." Tr. 188:18–20. His research responsibilities include "run[ning] a laboratory that studies how commensal microbes affect the development of the immune system," and "autoimmune diseases and also infections." Tr. 189:3–5, 8.

At Respondent's request, and without objection from Petitioner, Dr. Silverman testified as an expert in immunology and pediatric infectious diseases. Tr. 190:8–11.

B. Expert Reports and Testimony

1. Dr. Kinsbourne

In his expert report and testimony, Dr. Kinsbourne began with an explanation of HSV and HSV-1 encephalitis. Dr. Kinsbourne wrote that "[h]erpes virus encephalitis is caused by HSV, an enveloped, double-stranded DNA virus." Pet'r's Ex. 23 at 4. He explained that there are two types of HSV: HSV-1 and HSV-2, which "are both members of the larger human herpes virus (HHV) family." *Id.* Dr. Kinsbourne further explained that HSV-1, the "unanimous" diagnosis of S.N.'s treating physicians, "is a neurotrophic virus that infects mucosal or abraded skin surfaces in non[-]immune individuals." *Id.* at 3–4. He testified that "it can break out as blisters around the lips, and uncommonly, it does cause encephalitis of the brain." Tr. 133:19–20. Dr. Kinsbourne wrote that "[t]he virus replicates and destroys cells at the portal of entry[;]" it "infects nerve endings and is transported by retroaxonal flow to the nucleus of autonomic nervous system neurons in which it establishes a latent infection." Pet'r's Ex. 23 at 4. Dr. Kinsbourne testified that "about a third of the population has a latent herpes infection." Tr. 133:17–18. Dr. Kinsbourne explained that "HSV-1[,] rather than HSV-2[,] is responsible for

virtually all cases [of HSV encephalitis] in persons older than three months." Pet'r's Ex. 23 at 4. He noted that "HSV encephalitis is rare at two cases per million." *Id.*

For most people with latent HSV, Dr. Kinsbourne explained that "the herpes will be present in the ganglion but will be contained and cause no trouble by dint of the immune system." Tr. 138:2–4. Dr. Kinsbourne detailed the body's mechanisms to keep the disease inactive. "So[,] if the innate immune system has not succeeded in blocking off the infection immediately, then – and if the adaptive immune system using CD4 T cells hasn't stopped – blocked it from getting into the trigeminal ganglion, then the immune system holds the virus so it doesn't cause any trouble." Tr. 138:4–10. However, "when the immune system, and particularly the CD8 cells fall short, then reactivation occurs and then the disease appears in much the same way as it would have appeared had it been primary." Tr. 138:11–15. Even in people with active HSV, "the intensity of the exposure on the one hand and the ability of the immune system to hold it in check and usually the exposure is not so intense as to lead all the way to encephalitis." Tr.141:18–21.

Dr. Kinsbourne wrote that "[t]he intense immunosuppressive effect of measles infections is widely documented." Pet'r's Ex. 23 at 4. He relied on a paper by Manicken and Rouse for the proposition that "immunocompromised individuals develop viral encephalitis due to an inability to limit the spread of virus." *Id.* (citing Pet'r's Ex. 27).[26] He continued that, "[n]umerous studies have demonstrated that both cellular and humoral arms of the immune system contribute to the recovery from infection; however, T cells are ultimately required to protect the host." *Id.* Dr. Kinsbourne noted that S.N.'s T cell levels of both her innate and adaptive immune systems were "severely depressed." *Id.* at 5. Therefore, Dr. Kinsbourne concluded that S.N.'s "T cells . . . fell short of protecting her from the proliferation and spread of the [HSV] type 1." *Id.*

He explained that this "resulted in the striking inhibition of cellular immunity that was demonstrated in [S.N.'s] CSF and therefore her brain." *Id.* at 5. Dr. Kinsbourne wrote that "[i]n S.N.'s case, the infection was primary; there was no serological evidence of preexisting HSV infection." *Id.* at 3. Dr. Kinsbourne testified that prior to vaccination, nothing in S.N.'s history "indicate[d] a particular vulnerability." Tr. 147:19–20. During his testimony, he reiterated that "[t]here was no previous trace of any disorder that would lead to a [HSV] infection[,] and that there was no precursor that [he] could identify." Tr. 164:21–24. Dr. Kinsbourne wrote that "the MMR vaccination that [S.N.] received [sixteen] days before her encephalitis began induced a temporary immunosuppression." *Id.* Dr. Kinsbourne continued, "[t]he inhibition of cellular immunity lifted the control of T cells over the [HSV], which was able to proliferate and disseminate and thereby cause [S.N.'s] encephalitis, and secondarily, [S.N.'s] cerebral hemorrhage." *Id.* Dr. Kinsbourne maintained his position that S.N.'s infection was primary but testified that it would not change his analysis if the infection had been latent. Tr. 165:8–10.

Dr. Kinsbourne was asked if S.N. suffered from sepsis and he testified that there was no evidence of that in her medical record. He explained that sepsis "is a systemic event . . . almost always only seen in bacterial infection." Tr. 165:16–21. He noted that S.N.'s "disorder was

[26] Elanchezhiy Manickan & Barry T. Rouse, *Roles of Different T-Cell Subsets in Control of Herpes Simplex Virus Infection Determined by Using T-Cell-Deficient Mouse Models*, 69(12) J. OF VIROLOGY 8178 (1995).

limited to the brain," Tr. 166:5, and that he had "never heard or encountered an HSV-1 encephalitis causing general systemic damage," Tr. 166:16–17.

Lastly, on direct examination, Dr. Kinsbourne agreed that a two-week interval is the appropriate time frame for an immunosuppressive event that led to the development of S.N.'s encephalitis. Tr. 167:16–22. He concluded that "[i]t [was his] opinion[,] to a reasonable degree of medical probability[,] that [S.N.'s] MMR vaccination significantly contributed to the causation of her viral encephalitis." *Id.*

On cross examination, Dr. Kinsbourne agreed that a child can develop HSV-1 encephalitis even if that child has a normally-functioning immune system. Tr. 173:11–14.

2. Dr. Byers

Dr. Byers wrote in her first report that "it [was her] opinion, to a reasonable degree of medical certainty[,] that but for the vaccinations [S.N] received between November 29, 2012 and December 16, 2012, [S.N.] would not have suffered the viral meningitis and subsequent neurologic disease." Pet'r's Ex. 13 at 5. She "base[d her] opinion upon the biologic plausibility, the temporal association[,] and the absence of confounding factors." *Id.* Dr. Byers explained that "it is difficult to blame a single vaccine" for S.N. developing HSV encephalitis, because S.N. "was vaccinated with [eighteen] separate antigens[]" during the vaccinations at issue, including "[t]hree in the MMR [vaccine], thirteen in the pneumococcal [vaccine], one in the hepatitis [vaccine,] and one in the [flu vaccine.]" *Id.* at 4. She clarified during her testimony that "the MMR vaccine . . . concentrating on the measles component, -- immunosuppressed [S.N.] so that she -- so that it allowed the HSV to grow and flourish." Tr. 50:3–6.

Dr. Byers wrote that the "MMR vaccine is live attenuated viruses." Pet'r's Ex. 13 at 5. She explained further that in the wild, the measles virus "affects the pulmonary macrophages, monocytes, et cetera." Tr. 52:3–4. Dr. Byers continued, "all members of the lymphoid system" are affected, "especially the T and B cells." Tr. 52:5–6. She explained that cytokines are secreted "that produce dysregulation so that really many of the cells can't work very well." Tr. 52:10–11. Dr. Byers asserted that "[w]ild type measles disease is very immunosuppressive, and this quality is retained to a lesser extent by the vaccine." Pet'r's Ex. 13 at 5. Therefore, the MMR vaccine "is particularly dangerous in immunosuppressed patients." *Id.*

Dr. Byers also mentioned potential immunosuppressive effects of rubella and mumps, but she testified that she was focused on the measles vaccine. Tr. 92:22.

In her testimony, Dr. Byers referred "anyone who wants to be more specific" to the Griffin article. Tr. 59:8–10; *see also* Pet'r's Ex. 25.[27] The article explains that measles "infection is also associated with several weeks of immune suppression with the consequence that the primary causes of measles deaths are secondary to infections." Pet'r's Ex. 25 at 2. The article further states that the "virus strain is an essential determinant of in vivo immune suppression," and that more research is necessary to define "the specific properties of [the

[27] Diane E. Griffin, *Measles Virus-Induced Suppression of Immune Responses*, 236 IMMUNOL. REV. 176 (2010).

measles vaccine that are] important for this characteristic." *Id.* Dr. Byers concluded that like the wild virus, the primary measles vaccine has been found to "[a]lter[] T cell function" and lead to "increased susceptibility to other infectious diseases," as occurred in S.N.'s case. Pet'r's Ex. 13 at 5. The article concludes that "[i]nfection with the vaccine virus isolate induces long-term protective immunity but is not associated with clinically significant immunosuppression." Pet'r's Ex. 25 at 2. Dr. Byers was asked about this discrepancy. She opined that the article was contradictory and pointed to the author's caveat that "virus strain is an essential determinant of in vivo immune suppression, but the specific properties of [the] measles virus important for this characteristic have not be defined." Tr. 98:2, 6–9.

To further support her contention, Dr. Byers cited to a paper by Stowe et al. and noted that the authors "found that between [thirty-one and sixty] days post-[MMR] vaccination[,] there was a significant increase in herpes infections." Pet'r's Ex. 13 at 5 (citing Pet'r's Ex. 34).[28] The article, entitled *No evidence of an increase of bacterial and viral infections following Measles, Mumps and Rubella vaccine*, confirms that despite this specific increase, "the MMR vaccine does not increase the risk of invasive bacterial or viral infection in the [ninety] days after the vaccination and does not support the hypothesis that there is an induced immune deficiency due to overload from multi-antigen vaccines." Pet'r's Ex. 34 at 1. The authors characterized that finding as an "exception" to the general finding that "no other diagnostic group showed a significant increase within the [ninety]-day risk period" of "severe infection, bacterial or viral." *Id.* at 3. They reasoned that the study "adds weight to the existing epidemiological evidence that multiple immunizations do not 'overload' the immune system and increase susceptibility to heterologous infection." *Id.* They also countered "specific concerns [that] have been raised because wild measles virus can have profound immunosuppressive effects," noting that "this has not been shown for attenuated vaccine virus." *Id.* The authors concluded that the study "provides further evidence of a possible short-term protective effect of [the] MMR vaccine against heterologous infection." *Id.* at 4.

Dr. Byers focused on the immunosuppressive effects during the thirty-one-to-sixty-day window but testified that she did not know if that increase was related to encephalitis or the herpes infection. Tr. 101:23. Dr. Byers contended that even though S.N.'s development of HSV-1 encephalitis did not fit within the thirty-one-to-sixty-day window, the temporal relationship was appropriate because "immune suppression can last for some period of time and statistics are weird things." Tr. 116:24–25.

Dr. Byers opined that S.N. was tested for evidence of immunosuppression but noted that cytokine level testing and a blood draw for the presence of in vitro mitogens was not conducted. Tr. 60:10–14. Dr. Byers conceded that evidence of leukopenia and leukocytosis following vaccination is "a little bit contradictory" and noted that the MMR strain was a key factor. Tr. 61:15–21. Dr. Byers testified that the evidence that she relied on to determine whether S.N. had an immune deficiency was a September 12, 2012 episode of "a very mild lymphopenia at 5.9 when the normal range is [six] to [fifteen]." Tr. 104:18–20. This episode was in connection with a viral infection. Tr. 105:2–4.

[28] Julia Stowe et al., *No Evidence of an Increase of Bacterial and Viral Infections Following Measles, Mumps and Rubella Vaccine*, 27 VACCINE 1422 (2009).

Dr. Byers wrote in her report that she "believe[d] there [was] sufficient evidence to consider [that S.N.] had a subclinical genetic immunodeficiency disorder[,] which was made clinically significant by the vaccinations she received between November 29, 2012 and December 15, 2012." Pet'r's Ex. 13 at 4. She based this opinion on the fact that S.N. "had several episodes of lymphopenia and [had] failed to respond to two [flu] vaccinations[]" prior to becoming ill on December 15, 2012. *Id.* Dr. Byers explained that there are two types of immunodeficiency disorders: (1) deficiencies "caused by defects in the innate immune system," or (2) deficiencies "caused by defects in the adaptive immune system." *Id.* She noted that "in most cases[,] patients show a decrease in only one cell line . . . ." *Id.* However, Dr. Byers wrote that "[a] factor mitigating against [S.N. having] a genetic immunodeficiency disorder [was] that . . . both [her] T cells (members of the adaptive immune system) and NK cells (members of the innate immune system) were seriously decreased." *Id.*

In her supplemental report submitted on September 7, 2017, Dr. Byers cited S.N.'s immune profiles taken during her hospital stay as basis for her belief. Pet'r's Ex. 35 at 1. She explained that doctors tested S.N.'s immune profile twice, "once just before [S.N.] was diagnosed with meningoencephalitis, and once the day before discharge," and both tests showed that S.N.'s levels of "CD16+56+, CD3 cells[,] and B cells were abnormally low." *Id.* Dr. Byers specifically noted S.N.'s levels of CD16+56+ cells, which she explained "are considered a primary protector from HSV[-]1," were "78 cells/mcL[, which was] well below the normal range of 80–920 cell/mcL." *Id.* Dr. Byers conceded that "the influenza test [S.N. underwent] was for the influenza antigen, and not for the antibody." *Id.* Dr. Byers wrote that S.N.'s "physicians never tested for the anti-influenza antibody," which she noted "is helpful to test for the functional activity of the immune system, as well as for the numbers of different B and T cell subsets . . . ." *Id.* at 2.

Dr. Byers could not remember during her testimony if Dr. Harel expressed concern that the MMR vaccine caused S.N. to suffer an immune deficiency. She stated, "I can't remember where – I mean, it's two years since I've reviewed the records." Tr. 107:24–25. Dr. Byers testified that while she was "retreating from [her] position that the child had a primary or a genetic immunodeficiency . . ., there was something wrong with her immune system because she could not protect against HSV." Tr. 67:20–24. She described testing in mice that isolated "the CD4 process," because it is "blasted out by measles" and depleted in patients where latent HSV becomes active. Tr. 69:1–2, 20–25. Dr. Byers also noted that while she did not find that S.N. suffered from a classic immunodeficiency disorder, at eighteen months old, S.N.'s immune system had not fully developed at the time of vaccination. Tr. 78:6. Dr. Byers later returned to her contention that "because [S.N.] developed HSV encephalopathy . . . she did have some sort of . . . immunodeficiency disorder, but it's not one of the classic ones and we don't know what it is." Tr. 102:20–23. She opined that an immunosuppressive disorder is a necessary condition for the development of HSV-1 encephalitis, "[b]ecause the majority of people who have HSV do not develop clinical symptoms." Tr. 103:3–4. Dr. Byers was unable to definitively assert her theory that the MMR vaccine played a role in S.N.'s HSV-1 encephalitis without the premise that S.N. had a suppressed immune system.

Dr. Byers also noted that, "[a]lthough rare, the association between MMR immunization and [the] occurrence of aseptic central nervous system disorders have been reported." Pet'r's Ex.

13 at 5. She cited to several articles to support this proposition. *See id.* The first is an analysis of a cross-over study conducted by Park, Ki and Yi. *Id.* (citing Pet'r's Ex. 30).[29] The authors of this study reviewed aseptic meningitis cases in Korea during 1998 to determine its association with the MMR vaccine. Pet'r's Ex. 30 at 3. The authors found thirty-nine children aged eight to thirty-six months old who had developed aseptic meningitis within one year of receiving an MMR vaccination. *Id.* at 3–4. The authors used a forty-two-day risk evaluation period, and found that, of the thirty-nine children, eleven developed aseptic meningitis within the forty-two-day period following an MMR vaccination, while twenty-eight developed aseptic meningitis outside that period. *Id.* at 4–5. These results suggest that in "vaccine adverse effect studies, this case cross-over design seems quite effective because the incidence of adverse events among vaccines is rare and only vaccinees' data are usually available." *Id.* at 2. The authors did not draw any conclusions on a potential causal effect of the MMR vaccine on aseptic meningitis but focused instead on the most effective analytical methods. *Id.* at 11.

The second article is authored by Dourado et al. Pet'r's Ex. 13 at 5 (citing Pet'r's Ex. 15).[30] In this study, the authors reviewed cases of aseptic meningitis in Salvador, Brazil, following a mass MMR immunization program undertaken in 1997. Pet'r's Ex. 15 at 1. The MMR vaccine administered during this campaign contained the Urabe strain. *Id.* The authors wrote that the results of the study "suggest a causal link between the MMR mass immunization campaign and the aseptic meningitis outbreak." *Id.* at 5. They also found "an increase in numbers of [aseptic meningitis] cases during the third to fifth weeks after vaccination and a return to normal levels thereafter . . . ." *Id.* Lastly, the authors found that "similar outbreaks were observed in three other states where the MMR mass vaccination was also carried out, indicating a consistent association of aseptic meningitis with the MMR campaign . . . ." *Id.*

The third article is authored by Souza da Cunha et al, who used "[d]ata from routine surveillance during two mass immunization campaigns . . . with . . . [the] MMR . . . vaccine using Leningrad-Zagreb mumps strain . . . to estimate the risk of vaccine-related meningitis and mumps." Pet'r's Ex. 29[31] at 1. The authors found "a marked increase in [the] number of notified cases of [aseptic meningitis] in the two states studied, [three-to-four] weeks after the [mass immunization campaign] using the [Leningrad-Zagreb] mumps strain MMR vaccine." *Id.* at 6. The authors wrote that "[t]he most plausible explanation for the increase . . . is that they are attributable to the MMR vaccine." *Id.* They continued, "[s]upporting a causal link are the clear temporal association (with the increase starting [three-to-four] weeks after the [mass immunization campaign] corresponding to incubation period for wild mumps infection) and the fact that the increase was restricted to the age group targeted by the campaign and to the aseptic form of meningitis." *Id.*

Dr. Byers agreed that the components of the former MMR vaccine were "inferior to the strains that are currently used in the United States [today.]" Pet'r's Ex. 35 at 2. However, Dr.

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[29] Taesung Park, Moran Yi and Sung-Gon Yi, *Statistical Analysis of MMR Vaccine Adverse Events on Aseptic Meningitis Using the Case Cross-Over Design*, 23 STATISTICS IN MEDICINE 1871 (2004).

[30] Inês Dourado et al., *Outbreak of Aseptic Meningitis Associated with Mass Vaccination with an Urabe-containing Measles-Mumps-Rubella Vaccine*, 151(5) AM. J. OF EPIDEMIOLOGY 524 (2000).

[31] Sérgio Souza da Cunha et al., *Outbreak of Aeseptic Meningitis and Mumps after Mass Vaccination with MMR Vaccine Using the Leningrad-Zagreb Mumps Strain*, 20 VACCINE 1106 (2002).

Byers took issue with Dr. Silverman's support for his argument, mainly the one-hundred and fifty-five page article by Demicheli et al., noting that the plain language section of that paper stated that "the MMR vaccine is associated with aseptic meningitis[,] and administration of the [MMR] vaccine is associated with febrile convulsions." *Id.* (citing Resp't's Ex. A, Tab 4 at 2).[32] She also wrote that the discussion section of that study noted that "febrile seizure (as first or as recurrent episode) has been found to be associated with [the] MMR vaccine (prepared with Moraten, Jeryl Lynn and Wistar RA) pithing two weeks after administration in preschool Danish children." *Id.* She also noted that "all these measles vaccine strains are associated with immunosuppression and/or aseptic meningitis and other infections." *Id.* at 3 (citing Pet'r's Exs. 19,[33] 29,[34] 32[35]).

Dr. Byers did not believe that S.N.'s "illness [was] comparable to septic shock and thus the low lymphocyte counts [were] simply due to serious illness." Pet'r's Ex. 35 at 2. Dr. Byers noted that S.N.'s lymphocyte count was tested twice during her hospitalization, and S.N.'s lymphocyte levels were "abnormally low on both occasions." *Id.* Dr. Byers also argued that "S.N.'s illness was not at all comparable to sepsis." *Id.* She explained that "[s]epsis is a severe systemic dysregulation [sic.] of many cytokines caused by bacterium and viruses and usually result[s] in death." *Id.* She noted that S.N. "was certainly ill, but the seriousness of her illness was NOT due to sepsis—she was ill primarily because of the location of the infection—the brain—not because it was systemic." *Id.* She continued, "HSV[-]1 usually produces cold sores, and there is no more reason to have the immune system severely compromised . . . just because of a cold sore, than with meningoencephalitis." *Id.* Dr. Byers reiterated during her testimony that she did not find evidence that sepsis was present during S.N.'s development of HSV, despite the opinion of Respondent's expert. Tr. 73:8–9.

Dr. Byers concluded her supplemental report by discussing the "mechanism of action." Pet'r's Ex. 35 at 3. She cited Dr. Kinsbourne's contention that "HSV[-]1 is found in the brains of about [thirty-five percent] of human[s] who have never suffered the disease." *Id.* Therefore, Dr. Byers explained that HSV-1 "is somewhat like the chickenpox virus (Herpes Zoster)[,] which remains dormant in the body after infection until with age the immune response cannot control it, at which time it re-expresses itself in the form of Shingles." *Id.* Dr. Byers argued that "the HSV[-]1 virus was probably dormant in S.N.'s brain until she was immunosuppressed with the MMR [vaccine] she received." *Id.* Therefore, she contends that "the important aspect of MMR vaccinations is . . . whether they can damage or alter the proper functioning of the protective immune response." *Id.* She argued that the paper by Pabst et al. showed that the "Uribe . . . strain, the Edmonston-Zagreb strain, the Schwartz strain, the Moralin strain, [and] even the Jeryl Lynn strain . . . all have some degree of alteration in some component of the normal immune response, and in some cases[,] . . . lead[s] to neurologic disease[,] such as

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[32] V. Dimicheli et al., *Vaccines for Measles, Mumps and Rubella in Children (Review)*, 2 COCHRANE DATABASE OF SYSTEMIC REVIEWS CD004407 (2012).

[33] Gregory D. Hussey et al., *The Effect of Edmonston-Zagreb and Schwarz Measles Vaccines on Immune Responses in Infants*, 173 J. OF INFECTIOUS DISEASES 1320 (1996).

[34] Souza da Cunha et al., *supra* note 31.

[35] Jens-Jörg Schnorr et al., *Immune Modulation After Measles Vaccination of 6–9 Months Old Bangladeshi Infants*, 19 VACCINE 1503 (2001).

aseptic meningitis, seizures, or abnormal T cell response." *Id.* (citing Pet'r's Ex. 21).[36] She also argued that the studies Dr. Silverman cited to support his contention that "large studies of MMR recipients have not found association with increased risk of bacterial or viral illnesses" all "failed to test the vaccine recipients for immune competence[,]" and are "[t]herefore[] inappropriate to access [sic.] causation in this case." *Id.* (quoting Resp't's Ex. A at 5).

Dr. Byers testified that the Edmonston measles strain was used in S.N.'s vaccine. Tr. 61:25. She noted that she had "not been able to find a head-to-head comparison of clinical trials with the Edmonston strain and another strain that actually shows that the Edmonston strain is less immunosuppressive and equally antigenic." Tr. 64:2–6. However, Dr. Byers relied on four studies to establish that the Edmonston strain has immunosuppressive properties. The first paper, Munyer et al., found the "[a]dministration of live, attenuated measles virus vaccine to children resulted in temporary suppression of lymphocyte responsiveness in vitro." Pet'r's Ex. 20 at 4.[37]

The Pabst article presented the hypothesis that "vaccine-induced immunosuppression was responsible" for "the greater than expected mortality from infections during a three-year period" in "infants immunized with high-titreed [sic] measles vaccine." Pet'r's Ex. 21 at 1.[38] The study "showed that the pre-vaccination value was the most important determinant of any value subsequent to vaccination, indicating that the pre-existing state of nonspecific immunity before vaccination was decisive for any subsequent response." *Id.* at 3. The extent of the immunosuppressant effects of the measles vaccine was also evaluated. The authors concluded "that cytokine generation by [phytohemagglutinin] stimulation was only minimally affected by primary MMR vaccination in [one]-year-olds." *Id.* at 3–4. While admittedly relying on the subjects as their own controls, the study found "that primary vaccination induced immunity changes are different from that seen in measles illness." *Id.* at 4. Ultimately, the authors concluded "that MMR vaccination induces a very mild but transient depression of immunologic memory, maximal at about [three] weeks." *Id.*

The Ward article identifies cytotoxic T lymphocytes, delayed-type hypersensitivity, and lymphoproliferative and cytokine responses as markers for cellular immunity to viral pathogens. Pet'r's Ex. 22 at 5.[39] The authors are clear to note that despite the identification of these factors, "[r]elatively little is known about how the characteristics measured by these tests are related to one another and to what extent each contributes to virus clearance and long-term immunity." *Id.* The article also notes that a "much more severe immune system disruption is characteristic of natural measles viral infection [versus vaccination.]" *Id.* However, the study showed that after measles vaccination, "measles antigen-specific [delayed-type hypersensitivity] and lymphoproliferative have generally been weak or absent." *Id.* The authors also reported

[36] Henry F. Pabst et al., *Kinetics of Immunologic Responses after Primary MMR Vaccination*, 15(1) VACCINE 10 (1997).
[37] Thomas P. Munyer et al., *Depressed Lymphocyte Function After Measles-Mumps-Rubella Vaccination*, 132(1) J. OF INFECTIOUS DISEASE 75 (1975).
[38] Pabst et al., *supra* note 36.
[39] B.J. Ward et al., *Cellular Immunity in Measles Vaccine Failure: Demonstration of Measles Antigen: Specific Lymphoproliferative Responses Despite Limited Serum Antibody Production After Revaccination*, 172(6) J. OF INFECTIOUS DISEASES 1591 (1995).

"observations of leukopenia and atypical lymphocytosis after revaccination [that] add to the growing list of measles vaccine-associated immunologic effects." *Id.*

The last article that Dr. Byers referenced in support of the immunosuppressive properties of the Edmonston measles strain is the Wyde article. Pet'r's Ex. 37.[40] The authors were concerned about the "significantly increased long-term mortality due to diseases other than measles" in children who received high-titred measles vaccines. *Id.* at 1. They were unable to establish a causal relationship between the vaccines and this increased mortality, but noted such a relationship may be possible, "given the singular pathogenic characteristics [of the wild-type measles viruses], particularly their ability to disseminate, persist and immunosuppress." *Id.* Furthermore, they noted, "it can be argued that the enhanced ability of the [Edmonston] vaccine virus . . . could be a key factor leading to the superior protective efficacy of this vaccine in infants with significant levels of maternal antibodies." *Id.*

Dr. Byers was asked about evidence for her contention that S.N.'s HSV-1 infection was latent. She testified that her opinion was "[b]ased on the data that Dr. Kinsbourne presented saying that about [thirty-five] percent of people – of the brains of people who have been checked are positive for HSV." Tr. 88:25–89:2. She reiterated the importance of the temporal relationship between vaccination and onset and the rarity of the condition, Tr. 90:17–19, but stated she "didn't know" and "would be less certain" if S. N. showed normal immune function during testing on December 19, 2012 and January 2, 2013, Tr. 90:13. She focused on the December 19, 2012 testing that showed "all of the lymphocyte subsets that [were] measured were down." Tr. 75:18–19. Dr. Byers opined that this was evidence of immunosuppression "sufficient enough to allow the HSV-1 to permeate if it was a latent virus." Tr. 75:24–76:1. She also pointed to "notes from some of the physicians saying that the MMR might be implicated" and to an appropriate temporal relationship. Tr. 76:9–11. Dr. Byers opined that S.N.'s family history of encephalopathy and leukopenia was suspicious, but not the likely cause of S.N.'s condition. Tr. 77:5–9. Dr. Byers testified that in some cases, even "an increased antibody response, increased neutralization ratio [can exist] at the same time that you're seeing immunosuppression." Tr. 109:18–20. In S.N.'s case, "the only thing we know . . . is that she had low T and B cells." Tr. 113:18–19. This, in Dr. Byers's opinion, is evidence of systemic immunosuppression but without proper testing, there is no additional evidence for support. Tr. 114:2–7. I asked Dr. Byers to clarify her position on whether S.N.'s immunosuppression preexisted the vaccination. Tr. 116:8–11. Her response: "I don't know that." Tr. 116:12.

3. Dr. Silverman

Dr. Silverman began his report by responding to the contention that S.N. had a subclinical immunodeficiency prior to receiving the vaccinations at issue. Resp't's Ex. A at 3. Dr. Silverman disagreed with this contention for four reasons. First, Dr. Silverman wrote that "S.N. did not exhibit the clinical signs or symptoms one would expect from a patient with immunodeficiency[,] such as frequent infections or poor growth." *Id.* Second, Dr. Silverman explained that Dr. Byers' contention that "S.N. was unable to mount an immune response to [flu]

[40] Philip R. Wyde, Nagendra R. Attibele & Walter L. Kemp, *Infection of Leucocytes by Measles Vaccine Viruses Edmonston-Zagreb and Enders-Moraten has Different Consequences: Potential Mechanism for Increased Vaccine Efficacy or Aberrant Activity in Field Trials*, 12(8) VACCINE 715 (1994).

vaccinations" was "not supported by the information in the medical record." *Id.* He explained that Dr. Byers based her contention on S.N.'s negative influenza antigen test. *Id.* However, this test "tests for the presence of the influenza antigen, evidence of a current infection," not "the ability of the patient to mount an immune response to vaccination." *Id.* Third, Dr. Silverman attacked Drs. Byers and Kinsbourne's contention that S.N.'s "abnormal lymphocyte values indicate an immune deficiency . . . ." *Id.* Dr. Silverman explained that "abnormal lymphocyte counts during severe illness are common and indicate that the [patient] is actively fighting an infection." *Id.* He also noted that "S.N.'s initial total lymphocyte count was elevated at 11.43 (normal range 1.58–6.83) at the presentation of her illness on [December 16, 2012]." *Id.* Dr. Silverman argued that S.N.'s "elevated lymphocyte count and overall white blood cell count suggest a robust immune response." *Id.* Fourth, Dr. Silverman agreed that S.N. "had low numbers of CD4 and CD8 T cells and CD16+56 cells on two occasions . . . during [her] hospitalization." *Id.* at 4. However, he noted that as S.N. "recover[ed] from her acute illness, . . . [these] cell numbers [rose], although not back to normal range." *Id.* Dr. Silverman wrote that these "moderate abnormalities . . . are common[,]" and S.N. should have undergone repeat testing once she fully recovered. *Id.* Dr. Silverman concluded that "S.N.'s lowest CD4 value was . . . mildly low and would not be expected to lead to increased susceptibility to infection." *Id.*

Dr. Silverman then addressed Petitioner's contention that the MMR vaccine S.N. received could impair her immune system. *Id.* Dr. Silverman agreed that "some attenuated measles virus strains can induce mild immune suppression," but noted that "the majority of those studies involve strains that are different from the strain that S.N. received." *Id.* Dr. Silverman wrote that "S.N. received the . . . more attenuated version of the Edmonston measles strain," which has been shown to "not suppress immune system functionality." *Id.* Dr. Silverman explained that "[o]ne study . . . examined the impacts of the MMR vaccination on in vitro immune system responses in children . . . [and found that it] elevat[ed the] immune system in some assays . . . and lower[ed] immune system function in other assays . . . ." *Id.* (citing Pet'r's Ex. 21).[41] Therefore, Dr. Silverman disagreed with Dr. Byers' "contention that the more attenuated measles virus that S.N. received weakens the immune system[,]" because it "[was] not supported by the evidence from studies performed decades ago provided by Dr. Byers." *Id.*

Dr. Silverman disagreed with Petitioner's argument that the "MMR vaccine increases the risk for infection." *Id.* Dr. Silverman noted that the studies used to support this contention by Dr. Byers "were done using different strains of attenuated virus vaccine." *Id.* Dr. Silverman wrote that one study cited by Dr. Byers to show that the MMR vaccine increases the risk for aseptic meningitis "includ[ed] patients vaccinated with the Urabe strain of the mumps virus." *Id.* at 4. He explained that S.N. was given a vaccine with the Jerly Lynn strain, "which has not been associated with aseptic meningitis." *Id.* Dr. Silverman also noted that another study quoted by Dr. Byers to show that there is "a very small increased risk in a one-time window following MMR vaccination for herpes virus infection" actually found "no association with [an] increased risk for encephalitis or bacterial infection or other oral infections." *Id.* Dr. Silverman wrote that the authors of that study "specifically comment[ed] on this . . . [and] argue[d] that the modest association between MMR and herpes virus infections is unlikely to be causal." *Id.* Dr. Silverman also wrote that "large studies of MMR recipients have not found association with

[41] Pabst et al., *supra* note 36.

increased risk for bacterial or viral illnesses including herpes virus infections." *Id.* (citing Resp't's Ex. A, Tab 4).[42]

Dr. Silverman concluded his first report by noting that "the timing of the vaccinations . . . is not inconsistent with the development of" HSV encephalitis on December 15, 2012. *Id.* at 6. However, he wrote that "there is insufficient evidence to suggest a connection between receiving the MMR vaccine and developing HSV[-]1 encephalitis." *Id.*

Dr. Silverman submitted a second expert report responding to Dr. Byers' supplemental expert report on October 10, 2017. Resp't's Ex. C. Dr. Silverman began by disagreeing with Dr. Byers' "contention that S.N.'s abnormal immune cell parameters during her severe infection indicate that she was immune suppressed before infection." *Id.* at 1. Dr. Silverman testified that S.N. "came in with a very robust immune response that was illustrated by an elevated white blood cell count." Tr. 208:9–11. He wrote that "S.N. developed sepsis due to [her] HSV infection." Resp't's Ex. C. at 1. He defined sepsis as a "systemic inflammatory response due to infection that leads to organ dysfunction[,]" and explained that "it is well-established . . . that sepsis induces alterations in immune cell parameters." *Id.* He noted that "a hallmark of sepsis-induced immunosuppression" is "lymphopenia, or low number of lymphocytes," which "can last for weeks after the initial illness." *Id.* Dr. Silverman argued that S.N. met the sepsis definition "based on [her] fever, elevated white blood cell count[,] and clinical status requiring intubation and admission to the [PICU]." *Id.* He noted that "S.N. had an elevated lymphocyte count on [December 16, 2012] . . . at the beginning of her illness . . ., which [was] a normal immune response to infection." *Id.* He argued that "[t]his fact makes it unlikely that immunosuppression left [S.N.] susceptible to infection . . . ." *Id.*

Dr. Silverman continued that "the immune system that is actively fighting a severe infection in an otherwise healthy child would not be expected to have the same immune system parameters found in a child not fighting an infection." *Id.* at 2. He noted that "[i]t is well documented and well accepted in the medical field that infection alters . . . immune system test results." *Id.* He explained that "the immune system behaves differently when fighting an infection[,]" including "up-regulat[ing] certain immune cells and down-regulat[ing] others to tailor the response to the particular infection." *Id.* Dr. Silverman wrote that "S.N. was fighting a severe, life-threatening viral infection, and she appropriately up-regulated her lymphocytes, . . . the cells primarily responsible for defense against viral infection." *Id.* Dr. Silverman testified that "[w]hen kids or any patients are ill, their immune system behaves differently." Tr. 213:2–4. He explained further in his report that, "[f]ollowing this initial strong response, many of [S.N.'s] immune cell subset[s] dropped[,] which is often seen during a severe infection as the battle rages on between the patient and the pathogen." Resp't's Ex. C. at 2. Dr. Silverman noted that this type of cell death, "including T cells and NK cells[,] occurs commonly during sepsis and severe illness." *Id.* He explained that as S.N. "recovered from the severe infection, her immune system slowly recovered as evidence[d] by her rising number of immune cells . . . ." *Id.* While he conceded that S.N.'s immune cells had not normalized by the time of discharge, he argued that this was "not surprising . . . since [S.N.] had a serious complication the week prior [to discharge], which required emergency brain surgery." *Id.* Dr. Silverman clarified during his testimony,

[42] V. Demicheli et al., *supra* note 32.

"when you look after somebody who is quite sick and see abnormalities, that most likely represents response to illness rather than a cause of illness." Tr. 213:11–13.

Dr. Silverman also wrote that "[v]accination is intended to generate an immune response," which "can induce fevers and associated febrile seizures along with sterile inflammation of the central nervous system called 'aseptic meningitis.'" Resp't's Ex. C. at 4. He explained that "[t]he association of MMR vaccination with 'aseptic meningitis' refers to the presence of immune cells in the [central nervous system] without evidence of bacterial infection." *Id.* Dr. Silverman also clarified his contention that S.N. developed sepsis. He relied on the Randolph paper factors, which include a high white blood cell count and fever, as the basis for his argument. Tr. 214:5-9 (citing Resp't's Ex. C, Tab 1).[43] Ultimately, Dr. Silverman testified that S.N.'s "main problem isn't that she meets the definition of sepsis. Her main problem is that she's quite ill from having a very serious brain infection." Tr. 214:13–16. Dr. Silverman noted that, "typically if one thought this was indicative of an immune deficiency, you would have gotten immunology consultation and then the child would have gotten a whole battery of tests once she was healthy to see if there was actually a sustained immune defect." Tr. 216:17–21.

As a clinician, Dr. Silverman treats children with immune deficiency and testified that "if you have a systemic immune deficiency and you have a viral infection, most typically, you'll end up seeing the infection manifest in many different places." Tr. 218:12–15. He noted that disseminated herpes virus is a "fairly terrible infection, which we see in neonates." Tr. 218:18–19. Dr. Silverman also noted that individuals with an immune deficiency "are kids who end up having repeated bouts of herpes encephalitis." Tr. 219:20–21. He explained that this is often due to a genetic defect: "there's a pathway called the toll-like receptor 3 pathway" that is affected. Tr. 219:22–23.

When asked why there were not more cases of idiopathic HSV-1 encephalitis given the prevalence of the herpes virus, Dr. Silverman admitted that "we don't' know the answer to that." Tr. 221:24–25. He discussed patients that are severely immunosuppressed due to chemotherapy and stated that he could not "think of a case where [he] saw that leading to just isolated herpes encephalitis." Tr. 223:7–9. In the cases he has seen, "kids tend to get the herpes really at their mucous membranes and really all over their body." Tr. 223:6–7. Dr. Silverman added that "it tends to lead to a really diffuse and systemic infection." Tr. 223:11. He agreed with Dr. Kinsbourne that the virus can "retrograde up those neurons into the brain," Tr. 223:24–25, or "get into the blood and cause a viremia from [HSV] and that can go . . . all over the body[,]" Tr. 224:1–2

Dr. Silverman made two main points to support his assertion that MMR did not cause HSV-1 encephalitis in S.N.'s case. Assuming that a necessary condition for Petitioner's theory is immune suppression, Dr. Silverman opined that "[t]here's no evidence here that the child had any immune suppression from the point of the MMR to the point that the child came in sick." Tr. 227:8–11. In fact, S.N.'s reaction to her sickness was a "very robust immune response." Tr.

[43] Adrienne G. Randolph and Russell J. McCulloh, *Pediatric Sepsis: Important Considerations for Diagnosing and Managing Severe Infections in Infants, Children, and Adolescents*, 5:1 VIRULENCE 179 (2014).

227:13. Second, the studies that have been done have found "spikes of herpes simplex encephalitis" during the "two week[], three week[], a month [period] after" vaccination. Tr. 228:11–12. Dr. Silverman noted that "even [in] the best piece of evidence, I think, that was cited to say there was an increase in herpetic infection in one time period, they didn't find any increase in encephalitis." Tr. 228:13–16.

IV. Applicable Legal Standard

To receive compensation under the Vaccine Act, Petitioner must demonstrate either that: (1) S.N.'s condition is a "Table Injury," and therefore resulted from the receipt of a covered vaccine or vaccines within the time frame prescribed by the Vaccine Injury Table set forth at § 14, as amended by 42 C.F.R. § 100.3; or (2) S.N.'s condition is an "off-Table Injury," one not listed on the Table, that resulted from her receipt of a covered vaccine. *See* § 11(c)(1)(C); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner's claim that S.N.'s vaccinations caused her encephalitis does not fall within the Vaccine Table. Thus, Petitioner must prove that S.N.'s vaccinations were the cause-in-fact of her condition.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that his vaccine was the cause of his injury. § 13(a)(1)(A). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is enough for recovery. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).[44]

In *Althen v. Sec'y of Health & Human Servs.*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278 (Fed. Cir. 2005). The *Althen* test requires a petitioner to set forth: "(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.* To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.* (internal citations omitted).

Specifically, under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question "can [the] vaccine(s) at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006), *cert. denied*, 551 U.S. 1102 (2007). This may be accomplished in a number of ways. "Reliability and plausibility of . . . pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory, so as to render it credible." *Id.* Additionally, "epidemiological studies and an expert's experience,

[44] The Vaccine Act also requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted for more than six months. § 11(c)(1)(D)(i). It is undisputed that this six-month requirement is satisfied in this case.

while not dispositive, lend significant credence to the claim of plausibility." *Id.* Medical literature published in respected medical journals is also persuasive. *Id.* "However, publication 'does *not* necessarily correlate with reliability', because 'in some instances well-grounded but innovative theories will not have been published.'" *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593–94 (1993) (emphasis in original)).

In addition to showing that the vaccine at issue can cause a particular injury, a petitioner must also, under *Althen's* second prong, prove that the vaccine actually did cause the alleged injury in a particular case. *See id.*; *Althen*, 418 F.3d at 1278. A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original) (internal citations omitted).

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Human Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period. . . . Without more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

V. Discussion

A. *Althen* Prong One

Dr. Kinsbourne asserts that the MMR vaccine produced a temporary immunosuppressive effect in S.N. and facilitated a herpes infection that exacerbated into encephalitis. In support, Dr. Kinsbourne's report has an entire section devoted to the "Effect of Measles/Measles Vaccine Immunosuppression." Pet'r's. Ex. 23 at 4. This section, however, only provides a discussion of the wild measles virus with citations to medical literature. *Id.* Petitioner has presented compelling evidence documenting the immunosuppressive effects of the measles virus. And though Dr. Kinsbourne concludes that the MMR vaccine has similar effects, he relies on Dr. Byers to "present[] extensive evidence that measles vaccination has a similar, albeit less powerful effect of immunosuppression . . . that has been reported in association with central nervous system disorders." *Id.* Dr. Kinsborne did not provide preponderant evidence in his written submissions that these properties are applicable to the measles vaccine generally, or the Edmonston strain specifically. During his testimony, Dr. Kinsbourne did not provide any supplemental evidence specifically applicable to immunosuppressive effect of the measles vaccine. He also noted that HSV-1 encephalitis can occur in a child without immunosuppression, undercutting Dr. Byers' claim. Dr. Kinsbourne provided a general overview of the herpes virus and HSV-1 encephalitis. It is less clear what his report and testimony added to understanding Petitioner's causation theory. Certainly Dr. Byers is qualified to describe what is known about the pathogenesis and progression of HSV-1 encephalitis without this additional background testimony from Dr. Kinsbourne.

Dr. Byers' interpretation of Petitioner's causation theory differed some from Dr. Kinsbourne. Dr. Byers stated that immunosuppression is necessary for the development of HSV-1 encephalitis generally. She was also unable to unequivocally state that the MMR vaccine could be linked to HSV-1 encephalitis without some evidence of vaccine-induced immunosuppression in the patient. Dr. Byers identified biological plausibility, temporal association, and the absence of confounding factors as the best evidence for the viability of her theory. There has been no assertion by Respondent that there are confounding factors to be considered in this case. Also, an appropriate temporal relationship is a necessary condition that will be discussed during the *Althen* prong 3 analysis.

The biological plausibility argument is undercut by Dr. Byers' refusal to address contradicting medical literature. The Griffin article, cited by Dr. Byers, focuses on the immunosuppressive effects of the virus. It concludes that "[i]nfection with the vaccine virus isolate induces long-term protective immunity but is not associated with clinically significant immunosuppression." Pet'r's Ex. 25 at 2. When asked about this conclusion, Dr. Byers stated that the article was contradictory. If that is the case, it is unclear why she provided said article in support of her argument. Dr. Byers relied on a second piece of medical literature titled, *No evidence of an increase in bacterial and viral infection following Measles, Mumps, and Rubella vaccine*, to support her contention that the MMR vaccine leads to a rise in infectious diseases including herpes. The article notes that there is an increase in herpes infections during the thirty-one-to-sixty-day window after vaccination; however, the authors believe this is an exception that "has not been shown for attenuated vaccine virus." Pet'r's Ex. 34 at 3. Additionally, there is no information provided about HSV-1 encephalitis specifically.

The plausibility of the argument that the MMR vaccine has immunosuppressive effects is also undercut when the applicable strain is considered. The articles that Dr. Byers presented notably expressed a need for further research to determine if the Edmonston measles vaccine strain was immunosuppressive. Indeed, one article found evidence of "the superior protective efficacy of the [Edmonston] vaccine in [some] infants." Pet'r's' Ex. 37 at 7.

Dr. Byers' inability to distinguish non-vaccine sources of the alleged inciting antigen makes her opinion comparable to the opinion she expressed in the Omnibus Autism Proceeding. *Wood ex rel. A.W. v. Sec'y of Health & Human Servs.*, No. 15-1568V, 2018 WL 1150730, at *3 (Fed. Cl. Spec. Mstr. Feb. 1, 2018). Indeed, other special masters have found that unlike the measles wild virus, there is no correlative period of immunosuppression after a measles vaccination. *See Hazelhurst v. Sec'y of Health & Human Servs.*, 03-654V, 2009 WL 332306, at *99 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). In *Hazelhurst*, it was explained that "'there are some immunologic changes that occur coincident with the [MMR] vaccinations,' however, [Respondent's expert persuasively] explained that there is no 'clinically important . . . immunosuppression . . . that occurs with the vaccine.'" *Id; see also Anderson v. Sec'y of Health & Human Servs.*, No. 02-1314V, 2016 WL 8256278, at *25 (Fed. Cl. Spec. Mstr. Nov. 1, 2016) (dismissing the discredited theory that the MMR vaccine has an immune-suppressive capacity). For an example of a special master's rejection of Dr. Byers' testimony in this context, *see Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, No. 01–162, 2009 WL 332044, at *65, *72–76, *102–04 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for reconsid. den.*, 2009 WL 764611, *aff'd*, 88 Fed.Cl. 706 (2009) (evidence demonstrating that measles vaccines are routinely given to children with challenged or compromised immune systems, without harmful effects, undercuts the theory that the vaccine virus is immunosuppressive or leads to viral persistence).

It is also important to note that while "biological plausibility" may well be an appropriate standard for continued medical research, it is not Petitioner's standard under prong one of *Althen.* Plausibility has been used as a floor for initial consideration of a theory in several cases in the Program. The Federal Circuit, however, has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019). It is not sufficient here.

Neither Drs. Kinsbourne nor Byers presented evidence of the clinical symptomology expected in an infant with vaccine-induced immunosuppression. Testing completed while an infant is actively fighting a potentially fatal illness cannot be the baseline. Without more, I do not find it more likely than not that the Edmonston measles vaccine strain has immunosuppressive effects that directly cause an otherwise unremarkable herpes infection to develop into HSV-1 encephalitis.

B. *Althen* Prong Two

While Dr. Kinsbourne opined that S.N.'s HSV-1 encephalitis was caused by a primary herpes infection, Dr. Byers stated that statistically, it was more likely that S.N. had a latent infection that was activated due to the MMR vaccine's immunosuppressive effects. Dr. Kinsbourne noted that there was no evidence in S.N.'s medical history that she suffered from any pre-existing immunodeficiency. He pointed to the testing done after S.N. was brought to the hospital following the onset of her HSV-1 encephalitis symptoms to show her immunosuppression developed post vaccination. The problem with this assertion, as was identified by Dr. Silverman, is that during her presentation at the hospital, S.N.'s lymphocyte count was elevated. This is evidence that her immune system was actively fighting infection. There is no way to interpret S.N.'s T cell count as indicative of her body's response to the MMR vaccination, without also considering the effect of the active herpes infection. Dr. Kinsbourne does not identify any evidence in the medical record or fact testimony to suggest that S.N. suffered from evidence of immunosuppression post vaccination but pre infection. Dr. Kinsbourne also does not distinguish between S.N.'s clinical progression and that of a patient with a normal immune system. I agree with Dr. Kinsbourne that there is no evidence that S.N. suffered from a latent herpes infection that was activated post vaccination. Dr. Byers' reliance on statistics is not persuasive. It is possible, however, to evaluate Dr. Byers' theory of immunosuppression in the context of a primary herpes infection.

In her written reports, Dr. Byers concluded that S.N. had "a subclinical genetic immunodeficiency disorder" that was exacerbated by vaccination. Pet'r's Ex. 13 at 4. During her testimony, Dr. Byers retreated from her position that S.N. had a classic or genetic immunosuppression but testified that there was "something wrong" with S.N.'s immune system, because she developed HSV-1 encephalitis. She then suggested that S.N.'s immune system wasn't fully developed but reversed herself again. She eventually opined that S.N. had an immunodeficiency disorder that did not have a classic presentation and was otherwise unknown. Dr. Byers was unable to clearly state if this immunodeficiency disorder is synonymous to "immunosuppression" or if the term accurately describes S.N. She reversed her opinion more than once and ultimately stated that S.N. got sick because her immune system did not work.

Some form of immune system failure occurs with every disease, regardless of cause, progression, or duration. This is not preponderant evidence of the application of vaccine-induced immunosuppression to S.N.'s development of HSV-1 encephalitis.

C. *Althen* Prong Three

Petitioner's failure to meet his burden by presenting a medical theory that causally connects the vaccine to the injury or a logical sequence of cause and effect precludes entitlement. However, Dr. Byers' assertion that this case presents an appropriate temporal relationship is also contrary to the evidence she presented. Dr. Byers did not present any evidence to support her contention that the measles vaccine has immunosuppressive effects during the two-and-a-half-to-three-week window that S.N. developed HSV-1 encephalitis. In fact, the literature Dr. Byers provided identifies thirty-one to sixty days as an appropriate timeframe for any immunosuppressive effects of the strain that was administered to S.N. When asked about this variable, Dr. Byers dismissed the discrepancy and stated that "statistics are weird things." Tr. 116:24–25. This general statement does not provide preponderant evidence that there was an appropriate temporal relationship between S.N.'s vaccination and HSV-1 encephalitis.

VI. Expert Preparedness

Dr. Byers provided the substantive foundation for S.N.'s claim, and her presentation, despite her esteemed qualifications, was equivocal, ill-prepped, and inconsistent. Furthermore, Dr. Byers' own admission that she had not reviewed the records in over two years prior to her testimony, displays a disregard for the purpose of an entitlement hearing and the amount time others spent in preparation. Dr. Byers' work in this case fell well short of what is expected from an expert. In her long career, Dr. Byers has participated in proceedings in the Vaccine Program many times. Special masters have both credited Dr. Byers' opinion and strongly criticized her performance. *Compare Sajbel v. Sec'y of Health & Human Servs.*, No. 14-741V, 2017 WL 1491912 (Fed. Cl. Spec. Mstr. Mar. 31, 2017) (finding Dr. Byers' opinion persuasive), *with Bigbee v. Sec'y of Health & Human Servs.*, No. 06-663V, 2012 WL 1237759, at *30 (Fed. Cl. Spec. Mstr. Mar. 22, 2012) (criticizing Dr. Byers and citing cases). This history of participating in cases in the Vaccine Program is consistent with Dr. Byers' estimate that she derives approximately fifty percent of her income from work in litigation. I expect that a doctor with this level of experience would be prepared and seek to maintain a positive reputation as an expert in this Program. However, Dr. Byers has been unable or unwilling to improve the quality of her work despite several warnings from several special masters over a period of years. *See, e.g*, *Jaafar ex rel. A.M. v. Sec'y of Health and Human Servs.*, No. 15-267V, 2018 WL 4519066, *3 (Fed. Cl. Spec. Mstr. Aug. 10, 2018) (noting that "Dr. Byers did not answer questions clearly or cite specific exhibits to support her points[]" and "made several statements that strained credulity."); *Wood ex rel. A.W.*, 2018 WL 1150730, at *5 (explaining that "Dr. Byers's work in this case fell well short of what is expected from an expert."); *Snyder ex rel. Snyder*, 2009 WL 332044, at *15 (noting that Dr. Byers' "testimony was disjointed and often unclear."); *Rego v. Sec'y of Health and Human Servs.*, No. 04-1734V, 2008 WL 1990844, *10 (Fed. Cl. Spec. Mstr. Jan. 30, 2008) (noting that "Dr. Byers' testimony was confusing, speculative, and frankly suspect as it [was] not supported by the record in this case or other reliable sources."). It is imperative to the integrity of the Vaccine Program that petitioners are able to obtain qualified experts. These

experts often present novel or undertested theories, and their persuasiveness depends on preparation and authority. Although the theory in this case was without adequate support even when the all filings were considered, Dr. Byers would do well in the future to approach all entitlement hearings with the diligence and professionalism they deserve.

VII. Conclusion

S.N.'s diagnosis was never in dispute, and her recovery is inspiring. Unfortunately, it is often unexplainable when children so young are subject to such traumatic and life-changing circumstances. To understand what happened in this case and why, the medical record, expert reports, medical literature, and hearing testimony were all thoroughly reviewed and considered, even if not explicitly referenced herein. In this case, Petitioner has not established by a preponderant standard that S.N.'s vaccinations caused her HSV-1 encephalitis.

Accordingly, I have no choice but to DENY Petitioner's claim and DISMISS this petition.[45]

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

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