In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-0477V

Filed: 2 September 2009

ASHLY WHITENER,	*	
	*	
Petitioner,	*	
	*	**PUBLISHED**
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Steven Dennis Goldston , Esq., Goldston Law Firm, Denton, Texas, for Petitioner;
Lisa Ann Watts, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT RULING[1]

ABELL, Special Master:

On 21 June 2006, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2] alleging that, as a result of the Meningococcal vaccination[3] she received on 30 December 2004, she suffered a severe and

[1] Petitioners are reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this ruling within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C. §300aa.

[3] The meningococcal vaccine was added to the Vaccine Injury Table, effective 1 February 2007.

debilitating bout of Guillain-Barré Syndrome (GBS)[4] (which had certain aspects of transverse myelitis (TM)[5]). Amended Petition at 2.

This petition was assigned to my chambers on 21 June 2006. Eventually, an evidentiary hearing on the ultimate issue of entitlement for compensation was held *in vitro* (telephonically) from the Court's Chambers on 24 March 2008. Hearing Transcript ("Tr.") at 1. Whereupon, the Court heard from medical expert witnesses for both parties: Dr. Marcel Kinsbourne for the Petitioner, and Dr. Arthur Safran for the Respondent. Tr. at 3. Subsequent to that hearing, the parties filed closing briefs with the Court, and the case is now ripe for a ruling.

As a preliminary matter, the Court notes that Petitioners have satisfied the pleading requisites found in § 300aa-11(b) and (c) of the statute, by showing that: (1) she is the real party at interest as the injured party; (2) the vaccine at issue is set forth in the Vaccine Injury Table (42 C.F.R. § 100.3); (3) the vaccine was administered in the United States or one of its territories; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 16 requirement that the Petition be timely filed have been met. On these matters, Respondent tenders no dispute.

The Vaccine Act authorizes the Office of Special Masters to make rulings and decisions on petitions for compensation from the Vaccine Program, to include findings of fact and conclusions of law. §12(d)(3)(A)(I). In order to prevail on a petition for compensation under the Vaccine Act, a petitioner must show by preponderant evidence that a vaccination listed on the Vaccine Injury Table either caused an injury specified on that Table within the period designated therein, or else that such a vaccine actually caused an injury not so specified. § 11(c)(1)(c).

I. FACTUAL RECORD

Despite their accord on certain factual predicates contained in the filed medical records, there is, unsurprisingly, a pronounced conflict between the parties on certain factual issues of viewing understood scientific mechanisms of vaccine injury within the context of the expert witness

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[4] Guillain-Barré Syndrome is "acute idiopathic polyneuritis." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 803, 1819; *see also* the "About GBS" page of the GBS/CIDP Foundation International website, available at http://www.gbs-cidp.org/aboutgbs.htm (describing GBS more specifically as "an inflammatory disorder of the peripheral nerves ... characterized by the rapid onset of weakness and, often, paralysis of the legs, arms, breathing muscles and face").

[5] Transverse Myelitis is "inflammation of the spinal cord" or, alternatively, "noninflammatory lesions of the spinal cord" "in which the functional effect of the lesions spans the width of the entire cord at a given level." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1209. "Transverse myelitis is characterized by the acute onset of signs of spinal cord disease, usually involving the descending motor tracts and the ascending sensory fibers, suggesting a lesion at one level of the spinal cord." K. Stratton, *et al*., eds. Vaccine Safety Committee, Institute of Medicine, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY (1994) at 37.

testimony and the medical records. Considering these disputes and the Court's commission to resolve them, it behooves the Court to explain the legal standard by which factual findings are made.

It is axiomatic to say that a petitioner bears the burden of proving, by a preponderance of the evidence – which this Court has likened to fifty percent and a feather – that a particular fact occurred or obtains. Put another way, it is required that a special master, "believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." *In re Winship*, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Moreover, mere conjecture or speculation does not meet the preponderance standard. *Snowbank Enterprises v. United States*, 6 Cl. Ct. 476, 486 (1984).

This Court may not rule in favor of a petitioner based on his asseverations alone. This Court is authorized by statute to render findings of fact and conclusions of law, and to grant compensation upon petitions that are substantiated by medical records and/or by medical opinion. §§ 12(d)(3)(A)(i) and 13(a)(1).

Contemporaneous medical records are afforded substantial weight, as has been elucidated by this Court and by the Federal Circuit:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary of HHS, 993 F. 2d 1525, 1528 (Fed. Cir.1993).

Medical records are more useful to the Court's analysis when considered in reference to what they include, rather than what they omit:

> [I]t must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant.

Murphy v. Secretary of HHS, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F. 2d 1226 (Fed. Cir. 1992), *cert. denied sub nom. Murphy v. Sullivan*, 113 S. Ct. 263 (1992) (citations omitted), citing *Clark v. Secretary of HHS*, No. 90-45V, slip op. at 3 (Cl. Ct. Spec. Mstr. March 28, 1991).

A. MEDICAL RECORDS *ET AL*.

The Court turns first to the recorded facts drawn from the medical records engendered and maintained by those responding to, and treating, Petitioner's condition. The Court gleaned the following from the most pertinent of the medical records:

Petitioner had preexisting Meniere's disease.[6] *See*, *e.g.*, Pet. Ex. 2 at 48. She received the influenza vaccine at work on 10 November 2004. Pet. Ex. 18 at 2. On 20 December 2004, Petitioner visited Dr. Zulfiqar Ahmed due to cloudy vision lasting three days. Pet. Ex. 20 at 1. Under "Allergies" were listed several medications, substances, and foods. *Id*. On a form checklist of potential complaints were marked sore throat and muscle aches. *Id*. Under "Assessment/Plan," Dr. Ahmed wrote, "Allergic Rhinitis" and "Mild Pharyngitis" in addition to other phrases describing Petitioner's then current state that are not relevant here.[7] *Id*. Later, Dr. Ahmed described Petitioner as suffering from "multiple allergies." *Id*. at 2; see also Pet. Ex 2 at 44-45 (noting Petitioner had "allergies to multiple drugs" and "multiple food allergies"). In her affidavit, Petitioner recounts that she also was experiencing muscle aches during that time. Pet. Ex. 1. On 30 December 2004, she received both the pneumococcal (Pneumovax)[8] and meningococcal (Menactra) vaccines. Pet. Ex. 16 at 2.

After being admitted to Del Sol hospital on 27 January 2005, Petitioner was evaluated by Dr. Johanan Levine, a neurologist, on 31 January 2005. His impressions were "1. Variable (over the course of one hour) weakness of both legs," and "2. Variable sensory loss to touch and pin and position sensation in the feet." Pet. Ex. 3 at 42. Under "History" Dr. Levine described Petitioner as "a 36-year-old woman with chronic low back pain and acute onset of more severe back pain for the previous five days when she came in on 1/27/05 ... [from 30 to 31 January, the pain had become] excruciating ... to the point where she could not walk. *Id*. at 43. His examination notes provide the following:

> Motor examination shows good strength and bulk in the arms with 2+ deep tendon reflexes at the biceps, triceps and brachioradialis bilaterally. Strength, tone and bulk in the legs was abnormal on the first examination with minimal force exerted at the hips, knees, ankles and toes. ... I encouraged her to try as hard as she could even if it hurt and 5/5 strength was demonstrated in [various muscles of her legs and feet]. Deep tendon reflexes on both occasions in the lower extremities were 2+ at the knees and 2+ at the ankles.

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[6] Meniere's disease (syndrome) is "hearing loss, tinnitus, and vertigo resulting from nonsupparative disease of the labyrinth with edema." DORLAND'S, *supra* at note 3, at 538, 1124.

[7] Allergic Rhinitis is "a general term used to denote any allergic reaction of the nasal mucosa; it may occur perennially or seasonally;" and Pharyngitis is "inflammation of the pharynx ... Called also *sore throat*." DORLAND'S, *supra* at note 3, at 1628, 1415.

[8] There is listed on the Vaccine Injury Table, at category XII "pneumococcal conjugate vaccines," added to the Vaccine Injury Table on 22 May 2001. In contrast, Pneumovax is a polysaccharide type of Pneumococcal vaccine. According to the notice adding pneumococcal conjugate vaccines, "Because the CDC only recommended pneumococcal conjugate vaccines to the Secretary for routine administration to children, *polysaccharide-type pneumococcal vaccines are not covered* under the [Vaccine Injury Compensation Program] or included on the [Vaccine Injury] Table." 66 Fed. Reg. 28, 166-01, 2001 WL 535250 (emphasis added). Therefore, any injury, or portion of an injury, that is found to have been caused by the Pneumococcal vaccine Petitioner received is outside of this Court's subject matter jurisdiction to redress.

Id. at 44. His assessment was that "Although initially it appears that she has weakness in her legs, with encouragement, the weakness is no longer evident. She is in pain and may well have some underlying arthritis or systemic illness producing pain including autoimmune disorders." *Id*. at 45.

By 2 February 2005, Petitioner was seen for paraplegia,[9] severe leg pain and neurogenic bladder,[10] this time by Dr. Mark Steinhauer. Pet. Ex. 2 at 40. He noted she had developed symmetrical pain in her feet and legs in the three or four days before admission, which led to increasingly debilitating weakness. *Id*. Her pain became intense and she lost the ability to void sometime after admission to the hospital. *Id*. Dr. Steinhauer's assessment was Guillain-Barré Syndrome. *Id*. at 42. According to him, Petitioner presented "with a classic pattern of ascending paralysis [] affecting her bladder and ... nerve pain problems. *Id*. He thought the condition might be affecting her breathing as well. *Id*. Dr. Steinhauer recounted the period leading up to the onset of these symptoms as including a "recent flare up" in November 2004 of her Meniere's disease, "three courses of high-dose prednisone for her Meniere's [disease] combined with shingles[11] exposure from rubbing her son's lesion (she has a history of cold sores)," and elevated IgG for HSV, which was "significant" to him. *Id*. He associated the blurred vision with the Meniere's disease. *Id*. Dr. Steinhauer did not believe that Petitioner had multiple sclerosis. *Id*. at 43. At that point he was guarded about the prognosis because of the severity involved, as manifested by the bladder involvement. *Id*.

Petitioner underwent an infectious disease consultation with Dr. Antonio Ortega thereafter, which reiterated the "abnormally high titers to Epstein-Barr virus antibodies as well as to herpes simplex virus," and noted an exposure to shingles "just about a month ago," adding "she had acquired the chickenpox [in childhood]." Pet. Ex. 2 at 44; *see* Pet. Ex. 3 at 55. His assessment was that "she had been infected with herpes simplex in the past," and that "her Epstein-Barr virus serology results denotes a previous or possibly a fairly recent infection with this virus." Pet. Ex. 2 at 44-45. He added that "[Varicella[12]] is a common childhood virus and again, most individuals in the United States would test positive for this." *Id*. Dr. Ortega did not recommend "any form of

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[9] Paraplegia is "paralysis of the lower limbs and lower trunk." DORLAND'S, *supra* at note 3, at 1368.

[10] Neurogenic bladder is "any condition of dysfunction of the urinary bladder caused by a lesion of the central or peripheral nervous system." DORLAND'S, *supra* at note 3, at 224.

[11] Shingles (a.k.a. Herpes zoster) is a skin rash caused by acute infection of the varicella-zoster virus, the same virus that causes chickenpox in children. It is:

> an acute infectious, usually self-limited, disease believed to represent activation of latent human herpes virus 3 in those who have been rendered partially immune after a previous attack of chickenpox. It involves the sensory ganglia and their areas of innervation, is characterized by severe neuralgic pain along the distribution of the affected nerve and crops of clustered vesicles over the area of the corresponding dermatome, and is usually unilateral and confined to a single or adjacent dermatomes. Postherpetic neuralgia may be a complication. In immunocompromised patients it may disseminate and be fatal.

DORLAND'S, *supra* at note 3, at 845.

[12] Varicella is chickenpox. DORLAND'S, *supra* at note 3, at 2008.

antimicrobial therapy," but thought "[t]he focus should be on arriving at the diagnosis as to the possible cause of her [then] current symptoms." *Id*. Petitioner also underwent a rheumatology consultation with Dr. Rajendra Marwah, who stated that she was "unable to lift her legs from the bed," but noted that her "deep tendon reflexes [were] normal." *Id*. at 48.

Petitioner was evaluated with neurodiagnostic testing: both electromyography[13] and a nerve conduction velocity report. Pet. Ex. 2 at 50. The interpretation of the nerve conduction was:

> Perfectly normal in the upper extremities. The F reflexes are more difficult to interpret because I am often finding that this particular machine here at Del Sol [hospital] I do not get F reflexes. However, in the upper extremities there were responses just inconsistent where as in the lower extremities I never saw anything close to being an F wave.
>
> The sural sensories are definitely low in amplitude. Motor responses were abnormal with regard to the distal latency and left tibial motor, and the peroneal motor responses were both abnormal in configuration and duration of the compound muscle action potentials.
>
> The velocities of the lower extremities were within normal limits but not as fast as the upper extremity which is marginally significant.

Id. at 51. The electromyography testing was not very "definitive" possibly because insufficient time had passed since onset, and electromyographic results had not yet shown themselves. *Id*. The conclusion was "abnormal nerve conductions in the lower extremities only," with "poor recruitment in the lower extremities on EMG," which findings were stated to be "compatible with the diagnosis of Guillain-Barre syndrome." *Id*.

Dr. Johanan Levine again saw Petitioner on 7 and 8 February 2005, for another neurology consultation. On 7 February 2005, Petitioner was noted to be able to move her legs, and normal touch sensation was noted; however, he also noted " variable leg weakness and sensory loss." Pet. Ex. 2 at 72. Dr. Levine then first raised the competing diagnoses of transverse myelitis and meningitis (possibly secondary to IVIG treatments or infection), and encouraged a "search for infection (especially viral, TB, [or] fungus)." *Id*. On 8 February 2005, according to Dr. Levine, Petitioner was "stable" and was "moving [her] legs better." *Id*. at 74. Dr. Levine abandoned GBS as a diagnosis, and thought the symptoms could be summed up as "just back pain [and] neurogenic bladder." *Id*. He thought she had suffered from "sterile meningitis" that was resolving with steroids and the cessation of IVIG. *Id*. at 74-75. He concluded by averring, "This is not and never has been Guillain Barre Syndrome (or viral meningitis)." *Id*. at 75.

On 9 February 2005, Petitioner was again evaluated by Dr. Steinhauer. He stated that she had "not really been out of bed yet," as she felt "quite shaky when she is standing on her feet" and

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[13] Electromyography is "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." DORLAND'S, *supra* at note 3, at 598.

"gets increased sensory, paresthesia in her legs with standing and walking," although by then "her pain [was] subsiding." Pet. Ex. 2 at 110. His assessment continued to be GBS, even though he was "aware that Dr. Levine does not necessarily support [the GBS] diagnosis but [Dr. Steinhauer's] assessment [was] based on a relatively typical clinical presentation as well as positive response to IVIG." *Id*. at 111. Regarding precipitating causes, Dr. Steinhauer considered the influenza vaccination and viral exposure, but did not mention either the meningococcal or pneumococcal vaccinations. *Id*. She was noted to be tachycardic,[14] which Dr. Steinhauer stated was "not unusual in [GBS] patients." *Id*. at 112. He was more optimistic regarding her prognosis than he had been originally, as bladder function was "markedly improved" by then, and physical/occupational therapy was planned. *Id*. Interestingly, her cerebrospinal fluid was "consistent with viral meningitis." *Id*. Dr. Steinhauer cited Dr. Levine's preferred diagnosis of aseptic meningitis caused, ostensibly, by IVIG administration; however, she "did not have a lumbar puncture with CSF analysis prior to administration of the IVIG," which "was administered to her based on [] concern that delay in treatment of [GBS] could lead to permanent impairment, including a permanent neurogenic bladder." *Id*.

Among other doctor's visits that followed the period of onset and climax of Petitioner's injury, her discharge summary from a 11-19April 2006 stay at Las Palmas Medical Center states the following to summarize Petitioner's clinical course at discharge from this other period of illness (i.e., not the injury alleged to be vaccine-related):

> The patient's recovery was slow and erratic but consistent. The workup did not show a conclusive diagnosis. ... [the results of] EMG and nerve conduction studies ... were compatible with normal findings. Dr. Cota['s] ... assessment included major depression with likely recurrent somatization[15] disorder. Dr. Antonio Ortega ... denies any possibilities of a demyelinating disorder, perhaps a variant Guillain-Barre due to this clinical presentation to be similar to previous one. Multiple allergies to antibiotics were recorded, and apparently the previously assessed meningitis according to Dr. Ortega was due to the use of immunoglobulin treatment that was initially prescribed on clinical grounds for what was suspected back at Del Sol last year in 2005 as an evolving Guillain-Barre. [A newer health problem which developed in 2005-06] was discussed with Dr. Zulfigar [*sic*] Ahmed over the phone and he explained that his impression was that in spite of the complex history, the patient's condition was most likely associated to somatization of a clinical depression. However, this remains presumptive diagnosis and are [*sic*] conclusive exclusion of other less common neurological disorders remains needed.

Pet. Ex. 15 at 3-4.

B. Testimony Bearing on Entitlement

1. Marcel Kinsbourne, MD

[14] Tachycardia is "excessive rapidity in the action of the heart." DORLAND'S, *supra* at note 3, at 1850.

[15] Somatization is "the conversion of mental experiences or states into bodily symptoms." DORLAND'S, *supra* at note 3, at 1721.

At the hearing, Petitioner "present[ed] Dr. Kinsbourne to support his opinion to a reasonable degree of medical probability that Petitioner Ms. Whitener's GBS was caused by her meningococcal vaccination that she received on December 30, 2004." Tr. at 5. Dr. Kinsbourne began his comments by reciting what he considered the essential facts in this case:

> Ms. Whitener was vaccinated with Prevnar and with Menactra on December 20, 2004. Thirty-three days later, ... on January 22 of '05 her feet became numb and tingling, and those manifestations rose up her body gradually so that by five days later they had reached her waist.
>
> At the same time she became weak and could not move below her chest, and, thirdly, she developed urinary retention and needed to be catheterized. She had severe lower back pain, found it increasingly difficult to walk and was admitted to the hospital on January 27.
>
> The investigations really cast no further light on the diagnosis, but the presentation was typical of Guillain-Barré syndrome, GBS, and there was a myelitic element which Dr. Safran referred to and which I referred to in my supplemental report, but there was no abnormality of the spinal cord on MRI. At any rate, GBS was diagnosed and she was treated with IVIG, and from that point on her condition got gradually significantly better.

Tr. at 8-11. As to her current diagnosis, more recent medical records mostly categorize her condition as GBS, "but one of her treating neurologists, Dr. Levine, favors transverse myelitis." Tr. at 11.

Dr. Kinsbourne explained his postulate that the meningococcal vaccine was causative of Petitioner's GBS, because "the GBS began within a proximate time period of the Menactra vaccination, that Menactra has recently been incriminated in causing cases of GBS," adding that "it's for that reason that Menactra was added to the Vaccine Injury Table, and I perceived no other viable alternative from causation for Ms. Whitener's condition." Tr. at 12.

Regarding the dispute between GBS and TM as to which syndrome more correctly describes the condition from which Petitioner suffered, Dr. Kinsbourne explained that Petitioner suffered from "a mixed syndrome":

> She shows abnormality of her peripheral nerves and also some abnormality of the spinal cord. Had she only had the peripheral nerves it would be a mainstream GBS. Had she only had the spinal cord findings it would be transverse myelitis. She in fact has both or evidence of both, and that is an unusual but by no means unheard of situation, and it would be generally regarded as a GBS variant. In any case, whichever name one uses would not affect my opinion.
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> ...[T]here are signs of some involvement of the spinal cord. Now, with these immune-mediated neurological disorders there's quite often significant overlap between conditions having separate beings. The word encephalomyelitis,[16] for

[16] Encephalomyelitis is "inflammation involving both the brain and the spinal cord." DORLAND'S, *supra* at note 3, at 610.

> example, indicates an overlap between problems of the brain and of the spinal cord. Similarly, there can be overlap of involvement of the spinal cord and the nerve roots and the peripheral nerves. The literature by and large does not reflect any difference in principle between the mechanisms of injury of these variants, and I don't think that one's conclusion just to causation would be affected depending on which particular GBS variant is involved.

Tr. at 12-14. Regarding whether distinct aetiology should be addressed in the event that Petitioner suffered TM instead of GBS, Dr. Kinsbourne clarified:

> It's one condition. I don't see her as having two distinctive disorders at all. I think it is a matter of the anatomical distribution of the inflammation caused by the vaccination, which involves both [areas of the nervous system]. ... [Distinguishing which of the two syndromes it bears more resemblance to is] a semantic issue and not a clinically meaningful one. Sometimes the brunt of the injury may be borne by the spinal cord and maybe there will be a certain amount of peripheral nerve involvement and sometimes the other way around. In this case you'll see both.

Tr. at 14-15.

There was a dispute between the parties' experts as to what weight to attribute to certain EMG test results from early-on during Petitioner's hospitalization, results upon which the GBS diagnosis was at least somewhat based. Tr. at 15. This dispute bears upon the question of whether the condition that affected Petitioner was more akin to GBS or to TM. If one must be included and one excluded, the record lends more support to a diagnosis of GBS than to TM, according to Dr. Kinsbourne:

> I see the report from [treating neurologist] Dr. Mark Steinhauer ... a clear conclusion as to a GBS diagnosis. I don't actually see in the record that those tests have been reinterpreted in any way, so I see no reason not to accept them for what they are reported to indicate. ... Perhaps I should add that the myelitic component must not have been there in March because it didn't show up on the MRI of the spinal cord, and actually in about nine cases out of 10 of transverse myelitis you would see some MRI abnormality of the spinal cord. I still believe that the spinal cord was to some extent involved, but not in a very severe fashion.

Tr. at 16.

On cross-examination, Respondent reminded Dr. Kinsbourne that "Petitioner actually received both the pneumococcal and the meningococcal vaccines on that day," and that "Petitioner had pharyngitis on the day of the vaccinations," and that "in about one-half to two-thirds of all GBS cases there's an antecedent infection," to which Dr. Kinsbourne acceded. Tr. at 18-19. Dr. Kinsbourne also conceded that "Petitioner's lab results revealed elevated titers for both Epstein-Barr virus [and] herpes simplex virus," that "Petitioner gave a history of being exposed to shingles prior to her hospitalization ... around the same time as the vaccination she received in December 2004," and that "an elevated IgG response to herpes zoster is what you would expect for a second exposure to that virus" oftentimes, in cases where "the immunity had held from childhood." Tr. at 19-20.

Dr. Kinsbourne explained why he considered, but ultimately declined, those viral infections as causative elements in Petitioner's condition:

> IgG elevations can last for years, many years, after an infection, and there's no IgG when the infection occurred. In fact, that is pointed out in [Petitioner's medical records (Pet. Ex. 2 at 44-46)]. The Epstein-Barr virus serology results denote a previous or possibly fairly recent infection, so you cannot base the assumption that this lady actually had an infection within the proximate time period from IgG findings alone. I don't find that of assistance in coming to a causation conclusion.

Tr. at 23. This led to the following interchange between Respondent's Counsel and Dr. Kinsbourne:

> Q Well, as I understand your opinion here today, you've discounted Petitioner's elevated Epstein-Barr virus titers, you've discounted her elevated herpes simplex virus titers, and you've discounted the elevated herpes zoster virus titers, in addition to the fact that she was exposed to shingles one month before her illness as a cause of her illness. You're discounting all of those, aren't you?
>
> A I don't understand what you mean by discounting. Everything that's a fact is potential evidence. However, I've already explained why these findings by themselves don't amount to the level of a reasonable probability of an alternative diagnosis. It doesn't mean I discount them. I just don't find them sufficient evidence.
>
> Q Now, you're aware, Dr. Kinsbourne, that your opinion in this case is that none of the treating doctors in this case attributed Petitioner's neurologic injury to a meningococcal vaccine in December 2004. You're aware of that?
>
> A Well, none of them attributed to that or to anything else. I mean, nowhere in the record could I find a definitive causation opinion.

Tr. at 25-26.

Concerning the MMWR Dispatch cited in Dr. Kinsbourne's report[17] (Pet. Ex. 15 at 4), Respondent pointed out in cross-examination that the conclusion of that study was that "The evidence is insufficient to conclude that meningococcal vaccine causes GBS," which Dr. Kinsbourne distinguished on the basis of the standard used: In stating a conclusion sufficient to satisfy the Program's burden of proof, "I don't need to rely on formal epidemiology." Tr. at 28-29. In contrast, Dr. Kinsbourne thought it probative that the meningococcal vaccine was added to the Vaccine Injury Table as a covered vaccine, adding "the reason that it was included was precisely the relationship with GBS." Tr. at 29-30. He added that "although formal epidemiology has not been done, the [Program's legal standard] for causation does not rise to a scientific level." Tr. at 30. As to why he cited the MMWR Dispatch as supportive of his opinion, he explained:

> [T]hat was the first report which took note of the apparent increased incidence of -- and there are actually further reports subsequently which strengthen that relationship. In my report on page 2 I cite a subsequent statement which says, "There appears to be a small increased risk for GBS after MCV4 vaccination."
>
> [F]ormal epidemiology has not been done. The evidence based standard of the scientific level of certainty has not been reached for this causation. The evidence was insufficient [*sic*] to put Menactra on the Vaccine Injury Table, and the reason for putting it there was specifically the relationship to GBS.

Tr. at 31-32.[18]

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[17] Dr. Kinsbourne's expert report contained the following summary:

> On September 30, 2005, the FDA and HHS issued a Health Alert regarding the Menactra meningococcal vaccine and GBS. On October 6, 2005, the CDC issued an MMWR dispatch, which featured summary reports of five cases of GBS following administration of meningococcal conjugate vaccine. They summarized the symptom onset time as occurring 14-31 days after the vaccination. An ACIP announcement dated February 21-22, 2007 overviews reports to VAERS and VSD of GBS among recipients of Menactra during the period, October 2006-2007. Two new cases were reported, raising the count to 19. The authors point out that the increased risk of GBS after Menactra in the VAERS data falls (slightly) short of conventional significance, as calculated by comparing the estimated background incidence with the incidence of reported cases following Menactra. However, it is recognized that passive reporting systems such as VAERS may capture as few as five to [ten] percent of the actual incidence. Therefore the statistical probability may be a gross underestimate of the vaccine's adverse effect. The Report concedes "there appears to be a small increased risk for GBS after MCV4 vaccination...". Also, "Timing of neurologic symptoms within 1-5 weeks of vaccination among reported cases is of concern." GBS within six weeks of Menactra vaccination is reportable to VAERS and the vaccine has been added to the Vaccine Injury Table.

Pet. Ex. 18 at 2.

[18] If fine, the MMWR Dispatch states:

> ...[T]he rate of GBS based on the number of cases reported within 6 weeks of administration of [the meningococcal vaccine] is similar to what might have been expected to occur by chance alone. However, the timing of onset of neurologic symptoms (i.e., within 2–5 weeks of vaccination) is of concern. In addition, the extent of underreporting of GBS to VAERS is unknown; therefore, additional cases might be underreported....
>
> To date, evidence is insufficient to conclude that [the meningococcal vaccine] causes GBS. An

That led Respondent to challenge Dr. Kinsbourne's categorization of Petitioner's illness as GBS instead of TM, based on the presence of a "sensory level," which is not associated with GBS. Tr. at 33. Dr. Kinsbourne responded that "GBS is not associated with a clearly demarcated sensory level," but that "there was a myelitic -- in other words a spinal cord -- involvement also, which may have been responsible for the sensory level." *Id*. Dr. Kinsbourne believed the presence of the spinal cord involvement is what led one treating neurologist (Dr. Levine) to state that Petitioner's illness "was not and never was GBS." *Id*. Dr. Kinsbourne pointed to the conflict between the treating physicians as proof of the combined/conflated nature of the illness as being both spinal/myelitic as well as peripheral. Tr. at 33-34.

The Court invited Dr. Kinsbourne to elaborate on the significance of the sensory level in this case, to which he answered:

> Well, if there is a lesion at the level such as the neck or the waist or the chest then the sensory tracts that bring back information from below that level can no longer reach the brain, and therefore the individual's ability to feel things is impaired below the level of the spinal cord injury.
>
> Now that, if it's caused in the spinal cord, is almost always associated with, or at least with something you can see on an MRI, and there was actually nothing to be seen on Ms. Whitener's MRI, so quite how discrete the sensory level was is hard to tell from the examination.

Tr. at 34.

Respondent also raised certain symptoms of "severe" myalgias and eye draining/matting mentioned by Petitioner herself in her affidavit, which she experienced between an influenza vaccine she received some time before the meningococcal vaccine, and the meningococcal vaccine itself. Tr. at 35-36. Dr. Kinsbourne saw no "evidence that any of [those symptoms] has anything to do with her GBS." Tr. at 36. Likewise, Respondent noted that on the day she received the meningococcal vaccine, Petitioner was diagnosed with suffering from allergic rhinitis and mild pharyngitis. Tr. at 37. Dr. Kinsbourne responded that these were often concurrent symptoms, and unremarkable. Tr. at 38.

Penultimately, Respondent challenged Dr. Kinsbourne's statement of biologic plausibility for the proposed association between the meningococcal vaccine and GBS. Respondent questioned whether Dr. Kinsbourne was asserting that there existed a proven association between the two that

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> ongoing known risk for serious meningococcal disease exists. Therefore, CDC is recommending continuation of current vaccination strategies. Whether receipt of [the] vaccine might increase risk for recurrence of GBS is unknown; avoiding vaccinating persons who are not at high risk for meningococcal disease and who are known to have experienced GBS previously is prudent.
>
> ...The manufacturer has sent letters to health-care providers and is updating the package insert to reflect GBS has been reported in association with the vaccine.

Pet. Ex. 18 at 6-7 (MMWR Dispatch, "Guillain-Barré Syndrome Among Recipients of Menactra Meningococcal Conjugate Vaccine — United States, June–July 2005," October 6, 2005 / 54 (Dispatch);1-3).

would satisfy scientific causation standards. Tr. at 39. Dr. Kinsbourne responded that his assertion concerned plausibility of a causal connection, not certifiable satisfaction of scientific certainty:

> The medical community is well aware that many different viruses and bacteria can set off a GBS. These facts are most clear for the influenza vaccine and the tetanus vaccine, and they are also clear for a variety of other infections. The one for which it's most clear is campylobacter [jejuni], but it's certainly recognized that numerous infections and vaccinations can on rare occasions cause GBS. ... If you're talking biological plausibility[,] it is perfectly clear from documents that we have reviewed that the medical community thinks it's biologically plausible that Menactra can cause Guillain-Barré syndrome. ... I do not think that that's a contentious point.

Tr. at 38-39. Lastly, Respondent questioned how Dr. Kinsbourne could distinguish the effect of the Meningococcal vaccine to precipitate GBS from the pneumococcal vaccine (pneumovax)[19] administered at the same doctor visit. Tr. at 41. Dr. Kinsbourne explained that, to the best of his knowledge, the meningococcal vaccine had been implicated as a potential cause for GBS, whereas the polysaccharide-type pneumococcal vaccine had not. *Id*.

2. Arthur Safran, MD

At the hearing, Dr. Safran reflected that, from his work as the director of a multiple sclerosis clinic, he had "treated a large number of patients with Guillain-Barré syndrome and with transverse myelitis," and had acquired "particular insight into the condition known as transverse myelitis." Tr. at 43. He added that he had "more than the standard neurologist's experience and qualifications [in] treating these illnesses." *Id*. Generally stated, Dr. Safran's medical opinion, "to a reasonable degree of medical certainty," was that Petitioner did not suffer "a vaccine-related injury as a result of receiving pneumococcal and meningococcal vaccines." Tr. at 44. Specifically, he dissected the questions or issues affecting his opinion into specific categories of: "the onset, the pathology, the sequelae, the physical findings, the issue of a continuum of illnesses between peripheral and central nervous system disorders, the electromyelogram, [and] the concept of a sensory level." Tr. at 45.

The first disputed issue Dr. Safran addressed was how to categorize Petitioner's illness into a single diagnosis, a discussion that he blended with alternative causata that may have caused Petitioner's condition, whatever it may have been. The Court notes that this discussion did not lend itself well to be logically understood by the Court. He began by describing GBS as "a disease of roots and nerves in the peripheral nervous system," "a predominantly motor weakness," "never associated with a sensory level, and all the reports of Guillain-Barré syndrome are reported with reflex change." Tr. at 45-46. He found the last descriptor especially important, as he stated all the cases of diagnostic overlap cited by Dr. Kinsbourne included reflex loss. Tr. at 46. For Dr. Safran, "even if one believes in the possibility of some overlap the reason that those stories come to light

[19] Pneumovax is a polysaccharide-type pneumococcal vaccine, not included on the Vaccine Injury Table, and therefore outside the bailiwick of this Court's subject matter jurisdiction. 66 Fed. Reg. 28, 166-01, 2001 WL 535250. Any injury, or portion of injury that can be attributed to the pneumovax vaccine is therefore not compensable in the Vaccine Program.

is because of the loss of reflexes because it's a peripheral nervous system disorder, so again it is often the sequelae or what follows a viral or bacterial illness in most of the cases." Tr. at 46. Even though Dr. Safran did not articulate the connection between those two premises, this statement led his discussion to address the "several other more reasonable explanations," perhaps for GBS, the illness he had been discussing, but maybe for TM, as that is what Dr. Safran believed Petitioner had suffered from:

> In the first place there was an active throat infection at the time that the meningococcal vaccine was given. In the second place, there was a very recent exposure to herpes zoster, which is known to cause this condition. The absence of any M component[20] to the elevation noted in the antibodies is expected for a reinfection, so those are at least two other more likely causes since they are known to be associated. Guillain-Barré syndrome usually runs a course with improvement, although it doesn't always get better, but it's important to point out that those people who have bladder involvement with Guillain-Barré syndrome are much more sick than those that don't, and of the patients who actually develop bladder retention 83 percent of them end up on a respirator, and it would appear to me that in the present instance that was nowhere near the case. So the examination findings, which include preservation of reflexes, in this instance the discovery of the presence of a normal H-reflex, which in effect is a fancy way of doing a reflex, the sensory level all exclude any kind of reasonable neurologist from considering this to be Guillain-Barré syndrome.

Tr. at 46-47.

Next, Dr. Safran engaged in *eisegesis*[21] to misstate the treating physicians notes: "Dr. Steinhauer felt [Petitioner] had an active viral syndrome in addition to Guillain-Barré, which would imply a causal relationship." Tr. at 47. Dr. Safran sought to summarize Dr. Levine, the treating doctor who he relied on the most to state that Petitioner's condition was more akin to TM than to

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[20] An immunoglobulin is "any of the structurally related glycoproteins that function as antibodies, divided into five classes (IgM, IgG, IgA, IgD, and IgE) on the basis of structure and biologic activity.... In addition to the effects produced solely by the binding of antigen by antibody, e.g., viral neutralization or the inability of some bacteria to invade mucosal surfaces when coated by antibody, certain classes of antibodies can trigger other processes when bound to antigen: IgM and IgG activate the classic complement pathway, IgA and IgG activate the alternative pathway, and IgM, IgG1, and IgG3 act as opsonins, triggering phagocytosis of the bound antigens by macrophages and neutrophils. DORLAND'S, *supra* at note 3, at 912.

[21] *Eisegesis* is the reading of content and meaning into a document or text by the reader's insertion, as contrasted to the proper interpretive hermeneutic of *exegesis*, reading a text to derive the meaning invested by its author or authors, so as to apply that contextual meaning to the present application. *See* Craig Allen Nard, "*A Theory of Claim Interpretation*," 14 HARV. J.L. & TECH. 2, 60-61 (Fall 2000); Jeffrey Brauch and Robert Woods, "*Faith, Learning and Justice in Alan Dershowitz's the Genesis of Justice: Toward a Proper Understanding of the Relationship between the Bible and Modern Justice*," 36 VAL. U.L. REV. 1, 15-16 (Fall 2001); Laura Kalman, "*From Slavery to Freedom*," 90 GEO. L.J. 161, 163-64 (Nov. 2001).

GBS,[22] saying Dr. Levine "thought she probably had transverse myelitis, and at one point he thought that it was largely hysteric[,] that he could fully persuade her to fully be strong with a lot of encouragement when she wasn't without a lot of encouragement." Tr. at 47-48. Dr. Safran added on that same topic that:

> in terms of anything that's now persisting neurologically there is no data that anything is wrong or that there's been any persistent deficit; that there appears to be a very substantial psychological difficulty. This has been well documented in the records, and one would be hard-pressed to say that there is any structural disease of the nervous system.

Tr. at 48. Unfortunately, Dr. Safran did not cite where in the medical records this was "well-documented" so that the Court could see for itself if such a broad claim is supported therein, especially in those records engendered during her hospital stay for the injury at bar.

Discussing the dispute between expert witnesses regarding proper categorization of Petitioner's injury, Dr. Safran stated that he and Dr. Kinsbourne agree "that there is a problem in the spinal cord," but distinguished his opinion from Dr. Kinsbourne's in that he saw "absolutely no reasonable evidence here to suggest that there is something wrong in the peripheral nerves." Tr. at 48. For Dr. Safran, the nerve conduction and H-reflex testing results serve to preclude peripheral nerve involvement, and thus a GBS diagnosis as well:

> The nerve conduction times in the electromyelogram ... are normal, and when they were repeated when she [had] "recovered" from this phase of the illness[,] there was no difference in the nerve conduction times. The fact that she continued to have a normal H-reflex should exclude the diagnosis [of GBS]. ... [Normal results for H-reflex require that both] the afferent, that is the sensory part of the nerve, and the efferent[,] or the motor part of the nerve[,] have to be normal. Now, that doesn't happen in a Guillain-Barré syndrome.

Id.

Dr. Safran thought "the absence of F-waves ... cannot be taken into account," perhaps because "that machine doesn't do well on" reading F-waves. Tr. at 49. Without further comment in support of that exclusion, Dr. Safran moved on to repeat what he had said before about equivalent values in nerve conduction in comparing "the time when she was felt to have active neurologic impairment and the time afterwards." *Id*. Altogether these results led Dr. Safran to the conclusion that "that test simply doesn't enter into a reasonable discussion of what's wrong here." *Id*.

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[22] Notwithstanding Respondent's statements in pleadings and Dr. Safran's perseveration throughout, the Court is unaware of a single treating doctor preferring transverse myelitis as a final, definitive diagnosis, and, to the Court's knowledge, Respondent has not proffered any evidence of such. As discussed *supra* at pages 4-6, Dr. Levine (*et al.*) entertained several potential diagnoses; Dr. Levine's conclusion in particular favored neither TM or GBS, but either aseptic meningitis or separate, more minor problems. The Court remains a bit surprised that neither party explored further the diagnosis of aseptic meningitis, considering the vaccine at issue was the meningococcal vaccine.

Next, Dr. Safran introduced transverse myelitis (TM) as "a very longstanding, well understood condition at least in clinical terms." Tr. at 50. He then proceeded to describe that understanding in connection with the case at bar:

> The first is that it very often has back pain with it, whereas Guillain-Barré syndrome does not. Ms. Whitener has back pain. Secondly, all instances of Guillain-Barré syndrome have reflex abnormalities, and in the standard text on peripheral nerve disorders by Schaumburg it says that if you have reflexes you should not seriously entertain the diagnosis. The third is that she has a sensory level, which is never seen in a Guillain-Barré syndrome. ... [I]f a person has a level below which they don't feel something normally the abnormality must be in the spinal cord. It cannot be, and I want to emphasize cannot be, in a peripheral nerve.
>
> The next point is the bladder involvement. It is certainly seen in both conditions, but when it's seen in the Guillain-Barré syndrome usually you end up on a respirator and you're severely weak and you can't walk at all. The bladder involvement in transverse myelitis is a hallmark of that condition.
>
> I already discussed the EMG so I don't want to press that, but there are examination findings also that relate to this. That is to say there are extensor plantar responses, so-called Babinski tests, who were found by two different doctors at different times. That is never -- emphasize never -- a part of the Guillain-Barré syndrome and almost always part of transverse myelitis.

Tr. at 50-52. He responded in the negative to the question asked on direct examination by Respondent, whether " the boundaries between Guillain-Barré syndrome and transverse myelitis are indistinct," a concept ascribed to Dr. Kinsbourne's theory. Tr. at 54-55. Dr. Safran concluded this distinguishment of the two conditions by asserting that, "I mean, I think that the idea that this is a Guillain-Barré syndrome would not be taken seriously in a discussion among neurologists." Tr. at 52.

The Court notes that this seems a singular (and unnecessary) insult to lay at the feet of not only Dr. Kinsbourne, but the treating doctors who diagnosed the illness as GBS. It also left completely unanswered whether Dr. Kinsbourne's theory of mixed symptomatology is medically plausible. Even if the descriptive, conceptual categories of GBS and TM are hermetically sealed, that does not answer whether an individual like Petitioner could sustain some of both to varying degrees. Since both GBS and TM are syndromic terms describing only observable or measurable phenomena, and do not implicate aetiology, pedantic obsessing about how to catalogue it is not nearly as helpful to the Court's task as identifying what might have caused it. If they are both typed as autoimmune reactions to immune challenges (which Dr. Safran stipulates (Tr. at 57)) and both have been credibly postulated (even if not proven) to be associated with the immune challenge of vaccination in some circumstances, the question is whether the instant case presents such a circumstance. *See* K. Stratton *et al.*, *supra* at note 4. In that regard, Dr. Safran's commentary was of more limited utility.

When asked how "the diagnosis in this case" affected his opinion, Dr. Safran responded:

> [T]he diagnosis here is transverse myelitis. Now, I just want to be clear that in all the instances in which there's felt to be a possibility an overlap has existed that has come up because the examining doctor found some reflex change, which caused them to then make further evaluation. None of the reported cases has preservation of normal reflexes and so I think that that immediately takes it out of this category. You can't have an overlap until you have the first diagnosis, and the criteria I think in fact made available and referred to by Dr. Kinsbourne, the so-called Asbury criteria and more recently the Roper criteria, all require reflex change, so you can't even consider that diagnosis reasonably, as Schaumburg points out, in the presence of preserved reflexes.

Tr. at 55. Dr. Safran statement that the diagnosis was TM is rather more absolute than the evidence supports, as derived from the treating doctors' records, which indicate considerable disagreement over what "*the* diagnosis" was in Petitioner's case.

Also within this context, Dr. Safran discussed potential alternative causata: "there was apparently ... an antecedent pharyngitis" as well as "an antecedent varicella exposure, and the elevated immunoglobulins are consistent with a reinfection." Tr. at 51. The Court queried Dr. Safran about that pharyngitis, which was noted in concurrence with allergic rhinitis on the date of vaccination, whether it could be attributed to microbial influence or was merely allergy symptoms. Tr. at 50. Dr. Safran answered:

> I don't see how one can say, sir. Unless there's a long history of allergic pharyngitis, why would you choose to now be allergic out of no other precipitant? Sore throats are almost always viral. It seems to me that by far the likelihood is that it's a viral illness.

Id. The Court also asked Dr. Safran if transverse myelitis may be caused by autoimmune reaction, and he stated that it could. Tr. at 52.

Dr. Safran responded to direct examination to indicate that both varicella zoster ("the virus that causes shingles") and Epstein-Barr virus have been associated with TM, and that "Petitioner had elevated titers to both of those viruses." Tr. at 53-54. He was not aware of any causal association found between meningococcal vaccine and TM. Tr. at 54.

Regarding whether an aetiology emerged from the treating doctors, Dr. Safran testified that none of the treating doctors attributed Petitioner's illness to the meningococcal vaccine, but neither did they reach any conclusion about what to attribute causation to, even if they did consider the influenza vaccine and ongoing viral illness. Tr. at 53. He added later that "with transverse myelitis [it is] common that you won't be able to identify what caused it," and "even when you think you've identified it you do it by inference." Tr. at 56. He linked the appearance of TM with another condition with which he also has great experience: "A fair number of people who have transverse myelitis, probably approaching 50 or 60 percent, ultimately turn out to have multiple sclerosis, and that turns out to be the diagnosis. The diagnosis may not be made for many years after the initial transverse myelitis event." *Id*.

In response to cross examination, Dr. Safran conceded that supporting evidence was lacking to establish that Petitioner "actually had the shingles." Tr. at 58. Regarding the titer levels derived from testing, he agreed that the levels cited in the medical records do not allow determination of "when the exposures to these viruses occurred." *Id*. A question from Petitioner led Dr. Safran to stipulate that "if [Petitioner] had the chickenpox in her youth[,] that could be an explanation for having a high herpes zoster IgG level in her thirties [during which her injury occurred]," but led to the following exchange:

> A Well, there are two answers to that. The simple answer is yes, but in this instance we know she had an exposure. You wouldn't expect her to contract the disease a second time. That's exactly what the antibodies are designed to prevent, so I think it's an irrelevance when she was exposed to herpes. It's a highly, extremely infectious condition, 100 percent virtually, so we know that she had an exposure so you would expect her body to protect her. You wouldn't expect her to get herpes zoster or to get chickenpox again.[23]
>
> Q And I agree with you that it's irrelevant. We still don't know whether that IgG level is something that happened when she was six or 36.
>
> A Yes, but we know she was exposed in relationship to her illness.
>
> Q Well, that's really not my question. My question is the IgG level that you talk about in the blood test, you can't tell whether the herpes zoster exposure was when she was six years old or 36 years old.
>
> A That's correct.

Tr. at 58-59. Unfortunately, this led the testimony toward a bit of theatric absurdity, which did not aid the Court or elucidate Dr. Safran's opinion for the Court's understanding, as evidenced by the following exchange:

> Q Have you ruled out in your opinion today that the meningococcal conjugate vaccine such as Menactra could be one of those many potential factors for causing transverse myelitis?
>
> A You know, no reasonable physician would accept that in terms of scientific validity, but in terms of the Vaccine Injury Program biologic plausibility is a different standard and so anything is possible. It could have been the soup she ate the day before, let alone that particular vaccine. There's certainly no data in the literature to suggest that that vaccine has a relationship to transverse myelitis.
>
> Q You have stated this, but I just wanted to clarify. You're not saying that you've developed an opinion as an expert from a reasonable degree of medical probability that Ms. Whitener's condition was caused by exposure to shingles a month before her hospitalization, are you?

[23] Even if Petitioner might not experience the chickenpox again, shingles (herpes zoster) could reemerge in an individual who had suffered from the chickenpox as a child. *See supra* at note 11.

> A Well, yes, I think that's a reasonable possibility. I still think it's reasonably possible that the exposure to whatever it was that caused her pharyngitis is a reasonable possibility, or one may never know, or it may turn out, and I hope that's not the case, that 10 years from now she'll have multiple sclerosis.

Tr. at 59-61. A few moments later, Petitioner tried again to determine from Dr. Safran whether he thought shingles were a probable cause of Petitioner's injury:

> Q ...[I]is it your opinion here today to a reasonable degree of medical probability -- not possibility ... but to a reasonable degree of medical probability -- Ms. Whitener's condition was caused by an exposure to shingles a month before her hospitalization when holding her son?
>
> A I don't know how to answer that question frankly. It doesn't permit a yes or no answer.

Tr. at 61. These exchanges left quite unclear whether Dr. Safran thought it reasonably probable that the shingles exposure was a cause of Petitioner's injury. When asked if he thought so, he responded in the affirmative, but then immediately recategorized it as a reasonable possibility. Considering the over-broad interpretation he gives to the term "possible" the Court is unwilling to assume that he offered the shingles exposure as a causal "factor unrelated" to the vaccination at issue. Dr. Safran appeared to suffer from a common semantic fallacy encountered by the Court, one that confuses biologic plausibility with either scientific certainty at one extreme or overwhelmingly improbable but conceivable possibility at the other. Biologic plausibility, as that phrase is used by the Court, means neither of those things, notwithstanding such glibly conflating overstatement from Respondent's expert.[24]

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[24] "[W]ords and language are not just shells into which things are packed for spoken and written intercourse. In the word, in language, things first come to be and are. For this reason, too, the misuse of language in mere idle talk, in slogans and phrases, destroys our genuine relation to things." Martin Heidegger, INTRODUCTION TO METAPHYSICS § 11, page 15 (Gregory Fried and Richard Polt tr., Yale University Press 2000) (1935, first published 1953). See also Gen. 1:3 ("And God said, Let there be light: and there was light."); John 1:1, 3 ("In the beginning was the Word ... All things were made by him; and without him was not any thing made that was made."). The inverse of this *logos* is at best a caricature of madness, and, at worst, the inspiration of Mephistopheles:

> "When I use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean -- neither more nor less."
> "The question is," said Alice, "whether you can make words mean so many different things."
> "The question is," said Humpty Dumpty, "which is to be master -- that's all."

Lewis Carroll, THROUGH THE LOOKING GLASS, Chapter 6 (Messner 1982).

> `Tis writ, "In the beginning was the Word!"
> I pause, perplex`d! Who now will help afford?
> I cannot the mere Word so highly prize;
> I must translate it otherwise,
> If by the spirit guided as I read.
> "In the beginning was the Sense!" Take heed,
> The import of this primal sentence weigh,
> Lest thy too hasty pen be led astray!
> Is force creative then of Sense the dower?
> "In the beginning was the Power!"

Petitioner moved on to question Dr. Safran whether he thought something else, besides either the vaccine or the shingles, was the probable cause of Petitioner's injury, also to no avail. After some objection and dispute, the Court resolved the issue by summarizing Dr. Safran's stance thusly:

> The Court understands he's saying that many of these issues are reasonable possibilities, which is speculative. I have not yet heard to a degree of medical probability, which is 51 percent or 50 percent and a feather, but that the witness is saying that these are all reasonable possibilities.

Tr. at 63. Dr. Safran agreed with that summary.

C. Post-Hearing Submissions

At the conclusion of the hearing, the Court ordered briefing by the parties, whose arguments are summarized here.

Petitioner alleges or argues:

1. "The medical records of the hospitalization reflect a presentation typical of GBS, which was diagnosed by a treating physician, and there was a myelitic element, but there was no abnormality of the spinal cord on MRI." Petitioner's Posthearing Brief at 6-7.

2. "Respondent's MMWR Dispatch itself, detailing five cases of GBS following meningococcal vaccine, indicates clearly that Respondent admits that causation was neurologically possible. The meningococcal vaccine is now part of the Vaccine Compensation Program and the reason that it was included was precisely the relationship with GBS, although the scientific level of certainty has not been reached [to establish] causation." *Id*. at 7

3. Petitioner suffered from a "mixed syndrome," which included "abnormality of her peripheral nerves and also some abnormality of the spinal cord; Petitioner argues that "evidence of both" is "an unusual but not unheard of condition. ... There can be an overlap of involvement of the spinal cord and the nerve roots and the peripheral nerves. The medical literature does not reflect any difference in principle between the mechanisms of injury of the GBS variants, so one's conclusion as to causation should not be affected by the GBS variant involved.... A number of recent articles in the medical literature support the existence of a continuum of GBS and transverse myelitis." *Id*. at 7-8.

4. "The electrodiagnostic results of the EMG test clearly supported the conclusion and diagnosis of GBS by treating physician Dr. Mark Steinhauer." *Id*. at 8.

> Thus should it stand: yet, while the line I trace,
> A something warns me, once more to efface.
> The spirit aids! from anxious scruples freed,
> I write, "In the beginning was the Deed!"

Johann Wolfgang von Goethe, Faust 37 (A. Hayward tr., Edward Moxon & Co. 1860) (first published 1828-29).

5. Dr. Safran suggests that evidence of Petitioner's having been exposed to viruses during her lifetime is a possibility for the cause to her of transverse myelitis, but not GBS.... Dr. Safran's contrary view is based, in large part, on his speculation that a malfunctioning device created the results of the EMG test that recorded an absence of F-waves, which clearly supported the diagnosis of GBS." *Id*. at 8-9.

Respondent alleges and argues:

1. "Petitioner cannot establish actual causation without demonstrating that the meningococcal vaccine was *more likely that other contemporaneous potential sources* to have caused her claimed neurologic condition. That is, in order for Petitioner to successfully prove that the vaccine was the most likely cause of her injury, she must concomitantly demonstrate that other causes are less likely," citing *Munn* and *Pafford*, while acknowledging *Walther* as contrary authority (*see* citations *infra*). Respondent's Posthearing Brief at 5.

2. "None of Petitioner's treating physicians made that connection [of a causal link between the meningococcal vaccine and Petitioner's injury at issue], a fact that–given the Federal Circuit's preference for opinions of treating physicians–should weigh against a finding of entitlement in this case," claiming *Capizzano* as support. *Id*. at 6.

3. Dr. Kinsbourne agreed that "approximately two-thirds of all GBS cases" are preceded by infection, that "Epstein Barr virus, herpes simplex virus and herpes zoster virus are known prodromes to GBS," that Petitioner was exposed to shingles (the physical manifestation of herpes zoster) around the time of the vaccinations at issue, and that Petitioner showed elevated titers to those three viruses; nevertheless he did not find the foregoing to be persuasive as alternative causes for Petitioner's injury. *Id*. at 7.

4. Respondent believes the shingles exposure and a putative throat infection at the time of vaccination are "more likely prodromes for GBS," founded upon Dr. Safran's opinion. *Id*. at 7-8.

5. GBS is one of the adverse events listed for the Pneumovax vaccine that Petitioner received at the same time as the meningococcal vaccine, and Petitioner "fail[ed] to explain why the [Pneumovax vaccination] was not the cause of her illness." *Id*. at 7-8.

6. Following other arguments which assume that Petitioner's injury was, in fact, GBS, Respondent argues (apparently in the alternative) that, per Dr. Levine, the injury was "simply inconsistent with a diagnosis of GBS;" furthermore *all* instances of GBS have reflex abnormalities, back pain is rare, and it is not associated with a sensory level. *Id*. at 8. In contrast, Petitioner's injury included a sensory level, yet reflexes persisted throughout Petitioner's symptoms, which included back pain and bladder involvement, leading Dr. Safran (and ultimately Respondent) to conclude that Petitioner's injury was actually transverse myelitis.

II. ULTIMATE FINDINGS OF FACT

Both parties' experts were personally and professionally credible; that premise is beyond a cavil of doubt in the Court's mind. Having heard both experts on numerous occasions over the

preceding years, the Court was again impressed by the knowledge of each, and of their command over the subject matter addressed. They both comported themselves as professionals of class and academic distinction. However, the way to address whether an expert witness has proffered a credible, reliable theory, that logically conforms to the specific facts of the case, is to assess the theory, not to mask personal preference with expert witness credibility determinations. *Andreu v. Secretary of HHS*, 569 F. 3d 1367 (Fed. Cir. 2009) ("A special master [cannot] cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review. A trial court makes a credibility determination in order to assess the candor of a fact witness, not to evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence."); *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) (An expert witness' theory is scientifically valid when it supports the conclusion that "it purports to show."); *Garcia v. Secretary of HHS*, No. 05-0720V, 2008 WL 5068934 (Fed. Cl. Spec. Mstr. Nov. 12, 2008) ("the question of whether an expert's theory possesses scientific bona fides goes to the persuasiveness of the evidence on the question of aetiology and causation"); *contra Egan v. Secretary of HHS*, No. 05-1032V, 2009 WL 1440240 (Fed. Cl. Spec. Mstr. May 1, 2009) (unpublished) (viewing "Dr. Kinsbourne himself" as a "defect in petitioner's case," and explaining that it was "unfortunately becoming more and more clear to the special masters that Dr. Kinsbourne is moving inexorably from the category of credible witness to a pejorative hired gun," within an analytical framework of addressing "the areas of the experts' agreements, the lack of circumstantial evidence supporting the vaccine's alleged causative role ... and finally the finding that Dr. Kinsbourne was not credible as an expert in this case"); *Snyder v. Secretary of HHS*, No. 01-162, 2009 WL 332044 at *11-12 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); *Moberly v. Secretary of HHS*, No. 98-910V, 2006 WL 659522 at *5-6 (Fed. Cl. Spec. Mstr. Feb. 28, 2006).

Therefore, the Court's task is to analyze the differences between the opinions offered to determine whether Petitioner has established a logical sequence of cause and effect, having occurred in a medically appropriate time frame, which is biologically plausible to tie together the factual sequence and explain Petitioner's injury. *See Althen v. Secretary of HHS*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005); *Pafford v. Secretary of HHS*, 451 F. 3d 1352, 1355 (Fed. Cir. 2006), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007); *Walther v. Secretary of HHS*, 485 F. 3d 1146 (Fed. Cir. 2007); *de Bazan v. Secretary of HHS*, 539 F. 3d 1347, 1352 (Fed. Cir. 2008). Respondent summarized the conceded and disputed elements of this case for the Court's benefit, noting that Dr. Kinsbourne's theory satisfies the temporal association prong set forth in *Althen*, but disputing whether he has propounded a credible medical theory that links up into a logical, causal connection when overlaid with the facts of this case. Respondent's Posthearing Brief at 9. That is to say, Respondent disputes that Petitioner has satisfactorily proven that the meningococcal vaccine *can* cause GBS and that such vaccine *did* cause the injury in this case, even if the time interval between the vaccination and the injury at issue fits plausibly with the onset window for GBS.

The first, even if not the primary, issue to address concerns classification of Petitioner's injury. Among the potential descriptions given to Petitioner's condition in January and February 2005 are Guillain-Barré syndrome, transverse myelitis, viral meningitis, aseptic meningitis, psychosomatic phenomenon, and a combination of unrelated, non-critical symptoms.

The Court starts with the treating doctors who witnessed the phenomenon under consideration firsthand. The working diagnosis used for treatment upon presentation was clearly GBS, believed to be so mostly because of its "typical clinical presentation" of a "classic pattern of ascending paralysis," and the condition's "positive response to IVIG" treatments. Pet. Ex. 2 at 42, 111. Her infectious disease consultation did not challenge that diagnosis or ascribe her condition to anything microbial (which, presumably, would include viral meningitis); Dr. Ortega's foremost priority was aeitiology. *Id*. at 44-45. The electrodiagnostic testing results did not lead to a diagnostic challenge of the working diagnosis of GBS, but were instead concluded to be "compatible with the diagnosis of [GBS]." *Id*. at 51. The only contemporaneous treating physician brought to the Court's attention that countered this diagnosis was Dr. Levine, who, after *considering* the possible diagnoses of transverse myelitis and meningitis, abandoned the GBS diagnosis (and any other potential diagnoses, including TM) and concluded she suffered from sterile (a.k.a. aseptic) meningitis, with "just back pain [and] neurogenic bladder" as her only symptoms at that point. *Id*. at 72-75. Notwithstanding Dr. Levine's disagreement, Dr. Steinhauer maintained his opinion that Petitioner's condition was and had been GBS. *Id*. at 111.

In contrast, neither of the parties' expert witnesses discussed meningitis (aseptic or otherwise) at trial.[25] Instead, Petitioner followed the treating physicians who concluded the condition was GBS, and Respondent latched on to the mention of transverse myelitis as a possible diagnosis in Dr. Levine's discussion. Of note, prior to the hearing, Dr. Safran acknowledged that GBS and meningitis were the treaters' diagnoses and that his opinion contradicted them. *See*, *e.g.*, Resp. Ex. C. During the hearing, Dr. Safran argued that the Court should ignore diagnostic test results that were more consistent with the GBS diagnosis than TM. Tr. at 49. There was also a difference between the parties regarding what weight to assign this exercise in classification. By the proportion of his testimony he devoted, and the insistence expressed therein, Dr. Safran seemed to think this was quite important. Dr. Kinsbourne expressly stated he did not find the classification to be as critical as determining whether the injury suffered was caused by the vaccine.

Dr. Kinsbourne did not dispute that there were aspects of transverse myelitis evident in the medical records, but opined that these aspects coexisted with aspects of GBS, and that, in any event, were most likely autoimmune in its biologic mechanics: "[W]hichever name one uses would not affect [his] opinion," because "with these immune-mediated neurological disorders[,] there's quite often significant overlap between [separate] conditions," such that the medical community does not emphasize "differences in principle between the mechanisms of injury of these variants." Tr. at 13. Rather than suffering from separate disease processes, or "two distinctive disorders," Dr. Kinsbourne viewed Petitioner's injury as one "mixed" condition that manifested some aspects from both GBS and TM, and he opined that distinguishing or subdividing between the two was "a semantic issue and not a clinically meaningful one." Tr. at 14. Dr. Safran loosed a volley of words, assuming the role of nomenclator to militate against the diagnosis of GBS in favor of TM, but he agreed that TM and GBS are both autoimmune in nature. Tr. at 57. In doing so, his opinion fights a non-critical

[25] The Court pauses to state, merely in passing, that it might have explored and addressed further a strange condition, defying easy classification, resembling meningitis but without apparent microbial involvement, following a meningococcal vaccination. However, the Court is not a medical expert, and does not presume to adjure counsel for either party on litigation strategy.

battle while conceding the campaign. For the Court's focus is causation, and classification is only useful to the degree it addresses that central topic. *See, e.g., Kelley v. Secretary of HHS*, 68 Fed. Cl. 84, 100 (Fed.Cl.2005) (overruling the Chief Special Master's decision as contrary to law, holding that "[t]he Vaccine Act does not require petitioners coming under the non-Table injury provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury-regardless of the ultimate diagnosis").

If the Court accepts Dr. Kinsbourne's postulate of a singular, mixed syndrome, then Dr. Safran's demarcation based on the presence of a sensory level or the absence of reflex loss assumes a lessened importance. Dr. Safran disagreed with the proposition that, for purposes of diagnostic criteria, the categories of GBS and TM were porous, but he never negated the theory that an individual might experience symptoms from both. Nevertheless, in the event classification is truly of great importance, the Court, if it must choose, finds that the condition from which Petitioner suffered more resembled GBS. It does so based on the cumulative medical records (both the contemporaneous statements of the treating physicians and the diagnostic testing) and the testimony of the experts, taken as a whole. *See* § 13(b) of the Vaccine Act. However, as the *Kelley* opinion demonstrates, the Court is not constrained to pondering over classification. There is enough ambiguity in the Record (from both treaters and experts) to support the contention to a preponderance that Petitioner suffered from a "mixed syndrome," and thus the Court finds.

The Court's next question is whether the meningococcal vaccine *can cause* GBS or related immune mediated diseases, which is a question of plausibility–what the *Althen* opinion refers to as "a medical theory causally connecting the vaccination and the injury." *Althen v. Secretary of HHS*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). Here, it is clear that no statistical evidence exists to support this contention, as no large-scale epidemiological study has been performed. The MMWR Dispatch (*see supra* at note 15) provides no theoretical construct–no theoretical biologic mechanism–to explain how the meningococcal vaccine could cause GBS, but seems to stand for the proposition that, from the limited evidence available, and based on the temporal association in the incidents reported, there is an incidental association. For Petitioner's proffer of evidence propounding the theoretical mechanism, the Court refers to Pet. Ex. 18 at 26, page 45 of the 1994 IOM Report, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality* (*see supra* at note 4):

> A characteristic pathologic feature of GBS is the presence of mononuclear cell infiltrates in peripheral nerves and roots in both a diffuse and a perivenular[26] distribution.... Lymphocytes[27] in the infiltrate are primarily T cells ... Bone marrow-derived macrophages[28] swarm into the lesions and constitute by far the most

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[26] Perivenular (perivenous) means "near or around a vein." DORLAND'S, *supra* at note 3, at 1408.

[27] Lymphocytes are "any of the mononuclear, nonphagocytic leukocytes, found in the blood, lymph, and lymphoid tissues, that are the body's immunologically competent cells and their precursors." DORLAND'S, *supra* at note 3, at 1077.

[28] Macrophages are "any of the many forms of mononuclear phagocytes found in tissues." DORLAND'S, *supra* at note 3, at 1085.

> numerous pathologic cell types in nerves. Myelin destruction appears to be macrophage mediated, either by myelin lamellar[29] stripping by macrophage processes or by vesicular[30] disruption of myelin. The role of lymphocytes in myelin destruction is unclear. The pathologic appearance of GBS is characteristic of a delayed-type hypersensitivity response and closely resembles the lesions of experimental allergic neuritis [used in rodents to study demyelinating diseases]. In addition, there is abundant evidence of immune system activation in patients with GBS...

The parties' expert witnesses both appear to concur that Petitioner suffered from some immune-mediated, autoimmune demyelinating disease, even if there is disagreement about whether that disease is classified as GBS or TM. Dr. Safran was unaware of any finding of causal association between the meningococcal vaccine and TM. However, as this Court has concluded on more than one occasion, a vaccination can mount an immune system challenge sufficient to trigger the autoimmune process, leading to immune mediated demyelination. *See, e.g., Hargrove v. Secretary of HHS*, No. 05-0694V, 2009 WL 1220986, (Fed. Cl. Spec. Mstr. Apr. 14, 2009). Stated together, certain vaccinations can trigger autoimmune reaction, which can lead to immune mediated demyelination, which may then cause the symptoms of paralysis, numbness and/or pain in syndromes such as GBS. In sum, it appears to the Court that a vaccination may theoretically cause GBS, and the MMWR Dispatch seems to implicate the meningococcal vaccine as one vaccine for which this mechanism appears plausible.

Next the Court considers whether Petitioner has proven that the mechanism discussed above was actually at work in the instant case, i.e., whether Petitioner has demonstrated to a preponderance "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, *supra*, at 1278. As part of that burden, Petitioner must address, even if she is not bound to affirmatively disprove, potential alternative *causata*. *Walther v. Secretary of HHS*, 485 F. 3d 1146 (Fed. Cir. 2007); *cf. Pafford v. Secretary of HHS*, 451 F. 3d 1352, 1356 (2006). Therefore, the Court's focus turns now to the potential alternative *causata* raised by the treating doctors and Respondent's expert. It is important in this context to recall that the treating doctors never settled on a definitive aetiology. Tr. at 53. The treating doctors, it has been seen, did not even agree on how to descriptively categorize Petitioner's illness, let alone isolate one or more efficient causes for it.

Experts for both parties agreed that infections caused by certain bacterial and viral agents are known immune challenges that can lead to GBS. *See*, *e.g.*, Tr. at 38-39. If Petitioner had suffered an antecedent infection from one of those viruses or bacteria, such infection could compete with Petitioner's claim of vaccine causation as a potential cause. In this case, Dr. Kinsbourne thought the mild pharyngitis was concurrent with the allergic rhinitis, and that the two were unremarkable. Tr. at 38. Dr. Safran, on the other hand, believed that Petitioner's symptom of pharyngitis was the result of viral infection. *See* Tr. at 60 ("I still think it's reasonably possible that the exposure to whatever it was that caused her pharyngitis is a reasonable possibility"). However, in response to a question posed by the Court, Dr. Safran explained the uncertainty in distinguishing whether Petitioner's

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[29] Lamella is any "thin leaf or plate." DORLAND'S, *supra* at note 3, at 992.

[30] Vesicular means "pertaining to or composed of vesicles." DORLAND'S, *supra* at note 3, at 2036.

recorded pharyngitis was attributable to microbial infection or mere allergic response, although he thought viral illness more likely because "Sore Throats are almost always viral." Tr. at 50. Interestingly, Dr. Safran's opinion for why the pharyngitis was not allergic was that "Unless there's a long history of allergic pharyngitis, why would you choose to now be allergic out of no other precipitant?". *Id*. One note repeated in Petitioner's medical records was her high allergic reactivity to a number of allergens. Likewise, on the date of vaccination her pharyngitis was recorded in conjunction with her *allergic* rhinitis. As Dr. Kinsbourne pointed out, the two often go together.[31] All of this makes the proposition that the pharyngitis was virally caused fairly speculative. It seems equally likely, if not more likely, in Petitioner's specific position, that the pharyngitis was related to allergic response.

One potential alternative *causa* mentioned in the medical records was meningitis. Early on, the treating physicians considered a diagnosis of viral meningitis. However, that potential diagnosis was later abandoned, even shunned by Dr. Levine, who had concluded at one point that Petitioner suffered from aseptic (sterile) meningitis. Oddly enough, Dr. Levine thought that a likely cause for Petitioner's illness, if it was indeed aseptic meningitis, was the IVIG injections which Petitioner received to treat her illness, which would seem to be a circular reasoning. In any event, neither party's expert believed that Petitioner's condition had been meningitis, and neither proffered substantial evidence on the point. Since Dr. Levine's treatment of the subject is confusing, and the parties did not raise meningitis as a diagnosis or a potential cause, the Court concludes that meningitis is not implicated, based upon the evidence submitted.

The next possibility is that the GBS was caused or triggered by the Pneumococcal vaccine (Pneumovax) Petitioner received in conjunction with the meningococcal vaccine at issue. Respondent raised the issue to challenge Dr. Kinsbourne at trial, and again at the time of briefing. In fact, Respondent attached to her Posthearing Brief the safety information for Pneumovax 23, which lists GBS among several "adverse experiences reported in clinical trials and/or in post-marketing experience." Attachment to Respondent's Posthearing Brief at 6-7. Respondent argued that Petitioner had not done enough to negate the pneumococcal vaccine's influence, inasmuch as Dr. Kinsbourne was simply unaware of any association between GBS and that vaccine. Tr. at 41. However, the opinion offered by Respondent's own expert undermined this contention by outright contradiction, as Dr. Safran stated plainly that he did not believe the Pneumococcal vaccine triggered or caused Petitioner's condition. Tr. at 44. In its role as fact-finder, the Court is not bound to view Petitioner's case in chief solely on the basis of Petitioner's evidence alone, but may consider the entire record, including Respondent's proffered expert testimony to draw conclusions. § 13(b) of the Vaccine Act; *de Bazan v. Secretary of HHS*, 539 F. 3d 1347, 1353 (Fed. Cir. 2008).

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[31] A review of several consumer-based webpages confirms Dr. Kinsbourne's statement to this effect:

> Characteristic symptoms [of allergic rhinitis] include repetitive sneezing; rhinorrhea (runny nose); post-nasal drip; nasal congestion; pruritic (*itchy*) eyes, ears, nose or *throat*; and generalized fatigue. Symptoms can also include wheezing, eye tearing, *sore throat*, and impaired smell.

HealthScout.com page on Allergic Rhinitis, available at http://www.healthscout.com/ency/68/208/main.html, (emphasis added); see also the WebMD.com page on "Allergic Rhinitis - Overview," available at http://www.webmd.com/allergies/tc/allergic-rhinitis-overview, both last accessed on 31 August 2009.

Additionally, no medical literature was offered by Respondent prior to trial on this point, and the experts were not prepared to discuss it at trial because Respondent had not timely raised it as an issue. The Court finds the evidence insufficient to conclude that the Pneumovax vaccine caused Petitioner's injury.

Another potential cause for Petitioner's symptoms in early 2005 raised by certain treating doctors and by Respondent was somatization. Respondent did not press this theory in briefing, although Dr. Safran alluded to it at trial. In summarizing Dr. Levine, Dr. Safran, stated "at one point he thought that it was largely hysteric;" Dr. Safran also summarized any persistent defects or deficits as more psychological than neurological. Tr. at 47-48. However, Dr. Safran also hoisted himself by his own petard on this issue, inasmuch as he was adamant that there was actual spinal cord damage, which led him to categorize Petitioner's injury as TM. Tr. at 48. If Petitioner was merely faking or imagining her injury, whether wilfully or subconsciously, the injury could hardly be equated with the manifest, observable phenomena of either GBS or TM. If Petitioner's psychological state somehow caused the observable disease phenomena described in the majority of contemporaneous medical records, the Court has not seen evidence of the biologic mechanism therefor. In fact, Respondent's own arguments (to say nothing of Petitioner's) dispel this theory as a credible conception of Petitioner's illness.

Respondent's primary argument regarding alternative *causata* is that the immune mediated process was virally triggered by an infection (or reinfection) of either the Epstein-Barr virus, the herpes simplex virus, or the herpes zoster. This argument is based almost wholly on the elevated titer levels recorded for the Epstein-Barr and herpes simplex viruses upon Petitioner's admission to the hospital, but also on Petitioner's foregoing re-exposure to herpes zoster. Certainly, an infection of any one of the three could act as a triggering cause for autoimmune demyelinating disease, and all three were listed by Dr. Safran as possible causes of transverse myelitis specifically. Tr. at 67. The question then is whether one or more of them did. Respondent's primary argument on this topic is that viral exposure and infection was a more likely cause than was the meningococcal vaccine, founded upon Dr. Safran's opinion. Respondent's Posthearing Brief at 7-8. This is not the same as an affirmative "factor unrelated," which would have to be proffered as "more likely than not" an efficient cause, which Dr. Safran expressly disclaimed at trial. In fact, Dr. Safran did not proffer any potential cause as being a more probable than not cause, and did not believe any of the potential causes discussed (including the vaccines) to be so. However, he did think the viral causes were more probable than the vaccine as reasonable possibilities; although, to him, "anything is possible" (Tr. at 60), so that is to be taken *cum grano salis*.

Herpes zoster is the most likely of the suggested potential viral causata, because it was gleaned from Petitioner's reported medical history that she had been in physical contact with (her son's) shingles. In contrast, her medical records do not mention the recent exposure to, or tell-tale symptoms of, either herpes simplex virus or Epstein-Barr virus. Even still, Petitioner had suffered from chickenpox as a child, but had not suffered any herpes zoster symptoms since her childhood infection–even after the more recent exposure. Dr. Safran seemed to indicate that she could not have suffered a reemergence of herpes zoster symptoms since she had protective antibodies from her childhood chickenpox, but this is not supported by the medical literature sources available to the Court. Dorland's Medical Dictionary, in describing Shingles, notes that it may indeed affect those

who suffered from chickenpox as a child, so the fact that she did not suffer from reemergent symptoms is relevant in this regard. Also, the elevated titers related to the other two viruses, not herpes zoster.

Dr. Safran found it significant that there was a known external exposure to the virus. Even though he would not "expect her to [experience herpes zoster symptoms] a second time," inasmuch as that is what "the antibodies are designed to prevent,"apparently he thought that was enough of an immune challenge to mount an immune mediated, autoimmune, demyelinating disease. Tr. at 58-59. However, Dr. Safran also agreed that one would not be able to determine "whether the herpes zoster exposure was when she was six years old or 36 years old" simply from her IgG level. *Id*.

Even when initial infection subsides, often the body carries certain viruses in asymptomatic form for years afterward. From Petitioner's perspective, the titer results for any one of the suggested viral causes prove prior viral exposure to the respective virus, but not necessarily recent exposure, and therefore one "cannot base the assumption that [Petitioner] actually had an infection within the proximate time period from IgG findings alone," which then does not aid a causation determination. Tr. at 23. Dr. Kinsbourne did not believe that he was dismissing these potential viral causes out of hand, but rather that he considered them and then decided against them because the IgG levels did not surmount a level of probability. Tr. at 25-26.

In the Court's view, viral causation seems quite strong as an argument, looking at all three of these viruses in composite. However, looking at each one on its individual terms weakens its persuasive power. Firstly, even though Petitioner's "Epstein-Barr virus serology results denote[d] a previous or possibly a fairly recent infection with this virus" (Pet. Ex. 2 at 44-45), no such infection was related in any recent medical history among the records filed that the Court has seen. It may have been previous, but it was more likely than not in the more distant past, prior to the period relevant to this case. Secondly, Petitioner did not even know that she had the herpes simplex virus (although she did have a history of cold sores), and had to be told so by her doctors based on the titer levels. It is unlikely that she had suffered reinfection or some other exposure during the relevant period. Also, regarding both of these two viruses, it is worth noting that these titers recorded elevated levels of IgG: Immunoglobulin G. The Immunoglobulin G of hundreds of blood donors is what was injected into Petitioner to treat what Dr. Steinhauer diagnosed as GBS shortly into her hospital stay; it is the "IG" (immunoglobulin) in "IVIG" (intravenous immunoglobulin) treatment. It is not beyond the pale to consider whether these injections may have affected those readings.

Thirdly, the Court notes that there were not elevated levels recorded for the herpes zoster, and so there is little evidence to infer that she had a reinfection or other renewed response to that virus which could stimulate her immune system to a state of autoimmunity. There is evidence of re-exposure, which is lacking for the other two viruses discussed immediately above, but that is all. Petitioner certainly did not suffer reinfection of herpes zoster in the form of Shingles. As Dr. Safran conceded, the mere presence of IgG titer proves she had been exposed to herpes zoster at some point, but that point is inherently indeterminate, except that it was sufficiently in the past such that she had already developed antibodies thereto. For that matter, the Record is clear that Petitioner had been exposed to, and suffered an infection of, varicella zoster as a child, and had reacted with chickenpox. Other than the implication circumstantially raised by the mere fact that Petitioner had come into

contact with herpes zoster, there is a paucity of evidence to lead the Court to a finding that the herpes zoster was the triggering cause of Petitioner's injury.

Finally, now, the Court turns to whether the meningococcal vaccine was the triggering cause for Petitioner's injury. Dr. Kinsbourne believed the Meningococcal vaccine did cause Petitioner's injury, as "the GBS began within a proximate time period" from its administration, and he "perceived no other viable alternative" as a causal factor. Tr. at 12. Respondent concedes that the temporal association fits the "medically acceptable" time frame that would be expected between injection and onset of symptoms. *See de Bazan v. Secretary of HHS*, 539 F. 3d 1347, 1352 (Fed. Cir. 2008). Likewise, the Court has eliminated from preponderant probability the alternative causes raised by the treating doctors and Respondent.

The absence of alternative *causata*, paired with a time frame between vaccination and onset that matches the theoretical construct proposed by Petitioner's expert, together are strongly persuasive, and militate for a finding of causation. *Compare Althen v. Secretary of HHS*, 418 F. 3d 1274, 1281 (holding that "requiring that the claimant [to] provide proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes [] is merely a recitation of ... well-established precedent") *and Pafford v. Secretary of HHS*, 451 F. 3d 1352, 1356-58 (vindicating "the second prong of the Special Master's test [which] restates correctly that the petitioner must show that the vaccine was the 'but for' cause of the harm according to *Shyface*, or in other words, that the vaccine was the 'reason for the injury' as stated in the second prong of the *Althen* test," and stating "Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis")[32] *and de Bazan v. Secretary of HHS*, 539 F. 3d 1347, 1352 (Fed. Cir. 2008) (reinstating the Special Master's decision, by reconciling and restating the applicable rule, that, "So long as the petitioner has satisfied all three prongs of the Althen test, she bears no burden to rule out possible alternative causes....a petitioner may instead rule out possible alternative causes to prove causation-in-fact when evidence as to the Althen requirements is insufficient") *with Capizzano v. Secretary of HHS*, 440 F. 3d 1317, 1326 (2006) (holding that the Chief Special Master erred in disregarding testimony that "relied in part on the temporal proximity of [the petitioner's] injuries to the administration of the vaccine," because "evidence used to satisfy one of the *Althen* [] prongs [may] overlap to satisfy another prong," such that "close temporal proximity, combined with [a plausible theoretical construct] demonstrate[] that it is logical to conclude that the vaccine was the cause of the [injury]") *and Andreu v. Secretary of HHS*, 569 F. 3d 1367, 1375-76 (holding that where

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[32] The Federal Court in *Pafford* continued in further explication of the rule, which the Court finds helpful to state in greater portion here:

> Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury. Thus, it was entirely proper for the Special Master to require Pafford to prove but-for causation, including some showing of temporal relationship between the vaccination(s) and the onset of injury.

451 F. 3d at 1358.

"a claimant satisfies the first and third prongs of the Althen standard, the second prong can be met through medical opinion testimony," and finding such prong is satisfied when there is "no cause-other than the [] vaccination-to explain" the injury, and the injury occurred within a proximate time frame after the vaccination) *and Walther v. Secretary of HHS*, 485 F. 3d 1146, 1149 (Fed. Cir. 2007) (overturning as erroneous "the special master's decision, to the extent that it did place a requirement on the petitioner to establish a lack of alternative causation"); *but see Egan v. Secretary of HHS*, No. 05-1032V, 2009 WL 1440240 (Fed. Cl. Spec. Mstr. May 1, 2009) (unpublished), ("Dr. Kinsbourne, however, made no effort to show the logical sequence of cause and effect through his testimony, probably due to the fact that the only supportive information he drew upon was the medical theory and timing").

The fact that both parties acknowledge a proper onset time frame supporting vaccine causation, and that the disease process followed an unquestionably autoimmune, immune mediated course, together with the absence of probable alternative causes, leads the Court to conclude in favor of vaccine causation. Therefore, based on this legal direction provided to guide the Court in its fact-finding role, the Court finds that the meningococcal vaccine did cause Petitioner's injury.

III. CONCLUSIONS OF LAW

As aforementioned, the Court is authorized to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a cognizable Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). If Petitioner had claimed to have suffered a "Table" injury, to him would §13(a)(1)(A) have assigned the burden of proving such by a preponderance of the evidence. In this case, however, Petitioner does not claim a presumption of causation afforded by the Vaccine Injury Table, and thus the Petition may prevail only if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury alleged. *See* § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Secretary of HHS*, 956 F. 2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F. 2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F. 2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit has articulated an alternative three-part causation-in-fact analysis as follows:

> [Petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the

vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

As part of that analysis, the Federal Circuit recently explained:

> [T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's aetiology, it is medically acceptable to infer causation-in-fact.

de Bazan v. Secretary of HHS, 539 F. 3d 1347, 1352 (Fed. Cir. 2008).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury, they must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F. 3d 543, 549 (1994).

As a matter of elucidation, the Undersigned takes note of the following two-part test, which has been vindicated and viewed with approval by the Federal Circuit,[33] and which guides the Court's practical approach to analyzing the *Althen* elements:

> The Undersigned has often bifurcated the issue of actual causation into the "can it" prong and the "did it" prong: (1) whether there is a scientifically plausible theory which explains that such injury could follow directly from vaccination; and (2) whether that theory's process was at work in the instant case, based on the factual evidentiary record extant.

Weeks v. Secretary of HHS, No. 05-0295V, 2007 WL 1263957, 2007 U.S. Claims LEXIS 127, slip op. at 25, n. 15 (Fed. Cl. Spec. Mstr. Apr. 13, 2007).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F. 3d 1352, 1355 (Fed. Cir. 2006), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007), citing *Shyface v. Secretary of HHS*, 165 F. 3d 1344, 1352 (Fed. Cir.1999). This threshhold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that petitioner would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*. "[T]he relevant inquiry ...[is]... 'has the petitioner proven ... that her injury was in fact caused by the ...

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[33] *See Pafford v. Secretary of HHS*, No. 01-0165V, 2004 WL 1717359, 2004 U.S. Claims LEXIS 179, *16, slip op. at 7 (Fed. Cl. Spec. Mstr. Jul. 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd* 451 F. 3d 1352, 1356 (2006) ("this court perceives no significant difference between the Special Master's test and that established by this court in *Althen* and *Shyface*"), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007).

vaccine, rather than by some other *superseding*[,] *intervening* cause?' ...[The petitioner need not] rule out every possible explanation ...[but]... must simply show ... that her injury was caused by a vaccine." *Johnson v. Secretary of HHS*, 33 Fed. Cl. 712, 721 (1995), *aff'd* 99 F. 3d 1160 (Fed. Cir. 1996) (emphasis added).

Here, the Court has found that Petitioner had proffered a plausible theory explicating how the meningococcal vaccine *can* cause the injury Petitioner suffered, and found likewise, in large part due to the appropriate linkage with the medically appropriate time frame, that such vaccine *did* cause the injury. Following the statutory interpretation elaborated throughout several decisions of the Federal Circuit, the Court rules that Petitioner has satisfied the legal standard of actual causation by providing "a medical theory causally connecting the vaccination and the injury" and demonstrating "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," i.e., demonstrating that the injury would not have occurred save for the administration of the meningococcal vaccine as "cause in fact." *Althen*, *Pafford*.

Accordingly, the Court rules that the Petition is entitled to compensation, unless Respondent can proffer preponderant proof that a "factor unrelated" was the sole or superseding cause of the injury. Respondent has not argued that, to a preponderance, viral infection (or anything else) was either a cause in fact, or a proximate cause of the injury, let alone the sole or superseding cause. Hence, the Court **RULES** that Petitioners are entitled to compensation, to be determined by further proceedings.

IV. CONCLUSION

Therefore, in light of the foregoing, the Court **RULES** in favor of entitlement in this matter. The parties are instructed to contact the Court for further proceedings, regarding the issue of damages. The Court may be reached *via* my law clerk, Isaiah Kalinowski, Esq., at 202-357-6351.

IT IS SO ORDERED.

Richard B. Abell
Special Master