In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-1032V
Filed: May 1, 2009

MARY ANN EGAN, guardian ad litem of her infant, BRIDGET GUM,	*	NOT TO BE PUBLISHED
Petitioner,	*	DTaP Vaccination; Transverse Myelitis; Logical Sequence of Cause and Effect; Expert Witness Credibility; Prong II of Althen; Challenge-Rechallenge as proof of Causation
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Thomas P. Gallagher, Gallagher & Gallagher, Somers Point, NJ, for Petitioner.
Glenn A. MacLeod, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

GOLKIEWICZ, Chief Special Master.

On September 26, 2005, petitioner, Mary Ann Egan, petitioner, filed a Petition pursuant to the National Vaccine Injury Compensation Program (the "Act" or "the Program"),[2] on behalf of her daughter, Bridget Gum ("Bridget"). Petition ("Pet.") at 1. In her petition, petitioner alleged

[1] The undersigned intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is 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 will be available to the public. Id.

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

that Bridget developed "a condition known as Transverse Myelitis," as a direct result of receiving her Diphtheria-Tetanus-accellular Pertusis ("DTaP") and Haemophilus Influenza type B ("Hib") vaccinations on October 4, 2002. Id. On February 21, 2006, petitioner filed the medical expert report of Dr. Marcel Kinsbourne to support her Petition. Petitioner's Exhibit 6 (hereinafter "P ex."). Respondent filed respondent's report pursuant to Vaccine Rule 4, which included an expert report from Dr. Russell D. Snyder, asserting that compensation was inappropriate and that the petition should be dismissed. Respondent's Report, filed April 7, 2006; see also Respondent's Exhibit A (hereinafter "R ex."). The then-assigned special master convened a hearing in this case on August 24, 2006, during which Dr. Kinsbourne and Dr. Snyder provided expert testimony.

With the departure of the then-assigned special master, the case was reassigned to the undersigned on July 31, 2008.[3] In a status conference regarding the status of the case, conducted on August 12, 2008, the parties represented that, in their opinion, the evidentiary record in this case was complete and that, though offered, neither party required a supplemental hearing or additional briefing.[4] Pursuant to that conversation, the undersigned deemed the evidentiary record closed and the case ripe for decision. However, subsequent to that conversation and while the undersigned studied the record, the undersigned discovered that medical literature referenced by Dr. Kinsbourne in his expert testimony was never filed. At a subsequent conference call on March 23, 2009, the undersigned queried petitioner's counsel regarding this literature. Petitioner's counsel recognized that the medical literature had not been filed and requested additional time to file the articles Dr. Kinsbourne referenced during his testimony. Petitioner filed the medical articles on April 7, 2009; therefore, the undersigned now deems this case ripe for decision.[5]

I. CASE SUMMARY

In order to prevail, petitioner must prove by a preponderance of the evidence, that there exists: (1) a medical theory causally connecting Bridget's vaccinations to her alleged injury; (2) a logical sequence of cause and effect showing that the vaccinations were the reason for the injury; and (3) a showing of a proximate temporal relationship between the Bridget's vaccinations and her injury. Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278

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[3] The assigned special master resigned from the Office of Special Masters on July 18, 2008, and the case was reassigned to the undersigned on July 31, 2008. Order, filed July 31, 2008.

[4] Prior to the status conference, the undersigned was somewhat concerned that credibility calls might be problematic since the undersigned did not conduct the evidentiary hearing. But, fortunately, the undersigned has experienced both experts numerous times. Thus, the undersigned was conversant with the issues presented and with the experts presenting them.

[5] At the undersigned's urging, the parties also attempted several times to informally resolve this matter. These efforts were foreclosed with respondent reporting on March 25, 2009, that his client was not amenable to settlement.

(Fed. Cir. 2005). Petitioner, through her expert, was unable to provide preponderant evidence to prove the existence of "a logical sequence of cause and effect" showing that Bridget's vaccination was the cause of her alleged injury. As a result, petitioner fails to meet her burden and the case must be dismissed.

II. FACTS

The parties do not dispute the relevant facts in this case. Bridget was born on March 21, 2002, at the Hunterdon Medical Center in Flemington, New Jersey. See Petitioner's Exhibit 1 at 5 ("P ex. 1")[6] at 191-93; see also P ex. 1 at 15. Bridget received a hepatitis B vaccination before she was discharged from the hospital following birth. P ex. 1 at 194; see also P ex. 1 at 192-193. Bridget's medical records do not reflect that Bridget experienced any adverse reaction to her initial hepatitis B vaccination.

As an infant, Bridget received routine pediatric medical care from physicians at Hunterdon Family Practice in Flemington, New Jersey. See generally P ex. 1 at 123-29. Except for minor illnesses, Bridget grew and developed well between birth and October 2002. See generally P ex. 1 at 123-29. Bridget received an array of childhood vaccines, including DTaP, inactivated polio vaccine (IPV) and Hib on May 16, 2002. P ex. 1 at 123, 194. Bridget also received DTaP, IPV and Hib vaccinations on August 1, 2002. P ex. 1 at 123, 194. Bridget's medical records do not reflect that Bridget experienced any adverse reaction to her May 16, 2002 vaccinations or to her August 1, 2002 vaccinations.

Bridget presented to Hunterdon Family Practice on October 4, 2002 for her "6 mo[nth]s w[ell]c[hild]c[are]" evaluation. P ex. 1 at 123; see also P ex. at 129. All aspects of Bridget's physical examination were normal. P ex. 1 at 123. During this visit, Bridget received a DTaP vaccination and an Hib vaccination. P ex. 1 at 123; P ex. 1 at 81.

On October 7, 2002, Bridget's father telephoned Hunterdon Family Practice. P ex. 1 at 129. He reported that although Bridget appeared to have "a cold," she was "unable to cough." P ex. 1 at 129. A physician recommended the use of a "vaporizer." Id. The physician advised Bridget's father to schedule an "o[ffice]v[isit]" if Bridget's condition did not improve. Id.

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[6] Petitioner's medical records were labeled incorrectly. See Guidelines for Practice under the National Vaccine Injury Compensation Program, § II (B)(6) ("**B. Documents that Must Accompany the Petition** . . . . 6. Organization of Documents The documents submitted with each petition must be organized into **separately numbered** exhibits (e.g., Ex. 1 might be the birth certificate ...) Exhibits should be numbered in logical order (preferable chronologically).") (emphasis added) (available at www.uscfc.uscourts.gov). Fortunately, petitioner used numbers continuously through the filed medical records, with one exception. The undersigned will refer to the medical records using the number of the submission and the page number. For example, the records in "Petitioner's First submission of required medical records" shall be referred to as "P ex. 1 at ___."

Bridget presented to Hunterdon Family Practice on October 11, 2002, after experiencing a "cough [and] chest congestion," accompanied by a "possible fever" and "[decreased] energy," for "4 days." P ex. 1 at 129. Upon examination, Bridget exhibited a temperature of 101.6° Fahrenheit. Id. A physician diagnosed Bridget with an "U[pper]R[espiratory]I[llness]" and suggested "supp[ortive] measures," including the use of "Tylenol" as needed for "fever." Id. The physician also instructed Bridget's parents to "call if" Bridget became "worse." Id.

On October 21, 2002, Bridget returned to Hunterdon Family Practice. P ex. 1 at 129. A physician noted that Bridget was "worse." P ex. 1 at 129. Her "coughing" and her "secretions" had increased and Bridget was "more cranky." Id. A physician detected "rhonchi" in Bridget's "r[ight]l[ower]l[obe]" and diagnosed her with "bronchitis - bacterial." Id. at 130. The physician prescribed a five-day course of "Zithromax." Id.

Ms. Egan telephoned Hunterdon Family Practice on October 23, 2002. See P ex. 1 at 130. Ms. Egan reported that Bridget had begun "crying when she cough[ed]." P ex. 1 at 130. Ms. Egan sought advice regarding the use of "infant Robitussin" for Bridget's "congestion." Id. A physician recommended "Tylenol only." Id. The physician anticipated that Ms. Egan would "call" if Bridget did not improve or if Bridget displayed "fever." Id.

On November 12, 2002, Ms. Egan telephoned Hunterdon Family Practice and reported that Bridget appeared "very lethargic." P ex. 1 at 130. A physician scheduled an "o[ffice]v[isit]." P ex. 1 at 130. During her November 13, 2002 office visit, Bridget was "alert," but "cranky." P ex. at 131. The physician noted that Bridget had experienced a "vomiting episode [with] lethargy." Id. The physician commented that Ms. Egan had been "queasy" and "fatigued" as well. Id. The physician also observed "some redness" that was "dissipating" on Bridget's feet. Id. The physician diagnosed Bridget with "gastritis." Id. The physician instructed Ms. Egan to "monitor" Bridget "for rash" and "[increased] lethargy." Id. The physician planned a "C[omplete]B[lood]C[ount]," with "f[ollow]/u[p]" on November 13, 2002. Id.

Between November 12, 2002, and November 13, 2002, Bridget became "much worse." P ex. 1 at 131. She was "completely lethargic" and "limp." Id. She did not exhibit any "tone" in her "U[pper]E[xtremities] [and] L[ower]E[xtremities]." Id. In addition, her "feet" were "swollen and tender to touch." Id. Bridget presented to Hunterdon Family Practice on November 13, 2002, where a physician suspected a "viral" process or "septicemia" or "infant botulism" as the "etiology" for Bridget's condition. P ex. 1 at 132. The physician planned several laboratory tests, followed by "further w[ork]/u[p]" in the Hunterdon Medical Center Emergency Department. Id.; see also P ex. 3 at 841-65.

Doctor Margaret Bouffard (Dr. Bouffard), assessed Bridget in the Hunterdon Medical Center Emergency Room. See P ex. 3 at 856-59. In obtaining Bridget's medical history, Dr. Bouffard understood that Bridget had suffered "roseola and bronchitis" in October 2002. Id. at

857.[7] Dr. Bouffard described Bridget as "an alert infant who appeared oriented and behaved appropriately." Id. at 858. However, Dr. Bouffard observed "no spontaneous movement" in Bridget's "upper extremities" and only "occasional spontaneous movement" in Bridget's "proximal lower extremities." Id. Dr. Bouffard concluded that Bridget displayed "newly acquired neurologic difficulties." P ex. 3 at 859. Dr. Bouffard expressed "concerns" about "possible infant botulism vs. spinal cord disease vs. transverse myelitis." Id. Dr. Bouffard arranged to "transfer" Bridget to the pediatric "Intensive Care facility at St. Peter's [University] Hospital" in New Brunswick, New Jersey, "for further evaluation and treatment." Id.; see also P ex. 5 at 985-1182.

At St. Peter's University Hospital, Bridget underwent magnetic resonance imaging (MRI) of her "cervical spine," P ex. 5 at 1071, and of her "brain." P ex. 5 at 1072. The MRI of Bridget's cervical spine was "abnormal," revealing an "expanded contour to the cervical spinal cord with diffuse cord signal abnormality likely due to edema." Id. at 1071. The radiologist who interpreted the MRI included "transverse myelitis or tumor of glial origin" among the "[d]ifferential considerations." Id. The MRI of Bridget's brain was "normal." Id. at 1072.

In addition, Bridget underwent a lumbar puncture. See P ex. 5 at 985. Bridget's "C[erebro]S[pinal]F[luid]" showed "pleocytosis of n[orma]l inflamm[atory] cells," prompting a consulting pediatric neurologist to favor transverse myelitis as the diagnosis for Bridget's condition. Id. at 1005. The consulting pediatric neurologist mentioned that Bridget's history of a "viral syndrome [approximately] 3 w[ee]ks" before Bridget's hospitalization also supported a diagnosis of transverse myelitis. Id. The consulting pediatric neurologist noted that Bridget had begun a course of "high dose steroids." Id.; see also P ex. 5 at 1004. The consulting pediatric neurologist recommended "IVIG as well." P ex. 5 at 1005.

Bridget endured a "protracted" hospitalization at St. Peter's University Hospital. P ex. 5 at 985. At some point, her treating physicians instituted "Acyclovir" as an "empirical" measure. Id. at 1034. Her treating physicians also considered "plasmapheresis." Id. at 1027; see also P ex. 5 at 1029. Likewise, her treating physicians performed a battery of diagnostic tests, including viral cultures, see, e.g., P ex. 5 at 1006, 1009-1018, 1034; a repeat MRI of the "cervical spine;"Id. at 1063-1064; a repeat MRI of the "brain;" Id. at 1066; an MRI of the "thoracic spine;"Id. at 1065; an MRI of the "lumbar spine;" Id. at 1068; and a repeat lumbar puncture. See, e.g., P ex. 5 at 1034. A viral culture was "positive" for "Cytomegalovirus IGG Antibody." P ex. 5 at 1014; see also P ex. 5 at 1034. The repeat MRI of the cervical spine demonstrated "moderate improvement of the degree of cord expansion," that was consistent with "an inflammatory process such as transverse myelitis rather than a glial neoplasm of the spinal cord."

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[7] The parties agree that Bridget's medical records from October 2002 mention a possible history of Roseola and that there is no definitive medical diagnosis that Bridget suffered from Roseola in October 2002. Transcript (Tr.) at 43-46. However, respondent contended that it was a viral-based rash that appeared prior to Bridget's transverse myelitis. Id. at 46. Given how this case is decided, it is unnecessary to resolve the issue of whether or not Bridget suffered from Roseola.

Id. at 1063-1064. The MRI of the thoracic cord revealed that the "lesion" identified on Bridget's November 13, 2002 MRI of the cervical cord extended "to approximately the T3-4 level." P ex. 5 at 1065.

During her hospitalization at St. Peter's University Hospital, Bridget exhibited "very mild improvement in the paralysis of the upper and lower extremities." Petitioners requested that Bridget be transferred to Children's Hospital of Philadelphia." Id. Bridget was discharged from St. Peter's University Hospital on November 20, 2002 with the diagnosis of "Transverse Myelitis."[8] Id.

Bridget received treatment at The Children's Hospital of Philadelphia from November 20, 2002 through November 26, 2002. P ex. 2 at 806. Her doctors noted that there was a history of "familial paralysis" on the maternal side. P ex. 2 at 690. After multiple neurology consults and additional care, Bridget was discharged with the diagnosis of "[p]ost infectious neuromuscular weakness with decreased neuromuscular tone and function." P ex. 2 at 807. She tested negative for RSV, RRP and polio screens. P ex. 2 at 806; see also P ex. 3 at 972.

Bridget was transferred to The Children's Seashore House of the Children's Hospital of Philadelphia on November 26, 2002, to receive additional care and rehabilitative therapies. P ex. 5 at 972; see also P ex. 2 at 806. She was discharged on December 24, 2002, to continue her rehabilitation on an out-patient basis, with the diagnosis of "infectious anterior horn cell demyelinating disease versus transverse myelitis." P ex. 3 at 972. Bridget was ultimately diagnosed with transverse myelitis. See P ex. 1 at 156; R ex A. at 1.

Bridget presented for evaluation to Dr. Douglas Kerr, Director of the Johns Hopkins University Transverse Myelitis Center, on August 27, 2003. See P ex. 1 at 156-159. In his evaluation report, Dr. Kerr opined that "most likely etiology" of Bridget's transverse myelitis was a post-infectious etiology. P ex. 1 at 158. He further stated that, in his research, he had found "no conclusive or even suggestive evidence that vaccines induce transverse myelitis" and that the vaccination is "much less likely to be an etiological factor." Id. At the time of his visit, he also noted Bridget was recovering well. Id.

Bridget received a second DTaP and Hib vaccination on September 22, 2003, without any recorded adverse affect or aggravation of her neurological condition. P ex. 1 at 194; P ex. 6 at 5.

III. SUMMARY OF EXPERT OPINIONS

A. Petitioner's Expert

[8] Transverse Myelitis is inflammation of the spinal cord, often part of a specific disease process, in which the functional effect of the lesions spans the width of the entire cord starting at a given level. Dorland's Illustrated Medical Dictionary 1209 (30th ed. 2003).

Dr. Marcel Kinsbourne[9] opined both in his written report, P ex. 6, and testimony that Bridget Gum's October 4, 2000 DTaP[10] vaccination was either the cause or a "substantial contributing factor in her contracting" transverse myelitis (TM). Tr at 13; see also P ex. 6 at 3-4. Specifically, Dr. Kinsbourne fingered the tetanus toxoid component of the immunization for his theory of causation. P ex. 6 at 4. Tr. at 15. He stated that his opinion is "necessarily circumstantial", based upon "case supports" and the "logical plausibility of the mechanisms involved." Tr at 14. Dr. Kinsbourne posits that Bridget has an immune mediated disorder, which can typically "have many potential causes." Tr at 14. However, he stated that his opinion was limited to causes of transverse myelitis that have "some precedent and some literature."[11] Tr. at 25. Specifically, Dr. Kinsbourne believes the medical literature supports his opinion that the tetanus toxoid component of the DTaP vaccine can cause transverse myelitis. Tr. at 25. He says the rarity of transverse myelitis in children explains why "there is no epidemiological assurance of the absence of coincidence" in these type of cases. Tr at 14.

According to Dr. Kinsbourne, tetanus toxoid can on rare occasions generate an "immune mediated neurological adverse reaction," such as in Guillian-Barre syndrome (GBS). Tr. at 15. The causal relationship between the tetanus toxoid vaccination and GBS has been acknowledged by the Institute of Medicine (IOM).[12] Id. Dr. Kinsbourne stated that transverse myelitis and GBS

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[9] Dr. Marcel Kinsbourne was recognized by the then-assigned Special Master as an expert because he was recognized as such at previous proceedings. Tr. at 12. He is a board certified pediatrician, but does not have American Board of Neurology certification with a special competence in child neurology, though that has been the focus of his practice for many years. Id. Respondent had no objection. Tr. at 12.

[10] At several points in the testimony, references were made to the DTP vaccination. See Tr. at 13. There exists significant causal differences between the DTP vaccination and the DTaP vaccination petitioner received in this case. See Grace v. Sec'y of Health and Human Servs., 2006 WL 3499511 at * 9 (Fed. Cl. Spec. Mstr. Nov. 30, 2006) (noting, that scientists believe the DTaP vaccination to be less likely than the "DPT vaccine to cause neurologic reactions or other harmful side effects.") Since Dr. Kinsbourne is relying on the tetanus toxoid portion of the immunization, which is the same for both immunizations, the undersigned sees no need to discuss these differences. However, to the extent that the experts rely on information pertaining to the other components of the DTP vaccine, the proof was insufficient in this case to link that information to the DTaP immunization.

[11] Petitioner alleged that Bridget's Hib vaccination was a cause of Bridget's transverse myelitis; however, Dr. Kinsbourne stated that he does not believe that the Hib vaccination was the causal agent. Tr. at 7.

[12] The IOM has considered the general relationship between vaccines and demyelinating diseases of the central nervous system, including transverse myelitis. Kathleen R. Stratton, et al., Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality at 34-48, 83-86 (National Academy Press 1994) (hereinafter "1994 IOM Report"). While finding a causal relationship between tetanus vaccine and GBS, the IOM did not make a similar statement acknowledging any relationship between tetanus toxoid and transverse myelitis. Special masters commonly deem the conclusions from the IOM to be persuasive. As noted by the Court of Federal Claims,

> [d]ue to the IOM's statutory charge, the scope of its review, and the cross-section

are different neurological disorders that affect different parts of the nervous system[13], however, he asserts, without any support, that some scientists argue that there is a continuum between GBS and transverse myelitis. Id. He concludes that there "is nothing surprising or unusual about the idea that a given individual's transverse myelitis was, in fact, caused by the tetanus toxoid element of DTP." Tr. at 16-17.

Dr. Kinsbourne stated that Bridget exhibited the first onset or manifestation of her injury by November 12, 2002, thirty-nine days after her vaccination on October 4, 2002, which is within the medically appropriate time frame stated by the IOM. Tr. at 26. He says the IOM put forward forty-two days as the appropriate time frame in which a person may develop transverse myelitis after a vaccination. Tr. at 26. He also opined that to his knowledge Bridget had a respiratory illness that was within the medically accepted time frame for causing TM. Tr at 80. According to Dr. Kinsbourne, the first manifestation of Bridget's TM was the weakness reported by her parents and her subsequent visit to the Huntington Medical Emergency Center with some antecedent events as seen in the emergency room.[14] Tr. at 27.

Dr. Kinsbourne said that TM can be a post-infectious process caused by a bacterial or a viral infection. Tr. at 15, 87. He also stated that the operative cause of the transverse myelitis can not be inferred, in a single case, "from the clinical appearance of the disease." Tr. at 14; see also P ex. 6 at 4. He indicated that thirty to sixty percent of idiopathic TM cases have an antecedent upper respiratory or "gastro-testitis" illness. Tr at 90. Dr. Kinsbourne opined that Bridget was diagnosed with bronchiolitis[15], an upper respiratory illness, affecting the lungs, P ex. 6 at 1, and her upper respiratory illness was likely caused by a bacterial agent because of the method of treatment and the persistence of the illness, tr. at 87-88. Dr. Kinsbourne stated that the vast majority of children who have upper respiratory illness or receive vaccinations do not develop TM. Tr at 93.

In attempting to determine the etiology of the TM, the hospital doctors tested for viruses

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> of experts making up the committee reviewing the adverse events associated with vaccines, the court considers their determinations authoritative and subject to great deference.

Kelly v. Sec'y Health and Human Servs., 68 Fed.Cl. 84, 91 n.11 (2005) (quoting Althen v Sec'y Health and Human Servs., No. 00-170V, 2003 WL 21439669 at *11 n.28 (Fed. Cl. Spec. Mstr. June 3, 2003))

[13] GBS affects the peripheral nervous system and transverse myelitis affects the spinal cord, which is part of the central nervous system. See P ex. 6 at 3.

[14] Bridget was transported to the emergency room on November 13, 2002.

[15] Bronchiolitis is an inflammation of the bronchioles (which are responsible for the transfer of gases in the lungs), usually occurring in children less than two years of age resulting from a viral infection. Dorland's Illustrated Medical Dictionary 252 (30th ed. 2003).

known, according to case reports, to cause TM, including cytomegalvirus (CMV), Epstein-Barr Virus (EBV) and HHV-6. Tr at 95. None of these viruses were found in her blood, though evidence of CMV was identified in her urine. P ex. 6 at 2; Tr. at 95; see generally, Tr at 66. Dr. Kinsbourne dismissed the idea that CMV was the causal agent for Bridget's TM, asserting that for an agent to be a viable cause of an immuno-neurological disorder, it must be in the blood, making it an active agent. Tr at 98. He posited that CMV can remain in the urine for months and years "without in any way affecting the body as a whole." Tr at 66. He stated that Bridget did have a serious infection, tr at 65; however, because the test for CMV in the blood stream was negative, Dr. Kinsbourne opined that Bridget did not have an active infection of CMV; and therefore, CMV was not a "reasonable alternative cause" for her TM. Tr at 66.

He added that if there were an identified organism in the central spinal fluid (CSF), which is capable of direct invasion of the spinal cord, that would be the most likely cause before any vaccination or other post-infectious cause. Tr at 82. Dr. Kinsbourne believed that Bridget did not experience a direct invasion of the spinal cord, because the PCR tests on the spinal fluid was negative and Bridget received IVIG treatments, which is a treatment for immune mediated disorders. Tr at 64. He asserted that the IVIG treatment would not be used if the doctors thought there was a direct invasion because it might "actually make the child worse." Tr. at 63-64. However, Dr. Kinsbourne agreed that with respondent's expert's opinion that the polymorphonuclear aspect of the CSF suggested an invasion by a virus. Tr at 95.

On September 22, 2003, Bridget received a second DTaP vaccination, without any recorded adverse affect or aggravation of her neurological condition. P ex. at 194; P ex. 6 at 5. Dr. Kinsbourne opined that if Bridget had experienced an "exacerbation of an immunological" or systemic nature after the second DTaP, her reaction would have been "proof positive" of causation. Tr at 67-68. However, he opined her second vaccine was different and may have had a different make-up to which Bridget did not react. Therefore, he concluded that her lack of reaction to the second DTaP vaccination was not an appropriate reason to exclude the first DTaP vaccine as the cause of her TM. Tr at 68. He re-emphasized that the treating physicians did not find positive identification of a viral etiology for Bridget's TM, nor did they eliminate the vaccination as a cause. Tr at 68-69.

Dr. Kinsbourne stated that a respiratory infection is a generic term for a variety of causes and symptoms, whereas a vaccination is a definite cause; which is the "distinction that justifies a tilting in the direction of the vaccine" as the cause for her TM. Tr at 93. He stated that if the doctors had made a relevant finding of a virus in her blood, he would change his opinion. However, because they did not find a virus after an intense search, that tilts his balance of probabilities to an alternative causation - the vaccine. Tr at 100. Dr. Kinsbourne says that there is a possibility that Bridget's TM is a merely coincidental to her vaccine. But, he doesn't give that possibility as much weight as the possibility of her TM being caused by a virus or a vaccination - and he tilts toward the vaccination. Tr at 101-102.

B. Respondent's Expert

Dr. Russell Snyder,[16] respondent's expert opined that Bridget's TM was not related to her October 4, 2002 DTaP vaccine. Tr. at 30-31. Dr. Snyder opined that only in "very unusual circumstances" would an agent that causes peripheral nerve damage also cause central nervous system damage. R ex. A at 2. He stated that the "evidence is very slim" that tetanus toxoid causes transverse myelitis. Tr. at 31. He said that the IOM study of transverse myelitis could not establish whether the tetanus toxoid causes TM. Id.

In his testimony, Dr. Snyder opined that the majority of TM cases have a preceding viral like illness. Tr. at 32. He characterized Bridget's illness preceding the TM as viral like and opined that there was sufficient evidence to show that her TM was not vaccine induced. Id. Dr. Snyder says although he is not absolutely certain whether the causal agent was viral or bacterial[17], he "strongly favors" the conclusion Bridget had a viral illness because of "the clinical course." Tr at 33-34. He posits that this conclusion is further supported because she was treated for a viral illness with the anti-viral agent, Acyclovir, in addition to antibiotics. Tr at 35.

Dr. Snyder testified that the Bridget's treating physicians in the hospital describe the etiology of Bridget's TM as viral in nature "with the virus unknown." Tr at 37. Dr. Snyder opined that Bridget was infected with the cytomegalvirus, CMV, another form of the herpes virus, which is a "known cause" of TM, because evidence of the presence of CMV was recovered from her secretions on several occasions. Tr at 36.

Dr. Snyder stated that TM can be caused by a direct infection or invasion by an agent or an immune response to an agent. Id. Bridget's spinal fluid examination of the white cells in her spinal fluid showed 96 percent polymorphonuclear cells. Id. On this evidence, Dr. Snyder opined that this was an unusual immune response and therefore, it was more likely that "she had a direct viral invasion of the spinal cord." Id. The herpes viruses are known to directly invade the spinal cord. Id. He conceded that the cerebral spinal fluid did not culture any specific organism. However, Dr. Snyder asserted that since the test was done early in the illness, the virus may still been only in the spinal chord and not broken into the spinal fluid. Tr at 39. He also indicated the CMV produces a rash, such as the one observed by Bridget's doctors. Tr at 40.

Dr Snyder said that though he does not know the specific agent that caused the transverse myelitis, he believes that CMV is a possible agent. Tr at 42. Often a person infected with CMV can have no symptoms or they may have chronic malaise and intermittent fever. Tr at 49. However, he could not opine that the illness directly preceding the onset of Bridget's TM was

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[16] The then-assigned special master qualified Dr. Snyder as a medical expert in pediatric neurology. Petitioner had no objection. Tr. at 29.

[17] Bridget was treated for bacterial and viral infections with Zithromax, an antibiotic and Acylovir, an anti-viral agent.

more likely than not caused by CMV. Id.

If Bridget had an immune-mediated response to her October 2002 DTaP vaccination, Dr. Snyder asserted that he would expect to see another significant reaction to her second DTaP vaccination, which he referred to as "recall." Tr at 52. Dr. Snyder says that when there is no recall in this type of situation it is not "proof positive", but it is an important factor in eliminating the vaccine as a cause of the TM. Tr at 53. He asserted that if the DTaP was the cause of Bridget's TM, Bridget may not have developed TM after the second vaccination, but she would likely would have been very sick. Id. Bridget did not develop TM or have any adverse reaction to her second DTaP vaccination approximately one year later. Tr at 41.

Dr. Snyder posited that petitioner's family history was positive for HHV-6 virus which is also associated with causing transverse myelitis. Tr at 59-60. Dr. Snyder opines that the vaccination was not caused by Bridget's vaccination, but was more likely "post infectious" in nature or the result of an actual infection. Tr at 54. Post-infectious are symptoms that are not directly caused by "invasion of an organism." Tr at 55. They are immune responses. Tr at 55. Whereas, the term infectious means the agent is actually causing the problem. Id.

IV. LEGAL STANDARD

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.[18]

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). Petitioners in this case allege an off-table injury for the DTaP and Hib vaccinations, therefore petitioners must prove that the vaccinations in-fact caused Bridget's injuries, in this "off-Table" case.

To demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused or significantly aggravated the injury alleged. See, e.g., Bunting v. Sec'y of Dept. of Health & Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Sec'y of Dept. of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Sec'y of Dept.

[18] A preponderance of the evidence standard requires a trier of fact to "believe that the existence of a fact is more probable than its nonexistence before the [special master] 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, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

of Health & Human Servs., 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, "[petitioners must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Sec'y of Dept. of Health & Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Sec'y of Dept. of Health & Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Sec'y of Dept. of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Sec'y of Dept. of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges F.3d at 960;[19] see also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N.

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[19] The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that "Daubert is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Sec'y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert's opinion. Id. In other words, the "testimony must be supported by appropriate validation – i.e., 'good grounds,' based on what is known." Id. Factors relevant to that determination may include, but are not limited to:

> Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand from, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert, 509 U.S. at 594. However, the Supreme Court's only guidance to lower courts in determining the reliability of a novel proposition is that

> . . . submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Althen, 418 F.3d at 1280 ("The purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."); see also, Gall v. Sec'y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL

6344.

While petitioners need not show that the vaccine was the sole or even predominant cause of the injury, petitioners bear the burden of establishing "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation")); Hodges, 9 F.3d at 960. Finally, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

In Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioners' burden is to produce "preponderant evidence" demonstrating: "(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 the vaccination and injury." The Federal Circuit stated further that "requiring that the claimant 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 this court's well established precedent." Id. at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act's preponderant evidence standard that petitioners submit "objective confirmation," such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants." Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Sec'y of Dept. of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter "Capizzano III"]. Moreover, the Federal Circuit stated, "The purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id.

The Federal Circuit affirmed Althen's three-part test in Capizzano III and in Pafford v. Sec'y of Dept. of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). The panel in Pafford, however, explained that the three prongs in Althen "must cumulatively show that the vaccination

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1179611, at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." Pafford, 451 F.3d at 1355. Fairly interpreted, the Pafford court held that it is petitioner's burden to rule out other competing possible causes of the injury in establishing that the vaccine was the "but-for cause of the harm." Id. at 1355, 1357; see also Althen at 1281. ("[T]he elimination of other causes [] is merely a recitation of this court's well-established precedent."). But see Walther v. Sec'y of Dept. of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) ("[W]e conclude that the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes when the other evidence on causation is sufficient to establish a prima facie case.").

However, the legal requirement that petitioners support their proposed causation theory with a "sound and reliable medical or scientific explanation" is undisturbed. Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994); see also Grant, 956 F.2d at 1148 ("A reputable or scientific explanation must support this logical sequence of cause and effect."). Thus, when considering the evidence in a case, the special master is to "consider all relevant and reliable evidence, governed by the principles of fundamental fairness to both parties." Vaccine Rule 8(c); see also Campbell v. Sec'y of Dept. of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006) (Althen's requirement of a "reputable medical or scientific explanation" "[l]ogically [ ] requires a special master to rely on reliable medical or scientific evidence . . . ."); Manville v. Sec'y of Dept. of Health & Human Servs., 63 Fed. Cl. 482, 491 (2004); DeBazan v. Sec'y of Dept. of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) rev'd 539 F.3d 1347 (2008) (reversed on other grounds). Petitioners' case is measured against these standards.

V. DISCUSSION

Transverse myelitis cases are extremely difficult vaccine cases to resolve. There simply is not a great deal of reliable medical information linking transverse myelitis to immunizations.[20] Dr. Kinsbourne recognized that fact and accordingly based his opinion upon "circumstantial" evidence, case reports and "logical plausibility." Tr. at 14. The Federal Circuit has sanctioned utilizing this type of evidence to support a finding of entitlement. See Althen, F.3d at 1279, 1281. However, while Dr. Kinsbourne pays lip service to supporting circumstantial evidence, when examined closely it is clear beyond any doubt that the evidence Dr. Kinsbourne purports to rely upon is missing. Thus, the undersigned will discuss below the areas of the experts'

[20] The IOM describes transverse myelitis as "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." 1994 IOM Report at 37. The IOM acknowledges that demyelinating diseases of the central nervous system (CNS) "can occur after the administration of either live attenuated or killed vaccines (in the case of vaccinia virus and the swine influenza vaccines, respectively.)" Id. Therefore, the IOM recognizes as "biologically plausible" the proposition that a vaccine "might induce in the susceptible host" a demyelinating disease of the central nervous system. Id at 48, 85. However, the 1994 IOM study did not find sufficient scientific evidence to support or reject a causal connection between tetanus toxoid and demyelinating diseases of the CNS, including transverse myelitis. Id. at 86.

agreements, the lack of circumstantial evidence supporting the vaccine's alleged causative role and thus the illogical connection in this case and finally the finding that Dr. Kinsbourne was not credible as an expert in this case.

While the experts disagree on the ultimate conclusion of causation, there was a much agreement on the fundamental medicine regarding TM. Transverse myelitis (TM) is an uncommon condition. See Tr. at 14. Both experts, agree that TM occurs as the result of one of two reasons - a direct infection or an immune response. Id. at 38, 102. Petitioner's expert, Dr. Kinsbourne stated that tetanus toxoid is known to cause immune mediated neurological conditions, tr. at 15; therefore, he believes that "there is nothing surprising or unusual" about the possibility that the tetanus toxoid vaccine caused Bridget's TM, tr. at 16. Respondent's expert, Dr. Snyder stated that while the IOM stated that there exists a biological plausibility that tetanus toxoid may cause immune-mediated neurological disorders, such as TM, he believed in this case there were more likely causes of Bridget's TM. See Tr. at 30-31; R ex. A at 2-3.

Both experts also agree that transverse myelitis can have an infectious, post-infectious or idiopathic etiology. Tr. at 55, 82. Infectious transverse myelitis develops as a result of an active infection, particularly from a direct viral invasion of the central spinal cord and spinal fluid. Tr. at 38, 82. Post-infectious transverse myelitis develops after an infection as a direct consequence of the immune system "launching a double attack against," tr. at 16, against an "invading antigen," tr. at 14, and the body itself, tr. at 16. Post-infectious TM often follows a bacterial or viral illness manifesting as a respiratory infection. Tr. at 32; see also Tr. at 79, 87. Dr. Kinsbourne agreed that Bridget had a respiratory infection that preceded the development of her TM, that occurred within a medically accepted time frame for causing TM. Tr. at 80; see also Tr. at 93-94. During her acute treatment, Bridget was treated for a bacterial infection and a viral infection. P ex. 5 at 1034; P ex.1 at 129.

Drs. Kinsbourne and Snyder agree that if there were definite evidence of a direct invasion of the central spinal chord, (a characteristic of infectious TM) the infecting agent would be the most likely cause of Bridget's TM. Tr at 38-39 (Dr. Snyder); Tr at 82 (Dr. Kinsbourne). Specifically, petitioner's expert, Dr. Kinsbourne testified that if Bridget's doctors had found an infectious organism in her blood or central spinal fluid, that was "capable of a direct invasion of the spinal cord," he would choose that infectious agent as the cause for Bridget's TM. Tr. at 82. The experts agree that the cytomeglovirus (CMV), which is a type of herpes virus can be a causal agent for either infectious or post infectious TM. R ex. A at 2; see generally, Tr at 82-84.

Despite their areas of agreement on the basic science underlying Bridget's transverse myelitis, the experts disagree on the cause of Bridget's TM. Dr. Kinsbourne opined that Bridget's TM was caused by the tetanus toxoid component of the DTaP vaccination. He asserted that Bridget did not have an antecedent viral infection because there was no evidence of a virus found in her blood or spinal fluid. Tr. at 99. He opined that Bridget's TM was not post-infectious because there was not a definitive identification of a bacterial or viral agent as the cause for her respiratory infection. See id. at 87. Dr. Kinsbourne eliminated the possibility that

Bridget suffered from idiopathic TM because he believed there existed the possibility that DTaP, specifically the tetanus toxoid component of the vaccination, can cause TM. Tr. at 100-102.

Dr. Snyder believed that Bridget suffered from infectious TM, most likely caused by a direct invasion of her spinal fluid by the CMV. During her hospital treatment, Bridget tested "positive" for "Cytomegalovirus [CMV] IGG Antibody." P ex. at 1014; see also P ex. at 1034. Specifically, the CMV antibodies were present in Bridget's urine. Tr. at 40. Tests of her spinal fluid did not definitively culture any specific organism, though an examination of the spinal fluid of showed 96% polymorphonuclear cells. Tr. at 38. Dr. Snyder posited that this percentage of polymorphonuclear cells was more consistent with a "direct viral invasion of the spinal chord," rather than an immune-mediated response." Tr. at 38; see also Tr. at 38-39.

Dr. Kinsbourne points out that despite significant testing during her hospital treatments, the physicians were unable to conclusively identify a specific viral cause for her illness. Tr. at 34; see also P ex. 5 at 960-962. However, Dr. Snyder explained that the findings of the hospital physicians suggest that a virus directly invaded Bridget's central spinal chord. Tr. at 47. Dr. Snyder believed that the testing of the spinal fluid was done too early in Bridget's illness, before the virus was moved from her spinal chord, so that the doctors were not able to conclusively identify it as the causal agent. Tr. at 39. Dr. Kinsbourne did not rebut this critical testimony. Dr. Snyder also pointed out that it is not unusual to not identify the specific viral agent for TM. Id. at 34-5. Dr. Kinsbourne agreed, stating that "it's quite unusual to actually pin it down." Id. at 90. The experts also agreed that in 30 to 60 percent of the idiopathic cases of TM there is an antecedent respiratory illness. Id. at 79, 90, 92.

Dr. Snyder opined that Bridget's respiratory illness was viral in nature. Tr. at 42. He asserted that this conclusion was supported by the fact that Bridget was treated for a viral illness, with Acyclovir, which is an anti-viral agent. Tr. at 35. He also opined that her respiratory illness had the clinical characteristics of "any" viral illness, including the "clinical course, prolonged course [and] the associated rash," tr. at 34, which led him to "strongly favor, more likely than not," that Bridget's illness was viral, tr. at 33. Dr. Kinsbourne disagreed with this conclusion and opined that Bridget's illness was more likely bacterial in nature. See Tr. at 60-61.

In Dr. Kinsbourne's opinion, the vaccination is the more likely cause of Bridget's injury. Tr. at 102. He opined that the cause of transverse myelitis, or of related neuro-immune disorders can not be determined from the "clinical features of disease in the individual case." P ex. 6 at 4. Therefore, he asserted that "it is customary to identify the causal agent as any infection or vaccination which occurred within a medically reasonable period of time prior to the onset of the disorder and can cause neuroimmune disorde[rs], including transverse myelitis." P ex. 6 at 4; Tr. at 93. He says there is "distinction" between the respiratory illness and the vaccination as a cause, because with a vaccination you "know what you are dealing with." Id. He intimates that a respiratory infection does not provide a similar level of certainty because, he believes that a respiratory infection is "just a generic term for a bunch of symptoms and a bunch of causes." Id. He believes that this distinction "justifies a tilting in the direction of the vaccine" as the causal

agent for Bridget's TM. Id. He posits that the medical investigation into the cause of Bridget's TM did not identify the cause of Bridget's TM as post-infectious.

The experts' agreements and disagreements as to the medical information are analyzed under the three prongs of Althen. To begin, two of the three parts of the Althen test are not disputed: the experts agree that a vaccine can initiate an autoimmune response in a receptive host which in turn could lead to the development of a demyelinating disease. Tr. at 14, 38; see also 1994 IOM Report at 84. It is also not disputed that the timing for such a reaction was appropriate in this case. Tr. at 26; 1994 IOM Report at 85. The issue that remains is whether there was a "logical sequence of cause and effect show[ing] that the vaccination was the reason for the injury." Althen, 418 F.3d at 1280. As the Federal Circuit teaches us, this requirement - prong II of the Althen test - "is not without meaning." Capizzano, 440 F.3d at 1327 (Fed. Cir. 2006). As the Circuit stated:

> There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Id. (Emphasis in original). That is the case here. Dr. Kinsbourne made no effort to show how the vaccine was the logical cause of Bridget's TM; Dr. Kinsbourne "assumed" that the vaccine was the cause.

Dr. Kinsbourne recognized that either the vaccine or Bridget's respiratory infection was the likely cause of her TM. Tr. at 102. He also recognized that thirty to sixty percent of TM cases are preceded by respiratory infection. Tr. at 93. It is also not uncommon that physicians are unable to determine the exact cause of TM. Id. at 34, 79, 90. And there is nothing clinically to distinguish one cause of TM from another. Id. at 24. Thus, the court asked the critical and obvious question "given the potential in this case of several theoretical [causes], how is that you divide your probabilities?" Tr. at 83.

Dr. Kinsbourne responded in pertinent part as follows:

> both the vaccination and the respiratory infection are theoretical in that sense that the complete evidence isn't there. But, I think, to attribute the cause to an unknown virus, if there was a virus, is even more of a . . . theoretical than to contribute to a substance that you know is in the body because it was given, and that you know - that you believe, based on single case reports that discuss that type of evidence, to be a potential cause of transverse myelitis."

Tr. at 84. While recognizing that the vaccine's role could be mere coincidence, Dr. Kinsbourne agreed that absent a proven alternate cause,[21] he would opine that any case of a child suffering idiopathic TM within 42 days following vaccination of tetanus toxoid was more likely than not caused by the immunization. Id. at 101. In affect, Dr. Kinsbourne has in essence created his own two prong approach to causation: medical theory plus appropriate timing equates to legal causation. However, as the Federal Circuit logically noted in Capizzano, you can establish a reliable medical theory and appropriate medical timing and still fail to establish a logical sequence of cause and effect, otherwise the second prong would have no meaning. Capizzano**,** 440 F.3d at 1327. 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 medical evidence in this case from the treating doctors and the clinical information does "not suggest that the vaccine caused" Bridget's TM, and thus petitioner failed to prove prong II of Althen. Id.

The essence of the undersigned's ruling against a logical sequence of cause and effect and thus finding against petitioner is that the treating doctors did not consider the vaccine causative of Bridget's TM, Bridget did not react to a subsequent tetanus immunization thus undercutting Dr. Kinsbourne's medical theory of the case, and finally Dr. Kinsbourne's testimony was highly speculative and not credible. These reasons will be explored in more detail below.

Petitioner's medical evidence, which includes Bridget's hospital records and treating physician records, do not support a finding of causation. The Federal Circuit has provided the practical admonishment to pay particular attention to the contemporaneous medical records and opinions of the treating physicians. Capizzano, 440 F.3d at 1326 ("treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'"). On August 27, 2003, Bridget presented for evaluation to Dr. Douglas Kerr, Director of the Johns Hopkins University Transverse Myelitis Center. See P ex. 1 at 156-159. In his evaluation report, Dr. Kerr stated that "although we are investigating a potential link to prior vaccine administration, we have found no conclusive or **even suggestive evidence** that vaccines induce transverse myelitis." P ex. 1 at 158 (emphasis added). Dr. Kerr believed that the "most likely etiology" of Bridget's transverse myelitis was a post-infectious etiology. Id. Thus, Dr. Kerr both commented upon the dearth of medical support for vaccines causing TM - which is the opinion of Dr. Snyder, tr. at 31, and the finding of the

[21] The use of a differential diagnosis can be a legitimate means of proving causation. See Walther, 485 F.3d at 1151 (petitioner may use evidence eliminating potential causes to help carry the burden of causation.); see also Hocraffer v. Sec'y of Health and Human Servs., 63 Fed. Cl. 765, 777 (2005). However, that is not the case here. In this case, as Dr. Kinsbourne recognized, there are two equally viable potential causes of Bridget's TM - the vaccine and her respiratory illness. See Tr. at 102. As Dr. Kinsbourne testified, there is no means to distinguish clinically between these potential causes. Id. at 24. Dr. Kinsbourne did not conduct a differential diagnosis, but opined based on one being "more theoretical" than the other. Id. at 84. That is not a credible basis for an opinion. Also, as discussed, the treating doctors did not support Dr. Kinsbourne's conclusions.

IOM[22] - and considered the vaccine's possible role in Bridget's TM and rejected it. Dr. Kinsbourne recognized that fact, tr. at 70, and had no reason to disagree with Dr. Kerr's evaluation of Bridget. Id. at 38. Dr. Kerr's statements have meaning beyond that of a treater in that he is known to the undersigned as an expert in TM at Johns Hopkins Medical University. See Tr. at 19-20. Dr. Kerr has testified previously before the undersigned for respondent but has also supported cases for his patients who filed vaccine claims. His knowledge of and experience with TM is vastly superior to that of Dr. Kinsbourne.

Dr. Kinsbourne put forth the feeble disagreement with Dr. Kerr's conclusion based upon the speculative assertion that they differed on the "levels of probability," specifically that Dr. Kerr based his conclusion on a "scientific level" of probability, which is a much higher level of certainty than that required to render an opinion in a Program case. Tr. at 70; see also Tr. at 73. There is absolutely no basis in the record for Dr. Kinsbourne's supposition regarding Dr. Kerr's conclusion. Dr. Kinsbourne does not address Dr. Kerr's findings directly, in fact he stated that he did not take issue with Dr. Kerr's evaluation, tr. at 38, but contends that their different findings as medical doctors are due to Dr. Kinsbourne testifying on a level of "chance" or whether Bridget's vaccination was "more likely than not" the causal agent of her TM. Tr. at 73. However, whatever level of "chance" Dr. Kinsbourne is testifying to requires reliable evidence to support it, not mere words. Dr. Kinsbourne seems to believe that a treating doctor requires confirmatory medicine to support a diagnosis or opinion, while a testifying expert is free to engage in unsupported speculation. Dr. Kinsbourne has an obligation as an expert to ground his opinions in good medicine, clinical findings and supportable facts. See Khumo Tire, 526 U. S. 137, 152 (1999). That is what Dr. Kerr did as the treater, Dr. Snyder did as respondent's expert and what Dr. Kinsbourne failed to do. Accordingly, as will be discussed later in this opinion, Dr. Kinsbourne's testimony, and thus his credibility, was found deficient. See infra at p. 26.

In addition to Dr. Kerr, during Bridget's extensive treatment for transverse myelitis, none of Bridget's other treating physicians attribute her vaccination as the cause of her transverse myelitis. Dr. Kinsbourne stands alone in his opinion that the vaccine was the causative agent. He recognized his solitary position, agreeing that not a "single treating physician" found Bridget's TM was caused by her immunizations. Tr. at 70. It is noteworthy to comment that in reading through the comprehensive care records for Bridget, extensive efforts were made to determine whether the cause of Bridget's TM was viral versus immune, P ex. 5 at 961, and if viral what virus. See id. at 974. What is notably absent in these copious reports, see e.g. P ex. 5 at 972, is any attribution of blame, at any level of certainty, on the vaccine. Other than Dr. Kerr's consideration of and rejection of the vaccine as causative, no other treating doctor even discussed the possibility of the vaccine causing Bridget's TM. Dr. Kinsbourne had no medically-based explanation for this absence of attribution. See Tr. at 70. The undersigned in Capizzano explained the importance of the treating doctor's findings in resolving the legal question of logical sequence of cause and effect as follows:

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[22] See 1994 IOM Report, supra note 12 at 84-5.

> The treating doctors, at least in the vast majority of cases, are not through their records providing the causation evidence normally adduced through an expert, but are providing the medical "snapshot" through their contemporaneous notes, tests, and reports that allows medical experts and ultimately the decision-maker to tie the medical theory to the clinical course and determine whether the course of medical events is "logical."

Capizzano v. Sec'y of Health and Human Servs., No. 00-759, 2006 WL 3419789 at *14 (Fed. Cl. Spec. Mstr. Nov. 1, 2006) (Remand Decision); see also Carter v. Sec'y of Health and Human Servs., No. 04-1500, 2007 WL 415185 at * 19.

As the Federal Circuit stated in Capizzano, treating doctors' opinions and records are probative evidence on the issue of logical sequence of cause and effect. Capizzano, F.3d at 1326. In this case, the treating doctors considered and treated for bacterial and infectious causes for Bridget's TM. The treating doctors did not consider the vaccine as a causative agent. Dr. Kinsbourne's lame explanation that this is due to different "levels of probability" is the height of speculation. In fact, the undersigned has reviewed hundreds of cases where the doctors consider and discuss the possibility of the vaccine as a causative agent and even ascribe a causative role to the vaccine. Their failure to discuss the vaccine is powerful evidence that the clinical picture is not consistent with the vaccine being causative. In the face of this evidence from the treating doctors, the undersigned finds it illogical to say that the vaccine was the cause of Bridget's TM.[23]

A second very important clinical factor showing the illogic of Dr. Kinsbourne's theory that Bridget suffered an immune reaction to her tetanus vaccine resulting in TM was Bridget's receipt of a tetanus immunization approximately a year later without incident. Dr. Snyder testified that an agent which produced a reaction "as violent as transverse myelitis" would "likely" produce a similar reaction when introduced again. Tr. at 41. Bridget experienced no immunologic reaction to her receipt of the later immunization. Id. Dr. Snyder stated that it is not "proof positive" that the vaccine didn't cause it, but you would expect a reaction to a drug that previously produced an immediate or allergic reaction. Tr. at 53. As the court stated:

> If you receive a vaccine and suffer an injury, and then, you receive the vaccine again, and suffer the same injury, the medical community would accept that that establishes that the vaccine caused the injury?

Tr. at 53; Dr. Snyder agreed. Id; see Capizzano, 2006 WL 3419789 at *15 (noting that the IOM's discussions on proof of vaccine causality indicate that rechallenge is such strong proof of causality that the vaccine is understood to be the cause); see also 1994 IOM Report at 26, 89.

[23] In making this finding, the undersigned is aware that the doctors' extensive efforts did not uncover a cause for Bridget's TM. As the literature supports, and both Drs. Kinsbourne and Snyder agreed, the lack of a finding of cause is not uncommon. Tr. at 34, 79, 90.

Dr. Kinsbourne also agreed, stating that "[a]bsolutely, if the child had had a second DTP and shown some exacerbation of an immunological nature, or even of a systemic nature, that would have been really proof positive of that causation." Id. at 67-8. Dr. Kinsbourne recognized this occurrence as "challenge, rechallenge" and stated that it is an "immunologically valid grounds for drawing a conclusion." Id. at 68. In fact, the basis for recognizing an immunologic reaction to vaccines is the well-known and frequently discussed article in vaccine cases, the Pollard and Shelby case study. See P ex. 1E. (J.D. Pollard & G. Selby, Relapsing Neuropathy Due to Tetanus Toxoid: Report of a Case, Journal of the Neurological Science, Jan. 26, 1971, at 113.) Dr. Kinsbourne stated in his report that "[d]irect proof by challenge-rechallenge of tetanus toxoid causation of a neurological disorder was offered by Pollard and Selby (1978)." P ex. 6 at 3. What Dr. Kinsbourne conveniently failed to address in his report or in his direct testimony is why Bridget did not suffer a similar reaction to her second tetanus toxoid vaccination if she had suffered an immunological reaction to her first? When asked directly, Dr. Kinsbourne's response was less than satisfying.

In essence, while Dr. Kinsbourne agrees that challenge-rechallenge is proof positive of causation, the failure to respond to the second vaccination is not evidence that one did not suffer an immunological reaction to the first vaccination. Dr. Kinsbourne explained that:

> We don't know which [ ] epitope[24] [it] was that the child reacted to. A different daughter vaccine may have - [a] somewhat different constitution. They always do, being biological agents.

Tr. at 68. Thus, he concludes that the failure to react to the second tetanus immunization does not exclude the possibility of it causing the TM. Id.

Dr. Kinsbourne's testimony regarding the challenge-rechallenge issue epitomized his willingness to reach for any conceivable explanation to support his opinion. Dr. Kinsbourne damaged his credibility immensely with his testimony on this issue of challenge-rechallenge. The obvious question for Dr. Kinsbourne is if vaccines have different epitopes preventing consistent assignment of blame to a class of vaccines, why is it justified to assess causation to the vaccine under a challenge-rechallenge theory when the vaccine is the culprit, but not justified to use the same logic to exculpate the vaccine? Clearly, using Dr. Kinsbourne's logic, different epitopes could have been involved in the tetanus vaccinations reviewed by Pollard and Selby and thus the causal relationship between the three vaccinations and the case of GBS would be indeterminate and possibly coincidental. But instead, as Dr. Kinsbourne agreed, all three incidences were blamed on the vaccine, no matter the possibility of different epitopes. Dr. Kinsbourne's analysis is illogical and represents false reasoning as he uses the same biologics and reasoning to support two opposite conclusions - "we can [not] use [the different epitopes] to

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[24] An epitope is antigenic determinant. Dorland's Illustrated Medical Dictionary 632 (30th ed. 2003). An antigenic determinant is the particular chemical group of a molecule that determines immunologic specificity. Stedman's Medical Dictionary 523 (28th ed. 2006).

exclude the possibility of transverse myelitis being caused by the tetanus toxoid. Although, it - had been the other way around, it would have of course, have been a dramatic confirmation." Tr. at 68. This is simply faulty reasoning.

Dr. Snyder also discussed, in addition to the lack of reaction to her subsequent immunization and consistent with the medical records, other aspects of Bridget's clinical picture that call into question any causative role for the vaccine. Thus, Dr. Snyder discussed Bridget's CSF and the presence of "96 percent polymorphonuclear cells" as evidence of a direct invasion and not the immune response you would see with a vaccine reaction. Tr. at 38. While Dr. Kinsbourne questioned the evidence of a direct invasion, tr. at 63-4, he agreed that the presence of polymorphonuclear cells in the CSF is evidence of direct invasion of a virus. Dr. Kinsbourne stated that "[i]t's what you more typically get in the acute beginning of an invasion of a virus." Tr. at 95. Dr. Snyder also pointed out that the treating doctors treated Bridget for a viral illness, giving her Acyclovir. Id. at 35.

The undersigned is fully aware that the treating doctors also treated Bridget for a bacterial infection, tr. at 61, and tested for a variety of known causes for TM but were unable to determine the cause of Bridget's TM. Even Dr. Kinsbourne conceded that Bridget suffered a serious infection and had a known cause of TM, respiratory infection, within a medically appropriate time frame. Tr. at 66-67. This inability to determine the cause of Bridget's TM does not lead to the conclusion that the vaccine was the cause of the TM. Both experts agreed that not finding a cause is not unusual for TM. See Tr. at 90, 34-35. While there exists a medical theory to support vaccine causation and the timing was appropriate, there is no circumstantial evidence supporting the logical sequence of cause and effect. What little circumstantial evidence that does exist points to a cause other than the vaccine.

Dr. Kinsbourne's balancing of the probabilities in favor of the vaccine because "we have an organism [the vaccine] which has been documented to be associated with transverse myelitis[,] [o]n the other hand, we don't know what the organism is," tr. at 85, is highly questionable. First, "associated" may be too strong of a word. The IOM did recognize a biologic plausibility for a causal relation based upon two case reports. 1994 IOM Report at 85. However, they did not find sufficient evidence to accept or reject a causal relationship. Id. at 86.

Dr. Kinsbourne was asked about the IOM's findings. Tr. at 18. He stated that he agreed with them on the basis of "lack of epidemiology." Id. However, Dr. Kinsbourne is incorrect in stating that the IOM did not require epidemiology; the IOM relied upon a variety of information to establish causation, including case reports. See generally 1994 IOM Report at 19-33, 85-6. Dr. Kinsbourne was then asked whether he was aware of any additional information regarding a causal relationship between tetanus and TM since the 1994 IOM report. Dr. Kinsbourne's response was telling on several levels. He replied "I would have to see the dates of the literature that I submitted. I don't have it before me, but within the dates . . . is what I am aware of." Tr. at 18. First, Dr. Kinsbourne had testified earlier that he keeps abreast of the literature, answering "Intensively. . . . Definitely." Tr at 13. Based upon the undersigned's extensive experience with

Dr. Kinsbourne, keeping abreast of the medical literature is Dr. Kinsbourne's response to the criticism that he does not maintain a clinical practice and has not for many years. Not being able to answer a fairly fundamental question regarding the state of the knowledge regarding TM causation since the IOM report from 1994, which Dr. Kinsbourne as a frequent witness knows exceedingly well, is not a good indication of keeping abreast of the literature. Secondly, not having the literature with him at trial is not a strong indicator of being prepared for testifying. Thirdly, a review of Dr. Kinsbourne's submitted literature confirms what Dr. Snyder stated was the "slim" evidence of a causal connection between Tetanus and TM. Only one of the articles post-dated the IOM's 1994 report. The remaining articles pre-dated the IOM's report, in fact one of the articles is one of the two case reports relied upon by the IOM[25], and thus were presumably considered by the IOM. The remaining articles add little to the understanding of this case, and in fact were not discussed at the hearing.[26]

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[25] Read et. al., Encephalomyelitis after Tetanus Toxoid Vaccination, 339 Lancet, Volume 1111 (1992) (P ex. 1G) (Discusses a case of TM reported after a tetanus toxoid vaccination. The authors state that it is possible that the myelopathy occurred independently, however they believe that the tetanus vaccination caused the injury. They opine that timing and the absence of an alterative explanation may implicate tetanus toxoid as the cause.)

[26] Diekhofer et. al., (P ex 1A) was written in a foreign language. Petitioner did not file a translation of the article, and thus the undersigned did not consider it.

Patti L. Holliday, MD & Raymond B. Bauer, MD, Polyradiculoneuritis Secondary to Immunization with Tetanus and Diphtheria Toxoids, 40 Arch. Neurology 56 (Jan. 1983); (P ex. 1B) (Discussing a case report of a patient that did not have an antecedent infection, who after receiving his third tetanus containing vaccination, developed polyradiculoneuritis with paresis of the urinary bladder and bowel. The authors concluded that he likely suffered a neurological complication of tetanus and diphtheria toxoids, most likely tetanus, though it was not possible to clarify the mechanism by which the tetanus toxoid induced the disorder. The authors further opine that finding case reports of neurological complication following Td vaccinations is very difficult; nonetheless they state that tetanus toxoid induced neurological damage must be considered when neurologic abnormalities develop subsequent to a vaccination.)

Gerald Fenichel, M.D., Neurological Complications of Immunization, 12 Annals of Neurology 119 (Aug. 1982); (P ex. 1C) (Opining that a cause-effect relationship between immunizations and TM has been suggested but never proved. Acute TM is the acute onset of a spinal cord transection syndrome unassociated with an encephalophathy for which approximately 30% of all patients, of all ages, report a preceding systemic viral illness. All relevant and available data concerning a cause-effect relationship between a vaccination and TM is circumstantial and based upon the temporal relationship. The authors conclude that any neurological complications following DPT can be attributed almost entirely to Diphtheria.)

Pollard & Selby, Relapsing Neuropathy due to Tetanus Toxoid, 37 Journal of Neurological Sciences 113 (1978) (P ex. 1E) (Authors discuss the case of a man who inadvertently received 3 tetanus toxoid vaccinations, and after each vaccination suffered from Guillian Barre Syndrom (GBS). The authors concluded that there was little doubt that the three clinical episodes of GBS resulted from the administration of the tetanus vaccination. According to the authors peripheral nerve involvement after a tetanus vaccination is well recognized. The authors could not determine how a tetanus vaccination caused cellular hypersensitivity to myelin, which evokes destruction of the myelin.)

C.M. Poser, Neurological Complications of Infections and Vaccinations, 13 Saudi Medical Journal, 379

The only article post-dating the IOM's 1994, report states that in recent years, and in very rare instances, some neurological diseases that are classified as restricted to the central nervous system have been associated with severe peripheral nervous system (PNS) damage, when the appropriate tests are performed.[27] E. Marchioni et al., Postinfectious Inflammatory Disorders: Subgroups based on prospective Follow up, 65 Neurology 1057 (2005). However, the authors noted that recently proposed diagnostic criteria for TM did not include or discuss cases related to PNS involvement or its possible impact on treatment. Id. at 1068. This article suggests that the medical or scientific community as a whole does not find that PNS involvement is relevant to TM. The article does not support Dr. Kinsbourne's assertion - that there is a continuum between

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(1992) (P ex. 1F) (Asserting that the anatomical distribution and severity of the immune response to a vaccination is determined by the immunogenetic constitution of the recipient not the nature of the antigen. The author concludes that immune reactions to vaccinations are far more common than recognized; and that an important clue to vaccine-related injury is the involvement of the CNS and peripheral nervous system in a patient's reaction.)

Louis Reik, Jr. M.D., Immune-Mediated Central Nervous System Disorders in Childhood Viral Infections, 2 Seminars in Neurology 106 (1982) (P ex. 1H) (The author opines that the features of acute TM in post-infectious and post-vaccinal TM are the same and that both types of TM affect the CNS in children with thirty percent of all cases beginning three to ten days after an antecedent infection or vaccination.)

S. Lane Rutledge, M.D. & O. Carter Snead III, M.D., Complications of Immunizations, 109 Journal of Pediatrics 917 (1986) (P ex. 1I) (The authors state that the most commonly reported complication of Tetanus Toxoid (TT) is polyneuropathy-which affects the peripheral nervous system. According to the authors there is no proven cause-effect relationship between TT and polyneuropathy, encephalopathy or myelopathy with the exception of the Pollard Selby case study. The authors believe that the temporal relationship is the only data that connects TT to any of the previously mentioned neurological disorders, which does not support definite causation.)

G.K. Schlenska, Unusual Neurological Complications following Tetanus Toxoid Administration,,215 Journal of Neurology 299 (1977) (P ex. 1J) (The authors opine that neurological complications are extremely rare after TT vaccination.)

Tezzon et. al, Acute radiculomyelitis after Antitetanus Vaccination, 15 Italian Journal of Neurological Science 191 (1994) (P ex. 1L) (The authors state that it is known that active and passive vaccinations can lead to lesions on both the central and peripheral nervous system. Central nervous system lesions have been a reported as a complication after DPT vaccinations and are thought to be exclusively caused by Pertussis.)

Topaloglu et. al., Optic Neuritis and myelitis after booster tetanus toxoid administration, 339 Lancet 178 (1992) (P ex 1M) (Based upon a case study, the authors conclude that there exists a temporal association between the tetanus toxoid vaccination and optic neuritis and myelitis.)

[27] E. Marchioni et al., Postinfectious Inflammatory Disorders: Subgroups based on prospective Followup, 65 Neurology 1057. (2005) (P ex. 1D) (This study included observations of several post-infectious disorders, including ADEM and myelitis - defined as the acute development of focal or multi-focal clearly defined spinal cord damage or by evidence of transverse myelitis. The authors state that in recent years other neurological diseases classified as a central nervous system-restricted inflammatory disease have been found to be associated with severe peripheral nervous system damage, when appropriately searched for. In such cases there is a marked distinction from GBS.)

GBS, which affects the PNS, and TM which affects the CNS. Tr. at 15-18.

This raises another defect in petitioner's case, that is Dr. Kinsbourne himself. It is 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. While the undersigned recognized Dr. Kinsbourne's good efforts in Simon v. Sec'y of Health and Human Servs., No. 05-941, 2009 WL 623833 at *7 (Fed. Cl. Spec. Mstr. Feb. 21, 2008); my colleague recently expressed similar concerns about Dr. Kinsbourne in Snyder v. Sec'y of Health and Human Servs., No. 01-162, 2009 WL 332044 at *11-12 (Fed. Cl. Spec. Mstr. February 12, 2009).[28] He was also harshly criticized by my former colleague, who was the previously assigned special master in the case at hand, in Moberly ex rel. Moberly v. Sec'y of Health and Human Servs., No. 98-910V, 2006 WL 659522 at *5-6 (Fed. Cl. Spec. Mstr. Feb. 28, 2006). The criticism noted in those decisions apply equally to Dr. Kinsbourne's testimony in this case.

Unfortunately, the undersigned has seen the trend to unreliability in several recent cases such as this one. Dr. Kinsbourne's willingness to opine in cases based upon little more than a mere possibility, as in this case, is unacceptable. His failure to focus on and explain the medical issues in the context of the injured's clinical treatment and the doctors' records of that treatment, but instead offer opinions based upon his interpretation of the law is unacceptable. He is doing great harm to what was once a very positive reputation. Needless to say, the undersigned did not find Dr. Kinsbourne's testimony in this case credible. Dr. Kinsbourne's testimony amounted to

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[28] In Snyder, my colleague noted the following:

> [i]n what has become known as "the same intellectual rigor" test, the Supreme Court stated that a judge is obligated to ensure that the testimony of experts reflects "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., Ltd. V. Carmichael, 526 U.S. [137, 152 (1999)]. In a book chapter he authored . . . ., Dr. Kinsbourne included a chart on the causes of autism. In his testimony in Cedillo[v. Sec'y of Health and Human Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009)], he used the same chart, but with one addition; he included measles as a cause. A fair assessment of this change is that Dr. Kinsbourne was unwilling to say measles was a cause of autism in a publication for his peers, but was willing to do so in a Vaccine Act proceeding.
>
> Another concern is that Dr. Kinsbourne suffers from the stigma attached to a professional witness-one who derives considerable income from testifying in Vaccine Act cases. In the 20 years of the Vaccine Program's existence, Dr. Kinsbourne has appeared as an expert witness in at least 185 decisions. This figure does not include his opinions in the many unpublished cases adopting stipulations of settlement, nor does it reflect pending cases in which he has filed an expert opinion. Payment for expert testimony is expected, and the mere receipt of payment does not, of itself, cast doubt upon an expert's qualifications or opinions. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317 (9th Cir. 1993) (noting, however, that an expert's normal workplace should be "the lab or the field, not the courtroom or lawyer's office").

Snyder, 2009 WL 332044 at *11-12.

nothing more than *post hoc ergo propter hoc* reasoning, which has been consistently rejected by the Federal Circuit. See e.g. U. S. Steel Group v. U.S., 96 F.3d 1352, 1358 (Fed. Cir. 1996).

In this case, Dr. Synder, respondent's expert, provides the more reliable opinion, that is supported by the 1994 IOM study with which Dr. Kinsbourne essentially agrees. Dr. Snyder's opinion is supported by the treating doctors, particularly Dr. Kerr, and the clinical evidence. Dr. Snyder's testimony was far more persuasive than Dr. Kinsbourne's speculation.

VI. CONCLUSION

In the final analysis, the undersigned recognizes that this is a difficult case. Where a case presents as this one with an accepted medical theory, appropriate timing and an absence of other proven causes, one is tempted to throw up their hands and state, as Dr. Kinsbourne did, it has to be the vaccine. But it does not have to be the vaccine. There are many other accepted causes of TM, as were present and discussed in this case. It is also accepted that in a high percentage of cases, that the cause will not be identified. Therefore, it is not logical to reflexively conclude that it is the vaccine. Instead, as the Federal Circuit teaches, and Dr. Kinsbourne stated, you look for supportive circumstantial evidence. In this case, the circumstantial evidence, while not overwhelming, pointed away from the vaccine. Most meaningful was the evaluation and findings of Dr. Kerr, a noted TM specialist, the lack of any indication from the treating doctors that the vaccine was considered as the cause and the fact that Bridget did not react to a subsequent immunization - the lack of rechallenge. These cumulative pieces of circumstantial evidence point, not to the vaccine as Dr. Kinsbourne advocates, see Tr. at 102, but to some other unidentified cause.[29]

Accordingly, for the reasons stated herein, the undersigned finds that petitioner has not established by a preponderance of the evidence that Bridget's October 4, 2002 DTaP and Hib vaccinations were the legal cause for Bridget's transverse myelitis. Therefore, petitioner's claim is dismissed. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/Gary J. Golkiewicz
Gary J. Golkiewicz
Chief Special Master

[29] Because the undersigned finds that the petitioner did not meet her burden, the question of alternative causation is not reached. See Bradley v. Sec'y of Health and Human Servs., 991 F.2d 1570, 1575 (Fed.Cir.1993) (when petitioner has failed to demonstrate causation by a preponderance, alternative theories of causation need not be addressed).