In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-0694V

Filed: 14 April 2009

* * * * * * * * * * * * * * * *		
TYSHEEM HARGROVE, Jr., a minor, by his parents and natural guardians FELICIA WISE and TYSHEEM HARGROVE, Sr.,	*	
Petitioners,	*	
v.	*	**PUBLISHED**
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* * * * * * * * * * * * * * * *		

Lawrence R. Cohan, Esq., Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, Philadelphia, Pennsylvania, for Petitioner;

Michael P. Milmoe, Esq., United States Department of Justice, Washington, District of Columbia, for Respondent.

ENTITLEMENT RULING[1]

ABELL, Special Master:

On 27 June 2005, 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 DTaP

[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.

and/or other vaccinations Tysheem received on 20 May 2003, he suffered a severe and debilitating bout of transverse myelitis (TM).[3] Amended Petition at 1.

This petition was assigned to my chambers on 27 June 2005. Eventually, an evidentiary hearing on the ultimate issue of entitlement for compensation was held *in vivo* in Philadelphia, Pennsylvania on 30 May 2007. Hearing Transcript ("Tr.") at 1. Whereupon, the Court heard from Petitioner Felicia Wise herself regarding matters of factual circumstance, as well as medical expert witnesses for both parties: Dr. Marcel Kinsbourne for the Petitioner, and both Dr. John Sladky and Dr. Stephen McGeady for the Respondent. Tr. at 3, 4. 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) they represent the real party at interest as parents of 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 Petitioner's testimony and 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 fact witness 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.

---

[3] 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.

It is axiomatic to say that the 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, Tysheem's condition. The Court gathers the following circumstantial facts from the medical records:

On 20 May 2003, at a visit to his pediatrician, Tysheem received the DtaP, IPV and PCV vaccines. Pet. Ex. 9 at 14. It was his fourth DtaP, his third IPV, and his fourth PCV vaccination. Pet. Ex. 2 at 9. The pediatrician's notes from that visit indicate that Tysheem had a runny nose and a cough that day, although the vaccinations were still administered. Pet. Ex. 9 at 14.

That night, at around 10:50 PM, Tysheem was seen at the Childrens Hospital of Philadelphia (CHOP) emergency room, complaining of "fever [and] lumps where [he received the] shot." Pet. Ex. 4 at 7. He was observed to have "no colds," "no cough" and "no n/v/o."[4] Tylenol was recommended for the fever, which his mother was told to expect to last 24-48 hours. *Id.* at 7, 10.

Tysheem returned to his Pediatrician two days later on 22 May 2003, complaining of running a temperature of 101 degrees for the two days preceding, and arm pain where the vaccine was administered. Pet. Ex. 9 at 14. The pediatrician notes include a notation that Tysheem "will not move arm by self," that he had been "seen [at] CHOP [on 20 May 2003]," that he was "very weak," and that he was "congested" with "some cough." It was also noted that he was not using his left arm, and that the injection site was "not red, warm, swollen, tender or bruise[d]." Pet. Ex. 9 at 13 (emphasis in original). Also noted from that visit is the absence of local reaction to the immunization, and an unexplained reference to "URI" (upper respiratory infection). *Id.*

Tysheem was next admitted to the CHOP emergency room later that day, at about 6:50 PM, with a stated chief complaint of "not moving [left] arm." Pet. Ex. 5 at 10. His temperature was 99.86 degrees Fahrenheit and breath sounded coarse. *Id.* The box was checked "No" for the field marked "Is Patient Having Pain?". *Id.* The objective assessment at triage stated that Tysheem was "awake," "tired," and "appearing NAD."[5] *Id.* It repeats the history taken from Petitioner Felicia Wise, that he had "not [been] moving [his left] arm since Tues[day]," 20 May 2003, and had suffered "intermittent fevers." *Id.* It notes that the left arm had by then become "tender to touch." *Id.*

The Emergency Department Records from the evening hours of 22 May 2003 record, in the history taken from Tysheem's mother, that Tysheem had congestion and cough for the three days prior, and that Tysheem would not sit or stand on his own since that Tuesday, 20 May 2003. Pet. Ex. 5 at 12. The attending comments from that record note that Tysheem held his arm at his side. *Id.* The discharge impressions was "weakness" without specific description. *Id.* By 6:56 PM, Tysheem was losing, or had already lost, his ability to sit up, but was still then able to withdraw his legs. Pet. Ex. 5 at 14.

Late on the night of 22 May 2003, Tysheem received a neurology consultation at the hospital, which recorded a history (presumably given by his mother) of fever and decreased activity following vaccination, such that "within 3 hours he was 'wobbly on his feet and not using his [left] arm." Pet. Ex. 5 at 44 (unclosed quotation marks in original). At that time, Tysheem did not have any rash, and was apparently "pleasant[,] awake[,] alert [and] interactive." *Id.*

In an undated record from 5:30 PM (presumably on 23 May 2003), the history of present illness description notes that Tysheem was then "still refusing to move arm" and "won't sit or stand

---

[4] It is unclear what was meant by "no n/v/o." The Court was unable to find a meaning for that abbreviation in its examination of available sources.

[5] "NAD" used in this context most likely means either "no active disease," "no acute distress," "no apparent distress," "no appreciable disease," or "nothing abnormal detected." MEDICAL ABBREVIATIONS (12th ed. 2005) (Davis) at 241-242.

on own since Tuesday." Pet. Ex. 5 at 12. The same record also notes that Tysheem was positive for congestion and cough since three days previous, but was negative for vomiting and/or diarrhea and negative for "sick contacts." *Id*; *see also* Pet. Ex. 5 at 26. It notes his present state as "awake [and] alert." *Id*.

Tysheem's discharge summary, dictated on 15 June 2003 but addressing his hospital stay from 22 May 2003 until 29 May 2003, noted the following (inter alia):

> On the day of admission to the hospital, the patient had decreased activity and is [was?] at the point where he was no longer able to walk or sit. ... [An] MRI of his spine showed changes consistent with transverse myelitis at the C1 to C5 level. ... [A] lumbar puncture ... showed white blood cell count of 5, red cell count of 460, no growths from the culture, negative enterovirus PCR ... [and] was negative for RSV. ...
>
> ... On 5/27 the patient was transferred out of the Pediatric Intensive Care Unit to the regular Neurology Service. On arrival on the floor, he was in no acute distress. ... He did have some spontaneous movements in his upper extremities by proximal muscle but has difficulty moving his distal[6] arm, particularly the left. He had no spontaneous movements in his legs [and] ... did not react to pain in the legs. ... His legs were hypertonic and rigid with passive flexion with 2 to 3+ deep tendon reflexes.
>
> ... [T]his was thought to be ... transverse myelitis with no clear etiology."
>
> ... By discharge [transfer to Children's Seashore House], he was showing steady, continual regain of motor function. He was having more spontaneous use of his upper extremities but he was still very limited in the use of his lower extremities. He was more stable when seated and at discharge could sit without support or very minimal support.

Pet. Ex. 5 at 20-21.

During Tysheem's hospital stay, he was seen for an infectious disease consultation, for which the assessment was that the "time interval [between] receipt of immunization [and] onset of [symptoms], plus apparent intercurrent [*sic*] URI, [is] inconsistent with [a] causal link [between] immunization [and] his [injury] (either on allergic or autoimmune basis)." Pet. Ex. 5 at 42. The result of that consultation was a putative "viral etiology" based on "his URI [symptoms]." Nevertheless, as indicated above, this putative explanation was not sufficient for the discharge summary to reach a "clear etiology."

Tysheem again was seen by his pediatrician on 29 May 2003, when his diagnosis was acute transverse myelitis, which, by then, had "progressed to complete quadriparesis." Pet. Ex. 9 at 13. Noted the pediatrician, "All specialists agree that [there is] no relation [of the transverse myelitis] to vaccines – OK to continue usual vaccines." *Id*. Nonetheless, a VAERS form was filed. *Id*. The

---

[6] Distal means "remote; farther away from any point of reference; opposed to proximal." DORLAND'S, *supra*, at 553.

VAERS reporting form history description notes that the transverse myelitis diagnosis was confirmed by MRI findings and clinical indicia, that all cultures were negative, and that the presumed aetiology was viral, adding that infectious disease specialists "do not believe it is vaccine related." Pet. Ex. 2 at 63 (emphasis in original).

B. Testimony Bearing on Entitlement

1. Felicia Wise

As Tysheem's mother, Felicia Wise (Petitioner) possessed certain detailed knowledge of the development of his condition and ultimate injury, alleged by Petitioners to be vaccine-related, she was called to testify at the entitlement hearing convened by the Court on 30 May 2007.

Petitioner related that Tysheem developed normally through his first eighteen months, with no serious medical problems, and remaining active and playful as is typical of that stage of development. Tr. at 8. She took Tysheem into his pediatrician's office for a scheduled well-child check-up and set of vaccinations. Tr. at 9-10. According to Petitioner, no medical concerns or illnesses were noted by her at intake, not even a common cold. Tr. at 11. She added: "As his mother, ... my son did not have a cold. He did not have no gray mucous. I know about colds. My son did not have a fever. He would have had mucous coming out of his mouth when he coughed, and he had none of that." Tr. at 11.

In response to questioning, Petitioner addressed the pediatrician's records from that visit that discuss a cold. *See* Pet. Ex. 9 at 14, *supra* at 3. Petitioner figured that the mention of possibility of a cold was:

> because he was teething, and [insofar as] a runny nose, yes; but was there any green mucous, no. It was clear. He may have coughed a few times, something like this, but it was not as if his chest was congested. It was more of a dry cough. And if the doctor was concerned about it, I am quite sure that he would have given him an antibiotic or something else. We never discussed it.

Tr. at 12.

Petitioner said Tysheem remained "cranky" for a few hours after the administration of the vaccines, at which time she removed the bandages to examine the injection site, which she described as "a little red, a little swollen." Tr. at 14. When asked to describe in greater detail the redness and swelling, Petitioner explained:

> It wasn't a big lump, but it was a lump around where the dot was. It was red from this area to this area [indicating a 2-3 inch area of the deltoid], and this is like where the swelling was. And it was on both of his arms, but it was only around the site of the injection.

Tr. at 15.

The next day, said Petitioner, Tysheem developed a fever, with visibly manifest symptoms, and became increasingly cranky, upset, and antisocial. Tr. at 16. Among other things, he "guard[ed]

himself with his arm, like he didn't want [any]body to bother him, and didn't want to be touched." Id. Petitioner went on to explain and demonstrate that Tysheem began "holding his arm as though he didn't want anybody to touch them," which he did by withdrawing his upper left arm close in to his torso, and projecting out his left forearm and hand (usually closed, but not in a fist) into a guard position, while his right arm remained aloof, i.e., "kind of limp." Tr. at 17-18. Though he did not hold that position throughout the day, he did so when he became apprehensive of being touched. Tr. at 19. Eventually, that night of 20 May 2003, Petitioner took Tysheem to the emergency room out of concern for the fever he was carrying. Tr. at 19-20. After treatment and reassurance provided there, Petitioner took Tysheem home; he remained cranky but was able to sleep. Tr. at 21.

Throughout the day of 21 May 2003, Tysheem's fever was checked by tylenol, and he guarded his arm less gingerly, though he remained apprehensive about his arm being touched, retreating into the same guard whenever his mother tried to examine it. Tr. at 22.

On 22 May 2003, when his fever did not resolve, despite temporarily subsiding with medication, Petitioner returned Tysheem to his pediatrician. Tr. at 23-24. Petitioner explained the notation in the medical records that Tysheem would not move his arm by himself by explaining that he had returned to the guard position of the day before, and maintained that position due to pain and swelling in the arm. Tr. at 24-25. The medical record also had noted that Tysheem was "very weak," which Petitioner explained as lethargy and petulance due to being sick. Tr. at 25. At that time, Petitioner's recollection was that Tysheem's injection sites remained tender, though were not as inflamed or swollen as the day of administration; the marks from injection were still visible and remained warm, but were not red. Tr. at 25-26. Petitioner could not recall whether Tysheem showed cough symptoms at that visit. Tr. at 25. Petitioner said that, due to Petitioner's lingering concerns about Tysheem's arms, Tysheem's pediatrician then sent them for x-rays and then on to the hospital. Tr. at 26-27. At the time of admission there (between six and eight in the evening, Tr. at 33), Tysheem was still employing the guard of his left arm as before, and he still suffered tenderness. Tr. at 29. When questioned at the hearing, Petitioner did not recall whether Tysheem manifested congestion and/or coughing, as was noted in the intake records. Tr. at 29.

Petitioner noticed during that period that Tysheem "was more slouched than sitting up straight," which she attributed to discomfort from his fever. Tr. at 30. Doctors at the hospital started to notice abnormal responses from Tysheem when instructed to lift his arms: said Petitioner, "Tysheem would just look at him like he didn't want to be bothered, and he just laid there." Tr. at 31.

By the next morning, on 23 May 2003, Petitioner remembered that Tysheem's condition worsened through decreased responsiveness, to the point that he resembled "a rag doll" in Petitioner's recollection. Tr. at 33-34. Petitioner explained further:

> [H]e didn't have any strength, and he couldn't even lift it up, lift his arm up. All he would do is just move, and his eyes would be looking around and seeing what was going on. He was like limp. ...[A]fter they put him upstairs and put him in a room, and I would ask him to do something, and he just wouldn't respond. Before he was

> guarded, and now I am not getting any response, and that started triggering that there is something really wrong with my son.

Tr. at 34-35. Petitioner dated this development to the morning of 23 May 2003, after admission to the hospital, recalling that he was still able to maintain the muscle tension of his arm guard the evening of 22 May 2003 at the time of admission. Tr. at 36.

According to Petitioner, Tysheem's hospitalization lasted until the end of June 2003, after which he returned home. Tr. at 37. Not too long thereafter, Tysheem developed myocarditis, which his doctors thought at the time could have been linked to the transverse myelitis. Tr. at 37-38. Tysheem retained lingering sequelae of his bout of transverse myelitis, affecting his ambulation and bladder and bowel continence. Tr. at 39-40. Since the myocarditis, however, Tysheem has experienced no major, emergent health problems. Tr. at 48. As a precaution, however, Tysheem's doctors limited his continued vaccination schedule, she said. Tr. at 49-50.

2. Marcel Kinsbourne, MD

Dr. Kinsbourne's medical expert opinion reports (of which Petitioner filed three, found at Petitioner's Exhibits 11, 28, and 29) stated that it is biologically plausible that tetanus toxoid, such as is found in the DTaP vaccine, *could* cause a demyelinating disease of the central nervous system, such as is transverse myelitis, via an immune-mediated process of autoimmune reaction, and cited K. Stratton *et al.*, *supra* note 3, a report from the Institute of Medicine (IOM) Committee. Pet. Ex. 11 at 2. According to Dr. Kinsbourne, "It was only because support from epidemiological evidence is lacking that the Committee was disinclined to endorse the causal relationship between tetanus toxoid and transverse myelitis." *Id*., citing Stratton *et al.*, *supra* note 3 at 84. Dr. Kinsbourne admitted that there has not been published a "controlled epidemiological study of the relationship between tetanus toxoid and transverse myelitis," but he hastened to add that "transverse myelitis is considered usually to be immune-mediated, and tetanus toxoid is well known on rare occasions to induce immune-mediated neurological disorders." Pet. Ex. 11 at 2-3. *See also* Pet. Ex. 15 at 7, Pollard and Selby, "Relapsing neuropathy after administration of tetanus toxoid," 37 *Journal of the Neurological Sciences* 113, 117 (1978) ("There is little doubt that [rechallenge reactions] of demyelinating neuropathy resulted from the administration of tetanus toxoid."). Dr. Kinsbourne proceeded to cite a study which "listed transverse myelitis as a complication of tetanus toxoid," and two others for which transverse myelitis was reported following exposure to tetanus toxoid. *Id*. at 3.

As to the question of whether the vaccine *did* cause Tysheem's transverse myelitis, Dr. Kinsbourne explains the unusually brief period between the vaccination and the onset of the condition as follows:

> The relatively short interval between the vaccination and the onset of Tysheem's immune neurological disorder is presumably due to anamnestic[7] reaction, that is, an acceleration of the immune attack due to sensitization by Tysheem's three previous tetanus [] vaccinations. In a primed host, the lag phase between antigen challenge

[7] Anamnesis in this case means "immunologic memory." DORLAND'S, *supra*, at 73.

> and antibody response is shorter than to the initial challenge, and the antibody level is higher. ... The secondary anamnestic response is mediated by more rapid production of antibodies which is implemented by circulating B-memory cells, and which generally peaks in 1-3 days.

Pet. Ex. 11 at 2, citing Pet. Ex 21, Topalogou *et al*., "Optic neuritis and myelitis after booster tetanus toxoid administration," 339 *Lancet* 178-79 (1992) (onset of transverse myelitis followed three days after a tetanus booster). Dr. Kinsbourne also pointed out that "there is no evidence for any other reasonably probable cause for Tysheem's transverse myelitis in the medical records." Pet. Ex. 11 at 3; *see also* Pet. Ex. 13 at 4, Rutledge and Snead, "Neurologic complications of immunization," 109 *Journal of Pediatrics* 917, 918 (1986) (diagnosis of polyneuropathy following vaccinal administration of tetanus toxoid "is based on the exclusion of other causes of neuropathy and a temporal relationship between administration of toxoid and onset of symptoms").

Dr. Kinsbourne explained the putative mechanism of autoimmune reaction in his opinion through the process of molecular mimicry:

> In molecular mimicry, an invading epitope cross-reacts with a self-protein. B cell activation generates a cross-reactive antibody that escapes or overrides self-tolerance. ... [This may occur in] acute transverse myelitis ... and may be associated with the development of antibodies in response to an antecedent infection [in which] circulating antibodies may form immune complexes that deposit in focal areas of the spinal cord. Immune complexes are autoantibody-antigen complexes.

Pet. Ex. 29 at 3, citing Kerr & Ayetey, Immunopathogenesis of acute transverse myelitis," 15 *Current Opinion in Neurology* at 339-347 (2002) (internal marks omitted). In defending this theory against Respondent's experts, which Dr. McGeady in particular criticized and deemphasized in favor of a cell-mediated process, Dr. Kinsbourne cited a newer edition of the same text (seventh, instead of the third), which states that "Autoantibodies may initiate a direct injury to neurons" and otherwise discusses "circulating immune complexes." *Id*. Dr. Kinsbourne adds to this point that both cell mediated and antibody mediated reactions to provocative antigens are apt to accelerate with repeated exposure of the antigen challenge (the 'anamnestic reaction') ... such that the expected temporal interval between the antigenic challenge and the clinical onset shrinks" in both "direct antigen-antibody reactions [and] cell-mediated reactions." *Id*.

Dr. Kinsbourne supports his position concerning anamnestic reaction with reference to the IOM's Vaccine Safety Committee's findings, that a reaction from the combination of antibody and an antigen expressed on normal cells should take two to three weeks to develop, but would only take a few days upon re-exposure, adding that an immune complex mediated reaction "generally develops over [six] to [twelve] hours if antibody levels are already high." *Id*. at 4. The IOM's report supports the same principle, says Dr. Kinsbourne, in the scenario proffered by Dr. McGeady–that of antigen-specific lymphocytic stimulation: "On first exposure, the response peaks after about 3 weeks; on re-exposure the response typically peaks after 24 to 48 hours. *Id*. Dr. Kinsbourne synthesizes these sources to conclude that "immune-mediated reactions to an agent such as tetanus toxoid can occur as soon as within a day or two if the immune system has previous experience of the vaccine." *Id*.

Ultimately, Dr. Kinsbourne rests his opinion on what he views as "(1) a biologically plausible mechanism of injury, (2) supportive case studies in the peer-reviewed medical literature, (3) a reasonable theory of cause and effect applicable to this patient, and (4) a scientifically supported temporal interaval," coupled with the absence of "evidence in the medical records of any other potential alternative cause." Pet. Ex. 11 at 3.

After initially attaching some significance to the local reaction Tysheem seems to have experienced at his injection site(s) (based on his first reading of the medical records, contradicted elsewhere in other, more reliable records), Dr. Kinsbourne retreated somewhat in his first supplemental expert report, explaining that he "had pointed out that an inflammatory reaction is consistent with causation but [] had nowhere indicated that this is a necessary component for [his] causation opinion," adding that he is not "aware of any medical literature that argues that a vaccine cannot cause an immune-mediated disorder unless it caused substantial inflammation locally [first]." Pet. Ex. 28 at 1 (emphasis in original).

Dr. Kinsbourne challenged the experimental study report used by the IOM panel for constructing a time interval for onset, which was relied upon by Respondent's expert, Dr. Sladky, because the study used animal models which did not study the effects of "multiple challenges" of the agent, and do not therefore undermine his (Dr. Kinsbourne's) analysis of anamnestic reaction. Pet. Ex. 28 at 2. In fact, he explained, "the time parameters within which [the studied neurologic injury] appears in experimental animals are not definitive for the wide range of human autoimmune disorders." *Id*. He continues, "Although it is true that typically the onset of an immune-mediated disorder takes five days or more to become clinically apparent, this cannot be regarded as an invariable rule, particularly when multiple previous challenges of the causative agent have been delivered." *Id*.

Regarding the alternative cause of an upper respiratory tract infection, which was raised in the medical records (*see supra* at 4), Dr. Kinsbourne noted that "the virus that was involved, if any, was not identified," and, as such, it is indeterminate "whether this particular apparent infection would have been apt to cause immune-mediated neurological disorders." Pet. Ex. 28 at 2. This is because "[w]hether an upper respiratory infection [] triggers transverse myelitis depends on which virus (unknown in this case) is involved," adding that "there is no way of knowing whether Tysheem's symptoms of URI were in fact caused by a virus infection" or were caused by something else. Pet. Ex. 29 at 1. Dr. Kinsbourne also points out a subtle error of logic he ascribes to Respondent's position:

> URIs are exceedingly common, whereas transverse myelitis is rare, and even rarer in young children. The vast majority of URIs that precedes [*sic*] transverse myelitis has not been shown to be caused by a virus that has a known association with transverse myelitis. Though it may be tempting, it is inconclusive to attribute transverse myelitis wholesale to any URI, not further delineated, that might precede the onset of the transverse myelitis. The reasoning would be backward: if a URI preceded transverse myelitis, it must have caused the disorder. This type of reasoning is not acceptable when wild viruses are concerned. There is no way of knowing in

> retrospect whether a URI was caused by one of the few respiratory viruses that have been associated with transverse myelitis, or one of the hundreds that have not.
>
> [Scientific] causation [must be] established based on the [individual] case[, not] on the relative frequency of virus infections and vaccinations in general. When vaccine causation is proposed[,] it is not [] sufficient to say that vaccines sometimes cause the disorder in question. It is necessary to identify the actual vaccine that was administered, and to show that it is capable of causing the disorder. ... In the case of Tysheem Hargrove, the virus that caused the URI at issue is not identified, and [should not be considered] as a causal agent.

Id. at 1-2. Dr. Kinsbourne added that, contrary to Dr. McGeady's position on the likelihood of vaccine causation based upon population statistics (*see infra* at 18-20), "The relative frequencies of virus infections and vaccinations are not relevant for determining specific causation in the individual case." *Id*. at 2. His final point on the alternative potential cause of viral infection, manifested as a URI, is that "the URI began too late to have caused the transverse myelitis," assuming the URI did not truly appear until 22 May 2003, because "the temporal interval for immune-mediated disease caused by wild viruses is typically much longer, 2-3 weeks." *Id*. Dr. Kinsbourne did not accept as justifiable Dr. McGeady's explanation that the virus was in incubation[8] at the onset of transverse myelitis. *Id*.

Dr. Kinsbourne also defended case reports as a "usable basis" for determining causation in this case. Pet. Ex. 28 at 2. Whereas (it seemed to Dr. Kinsbourne) Respondent's expert Dr. Sladky would require epidemiologic evidence in cases where "there is no direct way" to determine causation, Dr. Kinsbourne countered that epidemiologic evidence "regrettably [] is rarely available where rare diseases are concerned," while conceding that such evidence "would be ideal." *Id*. Dr. Kinsbourne explained that he settles this evidentiary quandary by "resort[ing] to circumstantial evidence such as case reports and [by rendering] opinions to a reasonable level of medical probability though certainly not to a scientific certainty." *Id*. To Dr. McGeady's contention that the extant epidemiological evidence does not prove causation of transverse myelitis by tetanus toxoid, Dr. Kinsbourne countered that this is "because no such study has been performed," and therefore "epidemiology cannot be invoked as a source of relevant evidence" in this case, and we are left to decide the issue of causation "by means of circumstantial evidence." Pet. Ex. 29 at 4.

At the hearing, Dr. Kinsbourne began his comments by recanting his attribution of a causal relationship between the vaccines at issue and Tysheem's eventual episode of myocarditis, due to the overly long time interval between vaccination and transverse myelitis on one hand, and the myocarditis on the other. Tr. at 54-55, 100-101. Earlier statements in his expert reports had purported to tie the myocarditis to the vaccination. Pet. Ex. 28 at 2.

Dr. Kinsbourne reiterated the importance of anamnestic reaction in squaring the time interval between the vaccinations at issue and the onset of transverse myelitis: "[T]he immune response to any antigen [comes] sooner and [] stronger more often as the exposure is repeated," and thus "the

---

[8] Incubation in this context means "the development of an infectious disease from the entrance of the pathogen to the appearance of clinical symptoms." DORLAND'S, *supra*, at 922.

time interval between the vaccination and any positive or negative consequence would shorten with successive repetitions of the same vaccine." Tr. at 56.

Regarding what time interval would be standard for onset of transverse myelitis, Dr. Kinsbourne stated that "The Institute of Medicine suggested 5 days to 42 days, and called that conservative, which it is, and it also did not take account of the anamnestic factor," and stressed that such categorical boundaries are "not carved in stone." Tr. at 59.

Facts of significance for Dr. Kinsbourne's analysis were the local reaction to the injections in both arms, that Tysheem's fever began in the evening the day of administration, and that Tysheem "could not or would not move his left arm." Tr. at 56-57. The last of these facts raised a question for Dr. Kinsbourne, his answer for which is critical to his opinion on determining the precise onset of Tysheem's transverse myelitis:

> [D]id he not move it because he couldn't, because it was paralyzed as a possible precursor of what had happened subsequently, or did he not move it because it hurt to move it, and which the mother described as guarded, which is the correct term. And to resolve that, I look to her specific description of how he held the arm as follows. Had it been a matter of a paralyzed arm, it would have hung flaccidly by his side. It would have moved in a particular fashion if somebody pushed on it. It would not have hurt to move it. It is true that the first symptom of transverse myelitis often is pain, but it tends not to be pain in one limb. It tends to be a backache, and symmetrical pain, and it is not known to come with local tenderness. The way that the child is described as holding his arm indicates that he did have muscular strength because if he held it indeed as the mother showed, with the forearm up in the air, that means that muscular strength was maintained for him to do that. So my understanding is that he was holding his arm in such a manner to resist activation of the arm, which might then cause him pain. Now this of course is pertinent to the question of how soon after the vaccinations the actual neurological disorder first began. ...
>
> ...[W]hat is significant is what was not reported [in the emergency room intake notes]. It was reported that the child was -- and in my words -- cranky, and that the child's arm hurt, and that the child was feverish was reported. But what was not reported was that there any paralyses or other neurological symptoms. It was indicated on the form under the term "neuro" that there was attention paid to the nervous system at that time, and that being the case, it would be very surprising if a paralyzed child would have been overlooked.

Tr. at 57-60. He added that the asymmetrical guarding of the left arm (rather than equal guard or severity of symptoms) indicates that Tysheem's behavior prior to emergency admission to the hospital was not a manifestation of transverse myelitis, which itself "is a very symmetrical disorder." Tr. at 60-61. He later added that, "A local reaction [is] an interaction between the antigen and antibodies at a particular place." Tr. at 123.

Dr. Kinsbourne stated his opinion that onset of Tysheem's transverse myelitis followed the vaccinations by "approximately 48 hours, give or take," inasmuch as "the records first indicate it on the morning of [23 May 2003], which is beyond 48 hours [but] they don't say it was instantaneous[;] it must have been present at some time before [23 May 2003]." Tr. at 78.

Dr. Kinsbourne also opined on direct examination that the fact that Tysheem's pediatrician administered the vaccines as scheduled, in spite of his notation that Tysheem suffered from rhinorrhea and cough, indicates that the pediatrician "did not think those symptoms were complications to the vaccination." Tr. at 62. Dr. Kinsbourne also theorized that those symptoms could have been caused by an allergy (hay fever) or an unspecified virus in the upper respiratory tract, noting the apparent transience of those symptoms reflected in the medical records of that time period (i.e. it was noted to be present early on 20 May 2003, then noted to be absent later the same day, then noted as present again on 22 May 2003). Tr. at 62-63.

Dr. Kinsbourne's conclusion on causation embraces both of these potential diagnoses:

> If the Court finds that this child had allergy, then I would have no hesitation in attributing causation to the vaccine, to the vaccinations. If the Court finds that there was in fact a virus infection, then I would take the view that more likely than not *both of these conditions would have a significant [e]ffect on the causation of transverse myelitis*.

Tr. at 65 (emphasis added). His opinion, that the virus and vaccines both contributed as significant factors to the development of transverse myelitis, is predicated on the rarity of Tysheem's transverse myelitis, as many children commonly suffer upper respiratory infections and most children receive the DtaP vaccines. Tr. at 67. He elaborated on his opinion thusly:

> [B]oth the virus and the vaccines are challenges to the immune system, which would up-regulate any existing process, including adverse processes, and that given that the outcome is such a rare one, the idea that the conjunction of two or more causes resulted in this rare event is more attractive than to pick up one of them out as the cause.

Tr. at 83. He later described this mechanism further as follows:

> [T]he virus infection, assuming it was an antecedent to the vaccination, would have started off an autoreactive process at a supplemental level obviously, and that the vaccination amplified that process as I have described to make it robust enough to actually cause an event and damage.

Tr. at 121. Under this formulation, said Dr. Kinsbourne, "the time period would work quite well." Tr. at 123.

When asked to choose between "the virus or the vaccine" as to which had more support in the evidence to be accounted a stronger causative factor, Dr. Kinsbourne settled on the vaccine because of the specific information known about it from the medical record. Tr. at 87.

On cross-examination, Respondent challenged Dr. Kinsbourne on his combination and ranking of these putative causes, to which Dr. Kinsbourne responded:

> [I]f the history was such that there was a vaccination and no question of the URI, I would attribute causation to the vaccination. If there was a URI and no vaccination, I would attribute causation to the URI. I was discussing what to do when they are both the case, and I thought that it was most reasonable when they are both the case to think of them as both contributing to the up-regulation of the immune system, other than arbitrarily picking one and discarding the other, without having really anything that I know of to substantiate doing that.
>
> ...
>
> [W]hen one makes a differential diagnosis, one puts different weights on different contingencies, without eliminating necessarily any one of them, and all I am saying to the Court is that I think it is most likely.

Tr. at 95-97.

According to Dr. Kinsbourne, Respondent's theory of viral causation falls prey to the "*post hoc, ergo propter hoc*" fallacy more than does his own, as Respondent's linkage between "an unspecified upper respiratory infection and a subsequent transverse myelitis" assumes causation based upon temporal proximity and sequence, without knowing whether the unidentified viral agent presumed to be responsible is even plausibly capable of causing transverse myelitis. Tr. at 68. In fact, "blam[ing] the virus [in isolation] for the transverse myelitis ... would be ... based on speculation." Tr. at 82. He also thought it immaterial, for purposes of determining a causative agent, to rank possible causes by their statistical relative coincident occurrence with transverse myelitis, when both are accepted as potential causative agents in general medical opinion. Tr. at 69. Dr. Kinsbourne ascribed tetanus as the most potential cause, but acknowledged the potential effects of the pneumococcal vaccine, which have not been fully explored by the medical community at this point. Tr. at 70. On cross-examination, Dr. Kinsbourne amplified his theory on this point: "[A] cytokine release, which could come from more than one vaccination location, and more than one vaccine, could accumulate in up-regulating the immune system, and we know that cytokines can do that[, a]nd from the description of the local reaction by the mother, we can infer cytokines locally, and of course anything locally can get into the blood stream." Tr. at 102.

Dr. Kinsbourne agreed with direct examination that pointed out that nowhere in the medical records were the treating doctors able to ascribe an aetiology to Tysheem's transverse myelitis: "Any uncertainty that existed at the time of admission was not resolved by any investigation or any subsequent events." Tr. at 80-81. In fact, the infectious disease specialists, who ruled out the vaccines from the potential causes under their consideration, tried in vain to identify and confirm a viral agent to ascribe causation thereto. Tr. at 129.

Cross-examination illuminated a disagreement between Dr. Kinsbourne and some of the treating physicians who dismissed the vaccines as potential causative factors leading to Tysheem's transverse myelitis: None of Tysheem's treating physicians referred to anamnestic reactions among their diagnostic considerations. Tr. at 105. Dr. Kinsbourne first dismissed this circumstance by

asserting that "none of these people could care in the least about what caused the transverse myelitis," but later modified his response to a more nuanced stance, that "nobody wrote down anything remotely approaching the specificity of our discussion." Tr. at 106-107. At Respondent's questioning, Dr. Kinsbourne stipulated that he "certainly" disagreed with the treating physicians in certain respects, and "completely with the statement that the vaccinations could not have been involved."

Respondent, on cross-examination, challenged statements from one of Dr. Kinsbourne's last expert report, that "Tysheem's spinal cord may have been injured by targeted circulating immune complexes, reflecting the gradual sensitization of antibody reaction to the vaccine [which sets up for] an anamnestic reaction [in both] direct antigen-antibody reactions, and to cell-mediated reactions." Pet. Ex. 29 at 3; Tr. at 111-112. In response, Dr. Kinsbourne stated that "no direct evidence" exists in this case for either of those two mechanisms, which are both used by medical literature discussing transverse myelitis aetiology. Tr. at 112.

3. John Sladky, MD

In his written report, Dr. Sladky stated his reading of the relevant medical records in this case. Resp. Ex. A at 1. Without citation to a particular medical record, Dr. Sladky stated that over the course of 21 May 2003, Tysheem "lost the ability to sit or stand and persistently refused to move his left arm," and that when he was admitted into the emergency room on the night of 22 May 2003, "he exhibited flaccid paralysis of his left arm and bilateral lower extremities with apparently normal right arm function." *Id*. Dr. Sladky agreed with the diagnosis of transverse myelitis, noting that such illness "is conventionally thought to represent an autoimmune disorder." *Id*. at 2.

Dr. Sladky framed the question of causation into three medical issues: "[1] what is the relationship between immunization and transverse myelitis; [2] which of the vaccines is to be implicated in the causality argument; and [3] is there a more plausible alternative explanation for this child's medical conditions?" Resp. Ex. A at 2.

On the first of these three questions, Dr. Sladky found it "efficacious" to focus primarily, if not solely, on the IOM report cited by Dr. Kinsbourne. *Id*. He pointed out that the report, from 1994, is "somewhat dated," but explained that "more current literature fails to shed further light" on the subject. *Id*. at 2-3. Based upon the IOM report, Dr. Sladky conceded the biologic plausibility of vaccine-related transverse myelitis as a general proposition, summarizing the conclusion that "each of the constituents of the immunizations that Tysheem received [for which data are available] have been deemed to have biological plausibility as causal or contributory agents in autoimmune demyelinating disorders of the central nervous system." *Id*. at 3.

Having conceded general biologic plausibility of the mechanism propounded by Petitioners, Dr. Sladky nonetheless disputes vaccine causation on the facts of this case, and particularly on the issue of onset timing. *Id*. He disputes whether Tysheem's vaccinations could "have instigated an autoimmune response resulting in a fully developed case of transverse myelitis within less than 72 hours from the time of exposure," and concludes that "two to three days is an implausibly short time period to permit the complex cascade of immunological events necessary to effect tissue injury [as]

transverse myelitis." *Id*. Dr. Sladky explained that the IOM, in "determining the range of conceivable latencies between immune challenge and [] onset," relied upon "laboratory models of autoimmune demyelinating disorders." *Id*. He continued, the disorders studied were "acute demyelinating encephalomyelitis (ADEM) and Guillain-Barre Syndrome (GBS)," which were studied *via* "experimental equivalents" of "allergic encephalomyelitis (EAE) and experimental allergic neuritis (EAN)." *Id*. In this context, wrote Dr. Sladky, "the earliest manifestations of autoimmune demyelination in some of these animal models is about seven days, with the majority in the range of ten to fourteen days." *Id*. As a result, concluded Dr. Sladky, the study "dictated" that the temporal period of onset "must fall between [five] and [forty-two] days to be considered credible," a range which Dr. Sladky finds over-inclusive. *Id*. He assessed the facts of the instant case to indicate "under three days" as "the duration between vaccination and admission to the hospital," and believes onset occurred earlier, signaled by the "appearance of the initial symptoms" that were "certainly earlier." *Id*.

In support of his position on the facts of this case that the onset interval was too brief to implicate the vaccinations at issue, Dr. Sladky referenced recorded conclusions of the infectious disease doctors who shared that position. *Id*. Later Dr. Sladky summarized that Petitioners' theory of causation is merely "an hypothesis [that] is not supported by scientifically derived data or methods," adding that the onset interval "is to[o] brief to garner scientific credibility." *Id*. at 5.

Thirdly, Dr. Sladky raised the consideration of potential alternative causes (other than vaccine-related) to challenge Petitioner's theory. Without citation, Dr. Sladky referred to "numerous studies" concerning autoimmune demyelinating disorders, in which "about [sixty percent] of patients are able to identify an event which occurred in the six weeks prior to the onset of their illness," the most common being "upper respiratory tract infections followed by gastroenteritis." *Id*. at 4. In contrast, the frequency of vaccination as a coincident, potentially causative event "is around [five percent]," but varies somewhat with age. *Id*.

Dr. Sladky found it highly significant that Tysheem's bout with myocarditis followed so relatively soon after the transverse myelitis and opined that viewing their sequential incidence as "merely coincidence" would "require[] a Herculean exercise in suspension of disbelief," because "the odds that these two events are entirely unrelated, in this case, must be incalculably small." *Id*. at 5. Dr. Sladky suspected "an as yet undeclared underlying [autoimmune] disorder," which he expected would have manifested, had it not been for Tysheem's immunosuppression treatments, like "the second shoe to drop." *Id*.

As the peroration of his medical expert report, Dr. Sladky stated that "there is no scientifically sustainable argument that the relationship between vaccination and disease, in this case, is causal rather than coincident." *Id*.

At the hearing, Dr. Sladky reflected that he had treated between fifty and one hundred cases of patients afflicted with transverse myelitis, "virtually all of them" involving children. Tr. at 131-32. However, in only about thirty percent of those cases did he work in tandem with an infectious disease specialist. Tr. at 132.

Dr. Sladky largely agreed with Dr. Kinsbourne, "that there are probably two events associated with this episode of transverse myelitis; an upper respiratory tract infection and the vaccination," but noted nonetheless that "there is no firm scientific or clinical evidence that the vaccine should be causally implicated." Tr. at 132. Dr. Sladky referred back to the IOM report and how it addresses "the issue of coincidence"–i.e., how to handle "a temporal relationship [between a] rare event and [an] ubiquitous[] event." Tr. at 133. By Dr. Sladky's estimation, "the first aspect of the report is the temporal relationship, in terms of the latency between vaccination and appearance of neurological symptoms." *Id*.

Dr. Sladky believes the IOM's findings on the range of possible onset periods is already broad enough to reach the limits of plausibility, as it was based "most importantly" on laboratory experiments using "experimental allergic encephalomyelitis" (EAE) and "experimental allergic neuritis" (AEN), which were used to study the primary myelinopathies affecting humans, including, by extrapolation, transverse myelitis. Tr. at 133-135. These experiments were "typically" performed on rats, was "really not designed to look at the issue of vaccine" but "at the mechanisms of injury," and challenged each subject once. Tr. at 151, 153. However, said Dr. Sladky, those studies provide "analogous information that can be derived from looking at them." Tr. at 152. Explained Dr. Sladky:

> It is quite clear that there is a difference between infection and immunization. In the case of infection, you have no idea when the first immunologic exposure to the infectious agent was, because we talked about an incubation period that could range from days to weeks. In the case of an immunization, we know exactly when the immuno[logic] challenge occurred, and just as in the laboratory, we know exactly the latency between the immunization and the first symptoms. It is my firm belief that the IOM chose a very reasonable and in fact liberal time frame, and that when one talks about the occurrence of neurologic symptoms prior to five days, one is talking about a biologically improbable situation. There is simply not enough time to orchestrate an immune response that begins locally, somehow gets into the central or peripheral nervous system, which is a very complex process that requires traversing what is called the blood brain barrier. It then has to gain access to the central nervous system. There are activated T-lymphocytes which are directed against specific antigens within the nervous system. The T-lymphocytes will activate B-lymphocytes, which produce immunoglobulin. Both of those moieties, the T-lymphocyte and the immunoglobulin, direct microphages against specific antigen targets, and cytokins can either up-regulate the severity or down-regulate the severity of that process. Now that can't happen with 48 hours. It simply is implausible [as] an idea.

Tr. at 135-36. It is thus the onset timing that is "the principal reason that I think that there cannot be a biological causality between immunization and transverse myelitis in this youngster." Tr. at 136. Dr. Sladky did not "think there [was] any evidence that [bore]" upon Dr. Kinsbourne's theory of anamnestic response, even though he noted "an association," expressed in "a clear increase[d] incidence of neurological consequences in immunized versus the non-immunized patient." Tr. at 138. In his opinion, an onset window of even five days is a bit too brief; based on the data from those experimental animal studies, "it is more like 7 t o14 days." Tr. at 168. When the Court posed

a hypothetical scenario wherein the transverse myelitis manifested five or six days after vaccination, Dr. Sladky said he would accept the vaccines administered "as a possible or probable cause." Tr. at 139. He then qualified that statement, based on what he labeled a nonexistence of scientific evidence that the vaccines at issue could cause transverse myelitis, that he "could not for certain say that [he] would weigh one necessarily more than another." Tr. at 140.

Dr. Sladky contests Dr. Kinsbourne's reliance on the anamnestic reaction theory, inasmuch as such response "has never been described," and which would require "serial episodes of central nervous system injury in temporal relationship to exposures to immunization," although "that data is [*sic*] not available." Tr. at 142. He reiterated in relation to this point the timetable established *via* experimental models in the EAE/AEN study noted *supra*, in which "the shortest interval was more than five days." Tr. at 143.

Likewise, Dr. Sladky challenged Dr. Kinsbourne's theory of combined viral/vaccinal causation as "so inclusive to be nonspecific." Tr. at 140. According to Dr. Sladky, the maxim of Ockham's razor[9] "dictate[s] an approach that [requires] one cause or another," such that "if this particular child had a cold, got an immunization, and was hit by a slow moving bus, would we weigh them equally, ... because all of those are listed as potential causal factors in [] transverse myelitis." Tr. at 141. He then extended a theoretical combination of causes *ad absurdum*, noting that one "can keep adding identified associations and ultimately say, well, five things happened to this kid in the six weeks before transverse myelitis, and it could have been any one of them, or it could have been the combination." *Id*. Concluded Dr. Sladky, "That's not very scientifically satisfying." *Id*. Ultimately he concluded that Dr. Kinsbourne's ranking of three possibilities for causation were "really conjectural" and did not believe one could "bring clear data to answer the question." Tr. at 145.

Dr. Sladky relied upon the inconclusive conclusions of an IOM report that states, "The evidence is inadequate to accept or reject a causal relation between the tetanus toxoid, DT, or Td and demyelinating diseases of the CNS (ADEM, transverse myelitis, and optic neuritis)." Resp. Ex. E-7 at 1. He also "weigh[ed] quite heavily as a factor" the medical records in which "the treating physicians appear to have considered the vaccine as a cause and yet rejected it." Tr. at 145. On cross-examination, Dr. Sladky explained that the IOM committee was employing a standard of proof of "evidence based medicine," a term he defined as "a process of reviewing all the available discoverable world literature and trying to come to a conclusion sometimes using metaanalytic principles as to whether or not the cumulative amount of case reports constituted science or phenomenology." Tr. at 147-48. Dr. Sladky acknowledged the existence of case studies wherein transverse myelitis proceeded temporally proximate to administration of the tetanus vaccine, but reminded the Court that "the accretion of [anecdote] is not science." Tr. at 149. When asked on cross-examination whether, to him, "case studies do not become acceptable convincing evidence of the causal link between the tetanus vaccine and transverse myelitis until they rise to the level of

[9] Ockham's (Occam's) razor (after William of Ockham) is "the maxim that assumptions introduced to explain a thing must not be multiplied beyond necessity." RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE (2d ed., unabr. 1987) at 1339.

satisfactory epidemiology," he agreed that "that would be one fulfillment ... of an appropriate scientific understanding." Tr. at 150.

Dr. Sladky reiterated where the IOM drew its conclusions on the acceptable window of time within which transverse myelitis would be expected to manifest: from "the clinical studies, for which there is very little concrete data, and their extrapolation from experimental [animal] studies in which the latency between immunization and the onset of [the neurologic disease tested for] can be precisely determined." Tr. at 153. Thus, as far as Dr. Sladky knew, the accepted onset intervals accepted on the basis of those studies, "are based on a first exposure only." Tr. at 155.

While Dr. Sladky acknowledged that the anamnestic response was discussed "in basic immunologic textbooks," he posited that the concept "is essentially a local reaction," possibly including a fever as well, and not "something that is directed against a completely unrelated tissue." Tr. at 155-56. Dr. Sladky's argument started from the premise that, "in the case of routine immunizations, it is really [only] the local reaction" that should be expected, in order to reach the conclusion that, with the vaccines at issue in this case, "the sole outcome of multiple challenges is an increase in risk of local reaction," and therefore, "if you [administer] DtaP sequentially, you are apt to [observe] a larger local reaction with the fourth shot than the first shot" generally speaking. Tr. at 158-59. However, Dr. Sladky admitted that "there [was] no study" upon which he based his conclusion that local reaction constituted the only possible adverse outcome for the vaccinations at issue. Tr. at 158.

Regarding alternative causes (those other than the vaccines), Dr. Sladky negated the assertion of Petitioner's counsel that Dr. Sladky believed "a virus caused the TM." Tr. at 160. His opinion, "based on the available evidence [is] that one can't come to a firm conclusion about the cause" of Tysheem's transverse myelitis. Tr. at 162. Rather, his opinion is nonspecific: that "there is an alternative ... explanation, which *could be* a viral infection," but no such viral infection was "documented or seen anywhere." Tr. at 160 (emphasis added). Ultimately, he agreed, the treating doctors "tested for all the viruses that they could or that they deemed appropriate, and they were unable to identify any." Tr. at 161. Cross-examination of Dr. Sladky provided the following exchange:

> Q Certainly we all agree that there was some cause for this?
>
> A Correct.
>
> Q And there is no question about that?
>
> A Something happened.
>
> Q Something happened and there is a cause, but in this case, it is your opinion that whatever that cause is, it cannot be reliably identified, correct?
>
> A Correct.
>
> Q And not being reliably identified, and I want to make sure that I understand, that that means to a reasonable degree of medical probability, you aren't able to offer an opinion as to what the cause was of Tysheem Hargrove's transverse myelitis?

A I am generally reluctant to deal in a reasonable degree of medical probability. I want to see some science. I want to see some evidence.

Q Okay. So to answer my question in this case, you do not have an opinion to a reasonable degree of medical probability as to what the cause was of Tysheem Hargrove's transverse myelitis?

A I do not.

Q And you have postulated, if I can use that term, that it may have been a viral infection?

A That is certainly a possibility, and it may have been something else, but we have no idea.

Tr. at 163-64.

Although Dr. Sladky accepted the mechanism of viral infection as a cause of transverse myelitis, he was unaware of an identified mechanism by which the vaccines at issue could cause the illness. Tr. at 165. In his expert report and at trial, he acknowledged the conclusions of the IOM accepting the biologic plausibility of transverse myelitis caused by the tetanus vaccine, but he himself does not accept the validity of a causative relationship, in the absence of "high grade evidence ... including epidemiology." Tr. at 176. In his opinion, the IOM committee "came to the question with an open mind, with the intent of evaluating the available evidence, and coming to a conclusion [on whether] there [is] sufficient evidence one way or the other." Tr. at 176. Under those circumstances, they "examine[d] the evidence and [said] there is insufficient evidence to affirm or negate a causal relationship." Tr. at 177.

3. Stephen McGeady, MD

In his written report, Dr. McGeady recounts without citation that "On 5/22/03, he was found to be unable to stand and did not move his left arm," and "was admitted to CHOP from the ER on 5/23/03." Resp. Ex. C at 1. Apparently he based this account on the discharge summary, dictated on 15 June 2003, and not on the contemporaneous emergency room intake notes recorded on 22 May 2003, which do not record that Tysheem could not stand, but instead noted that he "appear[ed] NAD." *See supra*. Dr. McGeady next summarized the diagnosis and treatment of Tysheem's transverse myeltis and noted, regarding aetiological investigation, that, "Sophisticated testing for microbial agents known to be associated with transverse myelitis was completely negative." *Id*.

Dr. McGeady views the arm pain experienced by Tysheem the day of vaccination as the onset of his transverse myelitis, noting "[p]ain is ... the most frequent first symptom of transverse myelitis." *Id*. at 2, citing Resp. Ex. E-1, Dunne *et al.*, "Acute transverse myelopathy in childhood," 28 *Developmental Medicine and Child Neurology* 198-204, 199 (1986) ("Pain was the most frequent first symptom ... commonly in the back [], but also occurring in the trunk, groin and limbs. Frequently the distribution of pain was asymmetrical."). Dr. McGeady addded that it is "unlikely" that any "correlation [exists] between a local reaction to injected vaccine ... and the reaction which occurred in the child's spinal cord." *Id*. Later in the same report, however, Dr. McGeady noted the commonality of swelling and pain at injection site "that appears several hours after an infant is given

an immunization," a reaction caused "from the interaction of previously formed antibody with the injected vaccine," and which is typically "focal at the injection site, resolve[s] slowly, and apart from the discomfort ... [is] harmless." *Id*.

Dr. McGeady's reading of the medical records "make it almost certain" for him "that Tysheem had a viral respiratory infection which was at least in its incubation at the time of onset of his transverse myelitis," when he considered that a history of "recent respiratory infection ... within a few weeks is ... present in 30% of cases of transverse myelitis," which he statistically contrasted to "the prevalence of any neurologic sequela from tetanus immunization [estimated at] less than 1 per 2,000,000," a minority of which involve transverse myelitis. *Id*. To him, this "suggest[s] that respiratory infections are common concomitant with transverse myelitis while association with tetanus toxoid is exceedingly rare." *Id*. He also challenged Dr. Kinsbourne's citations, which discuss the "association between tetanus toxoid and transverse myelitis," as they "do not demonstrate a proved cause and effect relationship" and "may be [solely] coincidental." *Id*.

Most importantly, Dr. McGeady noted that the cell mediated autoimmune process (unrelated to antibody activity) commonly thought to be the mechanism of injury in transverse myelitis[10] "develops over a protracted time period of 48 [to] 72 hours," such that "it would be unheard of for a cellular immune reaction to develop within the several hours that elapsed between Tysheem's immunizations and the onset of his symptoms of transverse myelitis" (which he believed occurred on the same day as vaccination). *Id*. He added later, "The epidemiologic evidence does not support a causal role." *Id*. at 3.

Dr. McGeady thought the occurrence of Tysheem's transverse myelitis and myocarditis in relative temporal proximity meant that Tysheem "was in a highly autoreactive state," but that "[t]he ultimate cause of autoimmunity remains unknown" and evidence linking either condition to the vaccinations at issue was "minimal", allowing him to opine, "with a reasonable degree of medical certainty" that Tysheem's vaccinations on 20 May 2003 "bore no causal relationship to the transverse myelitis." *Id*. at 2-3.

At the hearing, Dr. McGeady explained his qualifications by stating that he was board certified in pediatrics, allergy, immunology, and diagnostic laboratory immunology, and that he ran an immunology laboratory. Tr. at 178. He does not think the vaccines at issue caused Tysheem's transverse myelitis. Tr. at 180.

Dr. McGeady explained at the hearing what he meant by his reference to an immune reaction developing over a period of 48 to 72 hours; he was referring to "the classic example of delayed type hypersensitivity ... in which an antigen ... [is] specifically injected into the skin," also known as the "Mantoux technique." Tr. at 181-82. Such technique, if performed correctly, is injected solely into the skin and "confined into a small area" there, the result being that a sensitive recipient will mount a reaction between 48 and 72 hours therefrom. Tr. at 182. Dr. McGeady admitted this reference was

---

[10] For this description of prevalent medical opinion, Dr. McGeady seems to rely on J.H. Menkes, TEXTBOOK OF CHILD NEUROLOGY (3rd ed. 1985). *See* Resp. Ex. E-4 at 1. As Dr. Kinsbourne pointed out, that textbook is currently in its seventh edition, published in 2006. *See supra* at 9.

of limited relevance to this case,[11] as it is not "applicable to the situation ... in this case," considering Tysheem's vaccinations were "given intramuscularly, and would have been allowed to disseminate a little bit more rapidly." *Id*.

Dr. McGeady next moved from hypothetical musings to discuss the problematic timing of onset in the instant case. To him, "what is in question is a reaction [in the central nervous system] that is far removed within the body from the site in which the antigen was introduced [the arm]. Tr. at 182. In his opinion, the blood-brain barrier "would be another impediment to the reaction occurring in any brief time period." *Id*. When asked on direct examination whether the 5 to 42 day onset period discussed by Dr. Sladky was "consistent with what [he] would expect to see if ... the tetanus vaccine[] were to have been responsible for Tysheem's transverse myelitis," Dr. McGeady was reluctant to state affirmatively a plausible time interval for onset. Tr. at 183. However, he spoke generally that "if [the tetanus vaccine] could have in any way caused that type of reaction, [it would necessarily] have been much later than [was] seen in this case." *Id*. He found it "counterintuitive" to conclude that the tetanus vaccine caused the transverse myelitis in Tysheem in approximately 48 hours of administration. Tr. at 184. He based these statements on his experience in the laboratory culturing lymphocytes to assay their response to stimuli, during which he harvests those cells when they are "maximally stimulated." Tr. at 183. When the stimulus used is the tetanus toxoid, maximum stimulation is reached on the seventh day, with manifest reaction lacking at initial culturation and the early period following. Tr. at 183-84. Low level reactions begin before the seventh day, "but certainly not within two to three days." Tr. at 184.

In light of this sticking point, which he believes renders Petitioner's theory immunologically infeasible, Dr. McGeady is in accord with Dr. Sladky in recognizing the brief onset period as the "cornerstone" of Respondent's opposition to vaccine causation. Tr. at 184-85. However, Dr. McGeady is "not even sure that [transverse myelitis] is immunologically instigated;" he himself thinks "it is an idiopathic disease," although he concedes that "the current thinking is that it probably is" immunologically mediated. Tr. at 203. He thinks the actual cause of transverse myelitis is "unknown" at this time. *Id*.

By Dr. McGeady's calculation, the onset period in Tysheem's case was far too short, as he "believed that Tysheem manifested transverse myelitis within several hours of his immunizations," in the form of the pain and fever Tysheem experienced the night of the vaccination. Tr. at 204-205. Dr. McGeady viewed the appearance of those two symptoms as "an early manifestation" of the transverse myelitis, but was unwilling to posit thus to a preponderance, albeit noting that it was "entirely possible that this was the initial prodrome of his disease and he progressed to full-blown." Tr. at 205-06. He agreed with redirect examination that any period "from four hours to 48 hours [] is still too short ... to show that there is an immunological connection between the vaccine and the onset of transverse myelitis." Tr. at 215.

---

[11] It remains unclear to the Court why Respondent proffered testimony on this point. If, as Dr. McGeady explained, discussion of this information was not relevant or related to this case, it is curious why he would nevertheless raise it in his medical expert report and again at trial. Suffice it to say that the Court typically entertains discussion of hypothetical scenarios that directly pertain to the case at bar, among other relevant testimony, and is dubious of evidence the proponent of which admits is unrelated to the case at hand.

Moreover, on cross-examination, Dr. McGeady was not comfortable accepting the period of 5 to 42 days noted by the IOM and referenced by Dr. Sladky: "I don't think that anybody could tell you that it has to be five days, or seven days, or anything like that." Tr. at 207. As to how long Dr. McGeady thought onset would take, he did not know, and was unsure whether anyone knows that. Tr. at 207-08. When pressed on this point, he conceded that he "ha[d] not researched that part of the medical literature which [Dr. Sladky] obviously [was] quite conversant with." Tr. at 208.

Dr. McGeady believes the local reactions on Tysheem's arms were "some reaction," but "[did] not think that it was an immunologically mediated reaction," which he said put him in concurrence with Dr. Kinsbourne. Tr. at 185. Thus, "if this was an immunologic response [to the vaccinations at issue,] it couldn't happen that quickly." Tr. at 185. However, Dr. McGeady could not render an opinion "[i]f it was an immunologic response to something else." Tr. at 185-86. His counterpoints to Dr. Kinsbourne's opinion were twofold:

> Number one, it makes no sense to me that an immune reaction which caused the havoc that this little boy experienced would give him no immune reaction at the sites of the injections, which would be the largest concentration of that antigen in his body. It could get into the blood stream, and it can travel through the blood stream, and eventually some of it could get to the central nervous system. But most of it is going to be where it was injected. It is going to disseminate out over a period of time. So if he is hyperimmunized as has been suggested by the anamnestic theory, if he is hyperimmunized, I would expect him to have much more reaction at the sites of injection, and for that reaction to be persistent. I am not denying that he had some reaction there, but it didn't persist in a time frame that makes me think it was immunologically mediated. So that is number one.
>
> And number two is that the patients whose lymphocytes that we study in my laboratory are also fully immunized to tetanus, but we still harvest their cells on day seven, because that is when you get your reaction.

Tr. at 186-87. In support of the first point, he cited Pet. Ex. 9 at 3 (*see supra*) which affirmatively noted the absence of redness, warmth, swelling, tenderness, and bruising on Tysheem's arms; the presence of such signs, if persistent beyond 48 hours, would have indicated an immunologically mediated response. Tr. at 187-88.

On cross-examination, Dr. McGeady indicated that he discounted Petitioner's proffered fact witness testimony about the apparent symptoms of pain and guarded, angled position of Tysheem's left arm, and drew upon the medical records to reach his opinion about insufficient reaction to corroborate immunologically mediated reaction. Tr. at 194. Dr. McGeady found the fact witness testimony contradictory to the pediatrician records from 22 May 2003: Petitioner recalled redness persisting at the injection site at that time, whereas "[h]e says not red," adding that "the physician is clearly unimpressed by anything at the site of injection." Tr. at 195-96. Such a localized reaction is crucial, posited Dr. McGeady: "[I]f you want to postulate that the boy was reacting as though he were hyperimmune to the injected material that you would have to have something at the site of the injection." Tr. at 196. In support of this stance Dr. McGeady could not cite medical literature, and

he admitted that the basis for positing this predicate as necessary was "[his] own experience." Tr. at 197-98.

Moving on to the body of medical literature pertinent to this case, and specifically on the "causal relationship between the tetanus vaccine and the onset of transverse myelitis," Dr. McGeady indicated that he found such literature "underwhelming" and unconvincing. Tr. at 188-89. On cross-examination, Dr. McGeady agreed that there exist "selected articles" of medical literature which "indicat[e] the association between a tetanus vaccine and transverse myelitis." Tr. at 191-92. He agreed that case study reports "certainly suggest [a connection between the tetanus vaccine and the development of transverse myelitis]," but "the epidemiologic evidence doesn't support that with how few and far between the case studies are." Tr. at 209-210. He later agreed with redirect examination that those case study reports illustrate a temporal association between the tetanus vaccine and transverse myelitis, and do not "tell you anything about cause." Tr. at 214.

Asked specifically on cross-examination to opine on the *can it* prong of causation, Dr. McGeady stated that though "anything is biologically plausible," he found it "unlikely" that "the tetanus vaccine can caused transverse myelitis." Tr. at 192. When challenged, he clarified the postulate of that statement to say that "*many* things are biologically plausible." Tr. at 193 (emphasis added).

On the matter of alternative causes, Dr. McGeady does not propound that Tysheem's transverse myelitis was "caused" by a virus, but thought it "the likely explanation" that "a virus in this case was associated with the development of Tysheem's transverse myelitis." Tr. at 211. He added, "Whatever viruses do, or if they do anything that brings this on, I think it is more likely." *Id.* He admitted that he was not "an expert on that subject," but said he was "always willing to give an opinion." *Id*. When the Court then asked him if he thought it more or less likely than fifty percent whether "the virus was the likely culprit," he thought it was "more likely than that." Tr. at 212. This question led to the following, rather curious discussion between Dr. McGeady and the Court:

> THE COURT: Would you put a percentage to that?
>
> THE WITNESS: Well, I think that I would retreat back into the observation that 30 percent or so of cases of transverse myelitis have a history of a viral illness within six weeks before that. So it seems to be a frequent association.
>
> THE COURT: But that would mean that seventy percent do not?
>
> THE WITNESS: That's correct.
>
> THE COURT: And I am presuming that the 70 percent you are telling me is idiopathic, or is there some other known causative agent?
>
> THE WITNESS: I am saying the 70 percent is idiopathic.

Id. Ultimately, however, Dr. McGeady did not attach importance to the lack of an identified virus in this case, "because [he] th[ought] [that in] a significant percentage of these people who have a history of an infectious illness the virus goes unidentified." Tr. at 215.

4. Rebuttal – Marcel Kinsbourne, MD

Next Dr. Kinsbourne was recalled for rebuttal. Tr. at 218. He reiterated a point from his last expert report, that the IOM report "specifically talks about how immune mediated damage will occur sooner after a challenge if it is a repeat challenge, rather than the first challenge [and] gives time frames which are shorter than the 5 to 42 days." Tr. at 218. That range was arrived at on the basis, largely, of the EAE mouse experiment results, but, said Dr. Kinsbourne, those studies did not contemplate one or more rechallenges of the affecting agent. Tr. a t 219. So whereas that range may be appropriate for a single challenge, it may be altered, by the estimation of the IOM study, when presented on rechallenge. *Id*. He said the IOM report indicates that "immune complex mediated reactions generally develop over as little as six to twelve hours if antibody levels are already high," such as in the case of rechallenge. Tr. at 220. He even gave the change in the cell-mediated mechanism that formed Dr. McGeady's earlier hypothetical: "On first exposure the response peaks at about three weeks, [] consistent with what Dr. McGeady testified to ... [b]ut on re-exposure the response typically peaks after 24 to 48 hours." *Id*.

Secondly, Dr. Kinsbourne distinguished, in similar relation to what Dr. McGeady theorized, epidermal injection from arrival and effect at the central nervous system. Tr. at 220. Said Dr. Kinsbourne, the IOM study was not stating their presumed onset period from injection to local reaction, but rather from the time of injection to the time of transverse myelitis onset. *Id*. In fact, he said, "the IOM never mention[ed] [skin reaction] as a condition for accepting an immune mediated causation." Tr. at 221.

Also, responding to Dr. McGeady's comment that anything is biologically plausible, Dr. Kinsbourne countered that he does not accept "that biological plausibility is just anything, and the IOM doesn't believe it either, because they were careful to preface every one of their discussions of a given [putative] reaction to determine whether it was biologically plausible, and had the criteria for doing so." Tr. at 221.

5. Rebuttal – Stephen McGeady, MD

Dr. McGeady was recalled as well, and stated that he would not contest Dr. Kinsbourne's point about the IOM report, but explained that he "think[s] more mechanistically [him]self," which leads him to conclude "it is just counter-intuitive that you a depot [*sic*] of antigen in the subcutaneous tissue or the muscle of the arm, and this is not reacting immunologically, and yet you are proposing that a remote tissue across the blood brain barrier is now being attacked vigorously by the immune system." Tr. at 222. He was unsure "why the IOM didn't address that," except that such symptoms as injection site soreness "was of minimal consequence." Tr. at 223.

C. Post-Hearing Submissions

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

Petitioner's principal closing brief surpassed forty pages, much of it duplicative and redundant. Petitioner's primary arguments were:

1. That direct, positive evidence of actual causation is not required by the law binding the Court in this case; instead, the Court as fact-finder may rely upon circumstantial evidence in its weighing of evidence. Petitioner's Closing Brief at 4, citing *Althen v. Secretary of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

2. That "[t]he fact that the [DTAP] vaccine was Tysheem's fourth [] is extremely significant ... as it provides significant independent support for Dr. Kinsbourne's anamnestic response theory. *Id*.

3. That Petitioner's fact witness testimony "supports the conclusion that Tysheem's [TM] developed more than 48 hours after vaccination," and diminishes the significance of the rhinorrhea at the time of vaccination, as Tysheem's mother thought the runny nose was simply a symptom of his teething. *Id*. at 9, 11.

4. That the Federal Circuit's reasoning in *Knudsen v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994)[12] undercuts Respondent's experts' reliance upon statistical prevalence as a indication of what occurred in the instant case.

5. That if the Court finds that Tysheem suffered from a virus that acted as a causative factor of the transverse myelitis, then the Court should heed Dr. Kinsbourne's opinion that the vaccine was yet a substantial, if complementary causal factor, and was not overborne or superseded by the virus as a cause in fact.

6. That *Bowes v. Secretary of HHS*, No. 01-0481V, 2006 WL 2849816 (Fed. Cl. Spec. Mstr. Sep.8, 2006)[13] is persuasive precedent in Petitioners' favor from an analogous case, in which two

---

[12] In particular, Petitioners repeatedly quoted the following passage:

> We also reject the government's argument, which again was relied on in the special master's decision, that evidence that there are more occurrences of encephalopathies caused by viral infections than there are encephalopathies caused by DTP vaccines is relevant. Viral infections themselves occur infinitely more often than do DTP vaccinations. ... The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

35 F.3d at 550.

[13] In *Bowes*, Special Master Hastings reasoned:

> Dr. Sladky, while nominally utilizing a "more probable than not" standard, in reality was, in effect,

of the three vaccines at issue here were also there at issue, and in which the Court found Dr. Sladky's skeptical approach too strict for the standard of proof applicable in Program cases.

7. That *Herkert v. Secretary of HHS*, No. 97-0518V, 2000 WL 141263 (Fed. Cl. Spec. Mstr. Jan. 19, 2000) supports the Court's validation of Petitioners' theory, as it represents another case of transverse myelitis following the fourth administration of the DTAP and upper respiratory symptoms on the day of vaccination, which the petitioner in the case proffered to be working in concert to cause the injury suffered.

8. That *Camerlin v. Secretary of HHS*, No. 99-0615, 2003 WL 22853070 (Fed. Cl. Spec. Mstr. Oct. 29, 2003) is on point because it involved transverse myelitis and a prior history of potential infection, and because Dr. Sladky testified for Respondent. The special master there found the vaccine to have acted as a substantial factor, even assuming there were other factors affecting the immunologic insult leading to neurologic illness.

9. That Dr. McGeady had originally agreed with a 48-72 hour onset period for the autoimmune process leading up to transverse myelitis, and only altered his opinion once he had heard the testimony of the other witnesses at the hearing.

Respondent's responsive closing brief raises several points of its own, including:

1. That "Tysheem's transverse myelitis occurred less than three days post-immunization, too soon to be reasonably related to the vaccination," quoting Dr. Kinsbourne's statement that "typically the onset of an immune-mediated disorder takes five days or more to become apparent." Respondent's Closing Brief at 4.

2. That greater credence should be afforded by the Court to Tysheem's infectious disease consulting doctors whose opinion excluded the vaccine(s) as a viable causative factor towards the

---

> utilizing a higher standard, more akin to "scientific certainty" than to "more probable than not." For example, in summarizing his opinion about this case, Dr. Sladky, quite tellingly, stated that he found no "compelling" evidence proving a causal relationship. The use of the word "compelling" seems to indicate, as does the tenor of his testimony in general, that Dr. Sladky would concede vaccine causation of an injury only if the evidence made such causation seem certain or near-certain. This attitude is understandable in the cautious world of medical science, in which, usually, to justify a "causation" finding, a scientist would need to see evidence beyond that of a mere "probability." However, the standard of "scientific certainty" is not the standard for showing causation that is applicable to this proceeding. ...
>
> ...Dr. Sladky [stated] what might influence him to acknowledge a "probable" causal relationship: an epidemiology study that explicitly demonstrates a statistically-significant association. Anything less, he seemed to suggest, is mere "hand-waving." But Dr. Sladky's apparent need to see an epidemiologic study, showing a statistically-significant association, before he could acknowledge a "probable" causal relationship, clearly indicates that he is using a standard inappropriately high for Program purposes.

2006 WL 2849816, *4-5. There the special master also cited *Althen* to state that "a petitioner's [actual causation] claim need not be supported by objective confirmation in medical literature, if it is supported by expert medical opinion." *Id*. at *5, citing 418 F.3d at 1279-1280 (internal marks omitted).

transverse myelitis, leading Tysheem's primary care physician to summate "all specialists agree" that the vaccines were not the cause of the injury. *Id*. at 7, citing *Capizzano v. Secretary of HHS*, 440 F.3d 1317, 1327 (Fed. Cir. 2006) and *DeRoche v. Secretary of HHS*, No. 97-643V, 2002 WL 603087, *38 (Fed. Cl. Spec. Mstr. Mar. 28, 2002) ("[E]ngag[ing] in or permit[ting] the 're-diagnosis' of a vaccinee's illness years later" is error, as it "sets a dangerous precedent in the absence of convincing evidence of the incorrectness of the concurrent diagnosis or treatment.").

3. That Dr. Kinsbourne's use of the phrase "presumably due to an anamnestic reaction" exposes the construct as mere hypothetical speculation without the support of "medical evidence" in the record. *Id*. Respondent points out on this point that, in their diagnostic analysis and treatment of Tysheem, none of the treating physicians linked the vaccinations aetiologically to Tysheem's transverse myelitis, and none even raised the idea of anamnestic response; instead they looked (in vain) to identify a viral agency. *Id*. at 4, 7-8.

4. That *Blutstein v. Secretary of HHS*, No. 90-2808V, 1998 WL 408611, *5 (Fed. Cl. Spec. Mstr. Jun. 30, 1998) dictates a requirement of "external evidence" where "medical records are silent" regarding a factual circumstance. Respondent's Closing Brief at 5. Respondent argued further that Dr. Kinsbourne's note of the paucity of other causes in the extant record, by logic of elimination, is insufficient to meet the preponderance standard. *Id*. at 6, citing *Huston v. Secretary of HHS*, 39 Fed. Cl. 632, 636 (1997) (a showing of biologic plausibility and temporal association is insufficient ... [without] a logical sequence of cause and effect..."). Respondent's basic point in this argument was that Petitioner had not satisfied the "did it" prong of causation, and that attempts to exclude alternative causes by reference their absence in the medical records cannot satisfy this requirement. *But see de Bazan v. Secretary of HHS*, 539 F.3d 1347, 1352, n.3 (Fed. Cir. 2008) ("a petitioner may instead rule out possible alternative causes to prove causation-in-fact when evidence as to the *Althen* requirements is insufficient."), explaining *Walther v. Secretary of HHS*, 485 F.3d 1146, 1149-50 (Fed.Cir.2007) and *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1357-59 (Fed. Cir. 2006).

5. That Petitioners have failed to eliminate other potential causes of the transverse myelitis, as required by governing authority, adding that if Petitioners are not able to exclude viral infection as a substantial factor in causing the transverse myelitis, their case in chief "fails as a matter of law." Respondent's Closing Brief at 9 (citing the Federal Circuit in *Althen*, 418 F.2d at 1278 and *Munn v. Secretary of HHS*, 970 F.2d 863, 865 (Fed. Cir. 1992), the Court of Federal Claims in *Pafford v. Secretary of HHS*, 64 Fed. Cl. 19, 35 (2005)) and the statute itself in 42 U.S.C. § 300aa-13(a)(1) ("Compensation shall be awarded under the Program to a petitioner if the special master ... finds ... that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated.")).[14] Respondent went even further to state that

[14] In a footnote, Respondent provides the following analysis from *Johnson v. Secretary of HHS*, 33 Fed. Cl. 712, 721 (1995), *aff'd* 99 F.3d 1160 (Fed. Cir. 1996): "[T]he relevant inquiry to be undertaken by the special master is collapsed into a single determination: On the record as a whole, has the petitioner proven, by a preponderance of the evidence, that her injury was in fact caused by the administration of a listed vaccine, rather than by some other *superseding*[,] *intervening* cause?" (emphasis added). That same decision states, in reference to the mandate in *Munn*, *supra*, for a petitioner to "prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual cause of the injury," that "This does not mean that a petitioner must rule out every possible explanation for her

the Act "requires the absence of other causes" for the Court to find in favor of Petitioner. *But see de Bazan v. Secretary of HHS*, 539 F.3d at 1351 ("[A] petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor.") citing *Walther*, 485 F.3d at 1150 and *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir.1999).

6. That, by the logic of *Knudsen v. Secretary of HHS* (also cited by Petitioners), the Vaccine Act does not enforce "a *per se* rule" excluding viral infection as an alternative cause that may be used by Respondent as a factor unrelated, even when the virus remains unidentified. Respondent's Closing Brief at 8. Said Respondent, "a viral infection *can* be an alternative caus[e], even though the viral infection is not in the particular case specifically identified by type or name" so long as the evidence implicates it as a causative factor. *Id*. at 9.

7. That Dr. Kinsbourne's testimony (vis-à-vis that of Dr. Sladky and Dr. McGeady) was unpersuasive and fluctuating, inasmuch as he initially relied on conflicted records to state that Tysheem suffered a more severe local reaction in the arm into which the DTaP vaccine was administered. In contrast, Respondent's experts "possess[ed] superior credentials and experience" with the subject matter of this case. Respondent's Closing Brief at 16. Specifically, Dr. Sladky "unequivocally" opined "from a purely medical point of view" that the vaccine(s) did not likely cause the transverse myelitis because of the time interval, and Dr. McGeady agreed, rejecting the "theory that Tysheem was a immunological 'primed host'" due to his previous DTAP vaccinations. *Id*. at 14-15.

II. ULTIMATE FINDINGS OF FACT

All three experts were personally and professionally credible; that premise is beyond a cavil of doubt in the Court's mind. However, the Court must 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); *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).

The factual disputes separating the positions of the parties are manifold, but underlying many of those disagreements is a fundamental, even definitional, disagreement about the standard governing the Court. As an prologue, then, the Court pauses to define certain terms and situate them in the Court's fact-finding framework.

Respondent is correct to point out the deference afforded by *Capizzano* (*inter alia*) to the opinion of treating physicians in diagnosing patients in the context of treatment. The Court is loathe to upset a definitive diagnosis reached by those for whom, "[w]ith proper treatment hanging in the

---

injury. Rather, petitioner must simply show, on the record as a whole, that it is more likely than not that her injury was caused by a vaccine." 33 Fed. Cl. at 721, n. 6.

balance, accuracy has an extra premium." *Curcuras*, 993 F.2d at 1528. But here it is important to define what the Court means by the term "diagnosis", and to ascertain which diagnostic elements were solidified in this case.

The first, and, for the Court, primary definition of "diagnosis" is "the process of determining by examination the nature and circumstances of a diseased condition [and/or] the decision reached from such an examination."[15] As the first definition focuses on description, the second focuses on aetiology: "a determining or analysis of the cause or nature of a problem or situation" or the determination reached. It is this distinction in the meanings of diagnosis that the Federal Circuit addressed when it elaborated,

> The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the child's injury or that the child's injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury.

Knudsen, 35 F.3d at 549. So, the Court is not charged with rendering a diagnosis of an injury, but is tasked to determine causation based on the preponderant evidence presented.

In this case, the unanimous "diagnosis" (under the first definition) was that the illness from which Tysheem suffered was acute transverse myelitis,[16] and neither party is contesting that diagnosis, reached by all of the treating physicians. For sake of shorthand, that assignation of a descriptive term to describe the illness at issue is what the Court generally means (and specifically means in this case) when referring to "diagnosis". The meaning of the second definition is what the Court attempts to embrace through use of the word aetiology. Of significance in the instant case, no definitive conclusion was reached in this case regarding aetiology, and therefore Petitioner's theory, strictly speaking, does not negate the "diagnosis" of the treating physicians. *See*, *e.g.*, the discharge summary, Pet. Ex. 5 at 20-21 ("this was thought to be ... transverse myelitis with no clear etiology") and the testimony of Dr. Kinsbourne, Tr. at 80-81 ("Any uncertainty that existed at the time of admission was not resolved by any investigation or any subsequent events").

The second term requiring definitional clarification is "plausible". In both its positive and negative connotations, it does not mean anything close to certain; it does not even mean probable. *Inter alia*, it means "having an appearance of truth or reason," "seemingly worthy of approval or acceptance," "credible," or "believable".[17]

---

[15] See RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE (2d ed., unabr. 1987) at 546.

[16] Transverse Myelitis is a syndrome, and, as such, describes a constellation of symptoms without definitionally indicating a causative aetiology.

[17] RANDOM HOUSE DICTIONARY at 1484.

The Court's *apercu* from reflecting on the medical records, and hearing the testimony presented at the hearing, was that Petitioners' combined theory, *i.e.*, molecular mimicry inciting an autoimmune reaction hastened by anamnestic response, was plausible, and Respondent's own experts seriously conceded the plausibility of certain components therein. *See* Dr. Sladky's expert report, Resp. Ex. A at 3 (the vaccine components at issue "have been deemed to have biological plausibility as causal or contributory agents in autoimmune demyelinating disorders of the central nervous system"). Both parties' expert neurologists stipulated that the IOM report was the pivotal source on this question, and the Court concurs.

On the other hand, comments from Respondent's immunologist to the effect that "anything is plausible" are disingenuous at best, and amending that overstatement by saying "many things are plausible" struck the Court as more glib than helpful or persuasive. As Dr. Kinsbourne stated well on rebuttal, not everything is plausible. If everything is plausible, then the term ceases to function as a specific designator; no, the term means something specific or else we would not be using it in general speech, and certainly would not be employing it as an integral aspect of the legal standard governing Program cases.[18]

To the best use of the Court's *dianoia*, plausibility's import is carried in the "could" proposition. Asking a medical expert the question of "could it" (and presupposing a process of

---

[18] "[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!"
> 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).

ratiocination by such expert in formulating a response) is how the Court addresses medical plausibility. That expert's consistency with the then-current opinion of the medical community at large is certainly a component of that device, and adds persuasive weight to his or her opinion.

These reflections on terminology illuminate two aspects of the facts to be found first in this case: first, there is no conclusive aetiology in the medical record for the Court to afford deference over and against Petitioners' theory; second, Respondent's experts concede the basic plausibility of a causal mechanism by which tetanus toxoid *could* be causally linked to transverse myelitis, even if they dispute its occurrence here because of the time interval of onset and because they are not persuaded by the theory of anamnestic response.

There is a derivative dispute between the parties' experts concerning the plausibility of Petitioners' theory that bears discussion at this point, and that is what types of evidence may be relied upon by the Court in assessing the plausibility of a medical theory. As noted when discussing the word's definition, "plausible" does not mean "proven" by either experimental repetition in a laboratory or epidemiologic statistical significance. It means reasonable or believable to the educated mind of someone with expertise in biologic processes and mechanisms.

Dr. Sladky expressed his reluctance to consider medical theories by the standard of a "reasonable degree of medical probability," and Dr. McGeady seemed wedded to epidemiologic evidence as the basis for plausibility. Tr. at 163-64, 209-10. Respondent's experts in this case seemed to repeat the error addressed in *Knudsen* and *Bowes*, that of assuming the occurrence of fact in a particular case based upon its statistical prevalence, or requiring epidemiologic evidence as the only sufficient proof of biologic plausibility. That rationale is found nowhere in the law of the Vaccine Program, as statistical representation is not determinative of biologic plausibility.

"The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." *Knudsen*, *supra*, at 548-49. Clearly, as even Dr. Kinsbourne conceded, if there existed epidemiological evidence from a study that demonstrated an association between the vaccinations at issue and transverse myelitis, that would aid Petitioners' case. In fact, the Court may conclude that a preponderance of the evidence supports vaccine causation "based on epidemiological evidence and the clinical picture regarding the particular child [even] without detailed medical and scientific exposition on the biological mechanisms." *Id*. at 549. However, the paucity of evidence eventuated by the non-occurrence of any such epidemiologic study does not doom Petitioner's case, contrary to what Respondent's experts argued. As the Federal Circuit has long held, "epidemiological studies ... are not dispositive of the actual causation question." *Grant v. Secretary of HHS*, 956 F.2d 1144, 1149 (Fed. Cir. 1992).

Thus, in this case, the IOM did not adopt a conclusion accepting a full causative relationship between the DTaP vaccine's tetanus toxoid and transverse myelitis, notwithstanding the fact that the commission accepted the biologic plausibility of such a relationship. Even Petitioners' expert conceded that their decision not to find a causative link was based on the dearth of epidemiological evidence; as Dr. Sladky pointed out, they were looking for direct, "evidence based" medical proof. *See supra* at 18; Tr. at 147-48. If such proof were required by the law governing the Court's

decision, it is clear that the Petition would fail. Dr. Sladky conceded, however, that the IOM accepted biologic plausibility of a causative mechanism leading from tetanus vaccination to demyelinating disorders such as transverse myelitis, even though he himself was not persuaded due to the absence of epidemiologic data or other clear proof. Resp. Ex. A at 3. Tellingly, Dr. Sladky characterized the position of the IOM commission as"c[oming] to the question with an open mind, with the intent of evaluating the available evidence, and coming to a conclusion [on whether] there [is] sufficient evidence one way or the other." Tr. at 176. That is precisely the Court's position here, and the Court does not have the luxury of not reaching a conclusion; the Court must reach a conclusion on the cause of Tysheem's transverse myelitis, at least insofar as whether the vaccine was involved as a cause or not. As the certainty upon which Dr. Sladky insists is a standard beyond that required by the Program, the Court looks to Dr. Kinsbourne and the IOM's report, to conclude that Petitioners' theoretical mechanism is biologically plausible.

Dr. Sladky expressed his reluctance to consider medical theories by the standard of a "reasonable degree of medical probability," and Dr. McGeady seemed wedded to epidemiologic evidence as the basis for plausibility. Tr. at 163-64, 209-10.

The principal factual dispute regards timing. Before the Court can reach a finding on whether the onset period in this case was plausibly medically appropriate, it must ascertain what symptoms signaled onset, and when onset occurred by the factual sources submitted.

Respondent's primary objection to Petitioners' claim of vaccine causation is the timing interval of onset. Dr. Sladky's opinion was that any period under 72 hours was too truncated for the biologic processes propounded to transpire (*see supra* at 15), and that onset in this case occurred in this case in less than 72 hours, i.e. from the time of vaccination to the admission to the emergency room on 22 May 2003. He based this conclusion on his reading of the medical records, which he read as indicating that Tysheem had already lost the ability to sit and stand by 21 May 2003, and was already flaccidly paralyzed in his left arm and lower body when he was admitted to the emergency room on 22 May 2003. By the Court's review of the medical records, this summary is unsubstantiated. Likewise, Dr. McGeady calculated onset of transverse myelitis at less than 24 hours following vaccination, based upon his opinion that Tysheem's local reaction and pain, first noted on the day of vaccination, constituted onset of transverse myelitis. He was less specific about what would be a plausible time frame, and doubted whether that interval could be stated with specificity, although he admitted his knowledge on that point was less then Dr. Sladky's. *See supra* at 22; Tr. at 207-208.

Onset for transverse myelitis is typically signaled by pain symptoms, "commonly in the back," but also manifesting "in the trunk, groin and limbs." Resp. Ex. E-1 at 2. Its presenting symptom, however, is "a spinal cord syndrome with weakness of the legs, sensory disturbances with a sensory level, sphincter dysfunction, and back pain that occurs acutely and evolves in an acute or subacute manner. Resp. Ex. E-2 at 1. When the pain progresses to weakness, the weakness may be asymmetrical, and may or may not affect the arms. Resp. Ex. E-1 at 3. The third edition of Menkes'

well-respected text on child neurology[19] characterized transverse myelitis as "the sudden onset of rapidly progressive weakness of the lower extremities, accompanied by loss of sensation and sphincter control," of which "pain in the back, extremities, or abdomen, or sensory loss" is the first symptom. Resp. Ex. 4 at 1. Fever is roughly as often present as it is absent, and fewer than half experience neck stiffness. *Id*.

Tysheem certainly experienced intermittent fevers in the time between his vaccination and his admission to the hospital on the night of 22 May 2003. He also experienced pain (accompanied early on by swelling at the injections sites) during the same period. However, both of these phenomena are easily explainable (as they were by doctors at the time) as a typical reaction to the administration of the vaccines at issue, especially as they constituted the fourth administrations of the DTAP and PCV vaccines. As such, there is no evidence in the record to persuade the Court that these somewhat general symptoms were signs of onset, especially when there is a manifest cause for them appearing in the record. True, Dr. McGeady purported to believe that such localized pain on the day of vaccination was onset of the illness, but when challenged, only iterated that pain "can" serve as an onset symptom, without explaining how is was so in the instant case, differentiable from the pain of injection and local reaction. In apparent contradiction, however, Dr. McGeady found a connection between local reaction at the injection site and an ultimate injury to the spinal cord unlikely. He even stated that pain at the injection site was too common an event to associate as a specific sign of manifestation, adding later that a sore injection site "was of minimal consequence." *See supra* at 20, 25. The Court did not find persuasive Dr. McGeady's assertion that pain at the injection site was onset of the transverse myelitis, in the face of medical records and other proffered testimony.

Also, earlier in the day of 22 May 2003, Tysheem was noted to be experiencing some generalized weakness, noted in conjunction with his fever and cold symptoms, but which was not noted to affect a particular area, nor as an acute, emergent symptom requiring immediate attention. Pet. Ex. 9 at 14. This weakness mentioned in the primary care pediatrician's notes could have constituted the onset of transverse myelitis, or it could have been weakness associated with being sick, feverish, and in discomfort in the days following vaccination. Therefore, the Court cannot say to a preponderance of the evidence that nonspecific weakness was the onset of transverse myelitis.

The remaining symptom experienced by Tysheem between his vaccination and full manifestation of transverse myelitis on 23 May 2003 that may have constituted onset was his limited movement in the left arm. No mention of that symptom appears in records from 20 May 2003; the first reference is from the visit to Tysheem's pediatrician on 22 May 2003, noting that he "*will* not move arm by self" (emphasis added). Pet. Ex. 9 at 13-14. The Court notes that the record stated he *would* not move his arm, not that he *could* not. By some hours later, when Tysheem was admitted to the emergency room at CHOP, the chief complaint was "not moving" his left arm. Pet. Ex. 5 at 10. However, interestingly enough, he still was able to hold his arm to his side, and had feeling in the arm, as it was noted to have become "tender to the touch." Pet. Ex. 5 at 10, 14. The Court finds it significant that the intake notes mention such tenderness but do not record any flaccidity or

[19] J.H. Menkes, TEXTBOOK OF CHILD NEUROLOGY (3rd ed. 1985). *See* Resp. Ex. E-4

paralysis of any limbs, an absence that would be remarkable indeed if such relatively obvious symptoms were apparent at that time. Later records that describe Tysheem at that time which are inconsistent are not as useful to the Court as the directly recorded observations at or very near the time of actual observed manifestation, which is the basis for the deference afforded contemporaneous medical records. *Curcuras*, *supra* ("These records are also generally contemporaneous to the medical events"). Petitioner's fact witness testimony corroborates the absence of paralysis at this time, in relating the recollection of the "guard" Tysheem had assumed in the poise of his arm during 22 May 2003. All of this evidence is inconsistent with paralysis or loss of sensation as manifesting symptoms present prior to emergency room intake on 22 May 2003. In contrast, full blown symptoms of flaccidity and insensitivity to pain were experienced by Tysheem later on. Pet. Ex. 5 at 20-21. As Dr. Kinsbourne pointed out, if numbness or flaccidity were present on the evening of 22 May 2003, movement of Tysheem's arm by outside force "would not have hurt." Tr. at 57-60.

Also of some significance is the written notation reflecting that Tysheem appeared "NAD", meaning either "no active disease," "no acute distress," "no apparent distress," "no appreciable disease," or "nothing abnormal detected." It seems odd that the intake notes would record this notation if Tysheem were experiencing acutely manifesting pain, progressive weakness, loss of sphincter control, and/or sensory loss, none of which were noted at that time.[20] However, his condition was significant enough for his mother to seek medical attention, first from the primary care pediatrician, and then at the emergency room. Additionally, it appears from the medical records describing the course of the transverse myelitis that the illness affected Tysheem's legs and spread upward, such that loss of sensation or voluntary movement in the legs would serve as a first symptom, by circumstantial reasoning.

The Court is unsure of how to understand the history given at admission on 22 May 2003, that Tysheem was "wobbly on his feet and not using his [left] arm" within three hours of receiving the vaccinations. Pet. Ex. 5 at 44. Tysheem was seen at the hospital that same day (20 May 2003), and no mention was made by Petitioner about a lack of stability or balance, nor is there any medical observation of it referenced in the emergency room records pertaining to that visit.[21]

After examining the medical records filed in this case, and considering the testimony proffered at the hearing, the Court cannot conclude that onset occurred prior to the evening of 22 May 2003. The Court is left to conclude that onset occurred in the evening and overnight hours of 22 May 2003, *i.e.* between 48 and 72 hours from the vaccinations at issue.

The next two questions to answer are thus: (1) is it medically plausible for onset of transverse myelitis to occur in 48 to 72 hours; and (2) if there is a biologically plausible mechanism that could

---

[20] Interestingly, though, Tysheem was described as being "in no acute distress" on 27 May 2003, even when he could muster "no spontaneous movements in his legs." Pet. Ex. 5 at 20. The Court is left to presume that the spelled out note of "no acute distress" was meant to be more specific than simply "NAD" in the intake notes, which was a more general reference for there being no manifest problem with the child at the time of intake.

[21] As a general observation, the Court did not find the fact witness testimony proffered by Petitioner to be "clear, cogent and convincing" enough to negate medical records, only to corroborate or amplify them. *See Stevens v. Secretary of HHS*, No. 90-221V, 1990 WL 608693, at *3. (Cl. Ct. Spec. Mstr. Dec. 21, 1990).

allow it to occur in that time frame, does the evidence in this case reflect that such mechanism was operating in this case?

The experts were of mixed opinions concerning what was a plausible time frame for onset of transverse myelitis related to tetanus vaccination. Dr. Sladky thought the IOM's range of five to forty-two days was generous–perhaps too generous–and that such onset should follow one to two weeks following vaccination, if at all. Tr. at 133-35, 168. As far as the Court can determine, Dr. McGeady may have thought seven days was an optimal onset interval, as he referred to his own laboratory experience in stimulating immunologic responses to tetanus in lymphocytes wherein maximum stimulation is reached on day seven. Tr. at 183-84. However, when asked, Dr. McGeady was dubious about establishing firm parameters on a plausible onset window, saying, "I don't think that anybody could tell you that it has to be five days, or seven days, or anything like that." Tr. at 207. This skepticism about setting firm boundaries on what is a medically-acceptable onset period was certainly shared by Dr. Kinsbourne, who opined that the IOM-accepted 5-42 day range "cannot be regarded as an invariable rule, particularly when multiple previous challenges of the causative agent have been delivered." Pet. Ex. 28 at 2.

The Court agrees with Dr. Kinsbourne regarding the IOM's conclusions, which are based upon artificially-manufactured neuropathies administered to animal test subjects: they are instructive, but perhaps not definitive. Clearly the biologic process by which transverse myelitis arises requires some quantum of time to transpire. However, the Court was sensitive to the fact that the results of that study (1) were based on animals (2) which were affected by a different (even if similar) neuropathy than transverse myelitis and (3) which were subjected to only one series of triggering stimulus. If there is a plausible theory to explain why onset could transpire more quickly than the range stated by the IOM report, the Court could be persuaded on this point. That is where Dr. Kinsbourne's reference to anamnestic response bears on the Court's analysis.

The concept of the anamnestic response is not novel or foreign to medical science. It is the basis by which "booster" doses are used to reinvigorate immunity. As Dr. Kinsbourne has described it, the Court is persuaded of its medical plausibility. Respondent has not undermined that plausibility through scientific or medical argument. Dr. McGeady's cryptic reference to the inapplicable situation of the "Mantoux technique," whereby an immune system stimulus is injected into the skin, itself accepts 48 to 72 hours as an appropriate window for immune response. He argued this was inapplicable to intramuscular injection, because the reaction would remain localized to the injection site. However, unlike the an injection limited solely to the skin, blood vessels do communicate from each muscle to the rest of the body, as Dr. Kinsbourne noted (*supra* at 14; Tr. at 102), and once the reaction was mounted, the Court does not see how a prolonged dormancy would then necessarily follow. Also Dr. McGeady did not discuss how long such reaction would require in the context of this case (intramuscular injection). Arguably, there may remain a question regarding how much time was required for the reaction to communicate from the bloodstream, across the blood-brain barrier,[22]

[22] Dr. McGeady did mention that the blood-brain barrier would pose an impedimental delay to an autoimmune reaction in the central nervous system that was begun by intramuscular injection in the deltoid; however, he did not elaborate with any particularity (or attempt to quantify) how significantly that interface would retard the spread of the reaction thereto.

to the spinal cord, but Respondent never articulated how much time that would require, and the Court is left with Dr. Kinsbourne's assurance that such could and did occur within a medically appropriate time frame. As such, the Court accepts 48 to 72 hours as a legally proximate, that is to say, medically appropriate time frame within which Petitioners' proffered theory could occur. *See de Bazan*, *supra*.

The Court is left then to consider the factual questions regarding whether Petitioners' proffered theory did actually occur in this circumstance. One aspect of that general question is to determine the circumstance and the effect of the putative upper respiratory infection of viral origin that wanders like a phantasm in and out of Tysheem's medical records during the period between vaccination and onset. On these questions, the Court hastens to point out that it is not bound to rely solely on direct, positive evidence to support its findings, but may consider circumstantial evidence, and is governed by a preponderance of the evidence standard, not scientific certainty through falsifiable proofs. Petitioners' theory surmounts this hurdle if it is medically plausible, and comports with and logically explains the facts of the particular case.

Respondent challenged whether anamnesis was actually evident in the medical records in this case, beyond the theoretical discussion of it proffered by Dr. Kinsbourne. The Court found Petitioner persuasive on this point. The fact that this was Tysheem's fourth DTAP, fourth pneumococcal, and third IPV vaccinations is itself circumstantially corroborative of Petitioner's argument that anamnesis was at work in the instant case. Without contrary circumstantial evidence indicating that there was no anamnestic response, and with no direct evidence either confirming or negating same, the Court finds it reasonable to conclude, based on a preponderance of the evidence, that Tysheem's autoimmune processes were accelerated by an anamnestic response.

The central question of fact bearing specifically on the Court's "did it" analysis is the transiently recurring but nonspecific appearance of upper respiratory infection described in the medical records during the period between vaccination and onset of transverse myelitis. The symptoms of runny nose and cough were positively noted as present at the time of vaccination, were positively noted to be absent later that same day, and were again positively noted as present two days later on 22 May 2003. This odd inconsistency raises a factual issue for the Court.

Experts for both parties, it seemed, attempted to provide a gloss to the medical records to make them comport with their respective explanations of the facts in this case regarding causation. Petitioners would suggest that the transience of these symptoms was caused by allergic reaction, *e.g.*, hay fever, which only persists immediately following exposure to an allergen. On the other hand, Respondent's experts often referred to these symptoms in conjunction with sources in the body of medical literature that paired upper respiratory infection with gastroenteritis as the manifestation of a virus causing transverse myelitis.

To be clear, neither gloss is manifest in the medical records themselves; no mention whatsoever is made therein to gastroenteritis or allergies, and the only mention of vomiting and diarrhea is a statement that they were not present. Pet. Ex. 5 at 12, 26. The Court believes that the treating physicians rendering the diagnosis of URI knew the difference between upper respiratory infection and allergies, and will not now upset the diagnosis of URI absent clear, cogent, and

convincing evidence that it should do so. Similarly, the Court will not read into the records the occurrence of gastroenteritis or its symptoms. Thus, the Court is left to conclude that Tysheem was affected by the intermittent symptoms of an upper respiratory infection–to wit, runny nose and cough, neither of which were severe enough to be cause for serious concern. On the one hand, Tysheem's mother thought the symptoms so slight as to attribute them to teething. *See supra* at 6. On the other, Tysheem's pediatrician thought they were insignificant enough to proceed with administering three vaccinations. *See supra* at 12. This upper respiratory infection was almost certainly viral, as bacterial infection was ruled out through testing once Tysheem was admitted to the hospital; however, the exact virus responsible was never identified, despite extensive testing to that end.

Therefore, the Court is left to conclude, based upon the circumstantial evidence available in this case, that Tysheem was affected by an infection of an unidentified viral agent. Of course, this finding raises its own question: As some, but not all, viruses are capable of causing or triggering the autoimmune process leading to transverse myelitis, how can the Court know whether the virus at issue was capable of causing transverse myelitis? Should the Court include such unidentified virus among the potential causes of Tysheem's transverse myelitis? Assuming that the virus was capable of causing the illness, and that it did, based upon the simple fact that it proximately preceded the illness falls prey to the "*post hoc, ergo propter hoc*" fallacy so often criticized within Program cases. Perhaps of help on this question is the absence of digestive disturbance. The medical literature studying and discussing transverse myelitis repeatedly noted the association of viral infections combining upper respiratory infections and gastroenteritis (with attendant diarrhea or vomiting). As the Court has found, this conjunctive pairing of viral manifestations was not present in this case; only the URI is evident in the evidence before the Court. In fact, this circumstance in the particular case undermines further Dr. Sladky's argument based on statistical likelihood: even if a substantial portion of transverse myelitis cases are associated with viral URI and gastroenteritis, that constellation of symptoms is not what was found in this case, and therefore his argument on that point is of lessened utility to the Court's decision-making process.

The nature of infectious agents as immune challenges also raises a question regarding when the virus was introduced to Tysheem's system, when it first mounted a challenge, when Tysheem's immune response retaliated, if there was an incubation, and, if so, how long it lasted. Dr. McGeady stated in his report that "Tysheem had a viral respiratory infection which was at least in its incubation at the time of onset of his transverse myelitis." Resp. Ex. C. However, the records reflect that URI symptoms were present before the onset of transverse myelitis, and thus by the very definition of the word, the URI was not then in incubation. Nevertheless, Dr. Sladky's point is correct: it is difficult if not impossible for the Court now to determine when the virus operative in this case was introduced, nor to estimate how long it incubated before causing the symptoms noted on the day of vaccination or thereafter. Ultimately, this does not appear determinative to causation or dispositive to the case, and so the Court leaves that question unanswered.

Ultimately, the Court accepts that it was biologically plausible for both or either the vaccinal tetanus toxoid and/or a virus to have caused the transverse myelitis, and understands from the record that these present the only two manifest potential causes under consideration. The Court understands and appreciates Dr. Sladky's reference to Ockham's razor. It is as impractical as it is logically

suspect to add overmultiplied elements and mechanisms to the understanding of a disease's causation, as some sort of physiologic Rube Goldberg machine. However, it does not transgress logic or the law of the Vaccine Program to acknowledge a plurality of causes for adverse events; the Court is not required to isolate one sole, specific cause for a claimed injury. *See generally Shyface*, *supra*. As between the medical experts who testified in this case, the potential for such plurality of causes is contemplated and accepted by Dr. Kinsbourne; however, it caused intellectual discomfort for Dr. Sladky, and he dismissed it out of hand.

The Court notes that Dr. Kinsbourne incorporates the existence of the viral infection into his theory of accelerated immune response, while still maintaining the role of the vaccine as substantial, even predominant. As such, Dr. Kinsbourne attempts to use this circumstance to corroborate his theory of causation and specifically to serve as evidence on the "did it" question. Admittedly, there is no direct, positive evidence to prove definitively that both (or either) of these potential causes were *the* cause(s) of the transverse myelitis, only circumstantial evidence of association and plausibility. Nevertheless, remaining aware of the potential pitfall of mere confirmation bias,[23] the Court accepts the facial validity of this combined explanation. The objections to such a combined theory tendered by Respondent's experts were addressed to logic, not medicine. In that regard, the Court is just as well-situated to render a determination as they. They did not address why the combined theory was medically or scientifically implausible or even unlikely so much as they challenged the possibility of multiple agent causation. To the extent they challenged the relative likelihood of the theory, they based their analysis on *statistical* (i.e. epidemiologic) prevalence as a measure of likelihood in the instant case instead of relying on the fact and circumstances of Tysheem's course of disease in particular. This runs counter to the law and logic of the Vaccine Program. Even in so doing, neither expert was willing to propound to a reasonable medical probability–by a preponderant weight of the evidence–that the transverse myelitis was caused by a virus, any virus.

The closest anyone came to relying on viral agency as an aetiological explanation was the infectious disease department with whom Tysheem consulted during his hospital stay. After dismissing the vaccines as potential *causata*, their report concluded with "viral etiology," based on Tysheem's runny nose and cough noted in the medical records. *See* Pet. Ex. 5 at 42. This conclusion, however, did not meet with unanimity among Tysheem's treating doctors, despite the claim to that effect by Tysheem's pediatrician in the VAERS report. Tysheem's discharge summary from the hospital recorded that there was no consensus or assurance of a "clear etiology" after he had been under hospitalized observation and examination for weeks.

Of some note, Respondent pointed out, and Dr. Kinsbourne agreed, that anamnestic response was not considered in the notes of the infectious disease specialists who were consulted during Tysheem's hospitalization. *See supra* at 14; Tr. at 105-107. Absent the anamnestic response, even Dr. Kinsbourne agreed that an onset period of 48-72 hours was quite likely too brief. If those specialists did not consider the possibility of that mechanism, it is only natural that they would exclude the vaccinations from their differential diagnosis, which, using the process of elimination,

---

[23] *See also* Murphy's Law of Research ("Enough research will tend to support your theory."); Hiram's Law ("If you consult enough experts, you can confirm any opinion.").

leaves only the unknown virus as a potential culprit. If, on the other hand, those specialists had contemplated the anamnestic response, which the Court accepts as a plausible accelerant to the immune (and therefore autoimmune) processes that were at work in this case, they may or may not have reached a different conclusion. Regardless, it is apparent from considering their recorded thoughts that their conclusion was reached primarily on the basis of a process of elimination, the very reasoning Respondent accused Petitioner of using and labeled logically (and legally) insufficient. After searching, through testing, to discover direct evidence of a specific virus to implicate, no conclusion could be reached therefrom because of the negative results for every virus tested for, which included the primary "usual suspects" for autoimmune demyelinating diseases. There is simply not enough evidence in the record for the Court to find the virus to be single-handedly, or even primarily causative of Tysheem's transverse myelitis, even if the Court accepts that there was some virus intermittently affecting Tysheem in the time between vaccination and onset of transverse myelitis. It is altogether corroborative of the evidence in this case, then, to find that the DTAP vaccine and the virus were both causes of the eventual onset of transverse myelitis, and substantial ones at that.

In sum, Dr. Kinsbourne's theory of combined causation, implicating both the vaccines and the virus behind the URI as accelerants for the autoimmune response leading to transverse myelitis, makes sense as a theoretical construct and fits the facts of this case (as reflected in the medical records), notwithstanding the lack of direct, positive evidence to prove its occurrence definitively. See supra at 13; Tr. at 95.

From a thorough review of the record in this case, the Court finds that Tysheem would not have suffered from transverse myelitis but for the intramuscular administration of vaccinal tetanus toxoid, and that both the vaccine and the unidentified virus (which led to viral infection and attendant symptoms) were substantial causative factors leading proximately and inexorably to the onset of transverse myelitis, *via* an autoimmune process that was expedited by anamnestic response to the repeated administration of the vaccines given. The Court cannot find that either causal factor was predominant, and certainly neither could be said to supersede the other given the paucity of proof on the subject.

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 etiology, 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 viewed with approval by the Federal Circuit,[24] 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

---

[24] *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).

(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 ... 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 the proffered biologic mechanism, molecular mimicry leading to autoimmune reaction, hastened by anamnestic response, was medically and scientifically plausible. It may thus be said that the tetanus toxoid "can" cause transverse myelitis, as a medical theory that links the two in a causative relationship.

The Court also found that the evidence submitted in this matter fits best within that construct, that the DTAP vaccine (as well as the unidentified virus) "did" cause Tysheem's transverse myelitis. As such, the Court found that a logical reading of the sequence of events in the medical record of this particular case causally linked the DTAP vaccine administered on 20 May 2003 with the onset of transverse myelitis over the course of 22-23 May 2003.

Based on these findings, it seems elementary to conclude that Petitioners should prevail in this case. However, Respondent has raised a legal issue regarding the combination of the vaccine and the unidentified virus as substantial causal factors. Respondent has argued that the Vaccine Act "requires the absence of other causes" for the Court to find in favor of Petitioner,[25] after Petitioner

---

[25] In making this argument, Respondent relies on the following statutory text:

> Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole--
>
> (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and
>
> (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is [also] due to factors unrelated to the administration of the vaccine described in the petition.

42 U.S.C. § 300aa-13(a)(1).

presumably disproves the universe of potential causes. On its face, this argument was specifically dispelled by the Federal Circuit in *Walther*, *supra*:

> The alternative causation issue is addressed in subsection (B). That provision does not specifically place the burden on the petitioner with respect to alternative causation. When juxtaposed with subsection (A)'s clear statement as to the burden of proof under that prong, the absence of any such language in subsection (B) suggests that the petitioner does not bear the burden as to alternative causation under the second prong. Moreover, it would be unusual to require a party to prove that "there is not a preponderance of the evidence," as our legal system rarely requires a party to prove a negative. A plain reading of the statutory text more naturally places the burden on the government to establish that there is an alternative cause by a preponderance of the evidence. Indeed, placing the alternative causation burden on the petitioner would essentially write § 300aa-13(a)(1)(B) out of the statute.

485 F.3d at 1150. In other words, the statute clearly burdens the Petitioner to demonstrate the proof required in subsection (A), but only speaks in a comprehensive sense of the Court's findings with regard to subsection (B), without allocating that content of proof to a particular party. The Federal Circuit's reading of this language places the burden of proof in those matters upon Respondent.

The Court recognizes that Respondent's argument, based on the textual language itself, makes a good point on its face. Were not the *Shyface* and *Walther* decisions (*inter alia*) binding on the Court (as they surely are), a *prima facie* reading of the statutory language belies the contemplation of multiple causes. Nevertheless, the appellate authority governing the Vaccine Program does not require the Court to find "the absence of other causes" to rule in Petitioners' favor.

This case does bring to the fore a textual ambiguity in this statutory provision, the application of which is always crucial, but often tortuous within Vaccine Program cases. A facial reading of the statute seems to require that preponderant evidence, showing the injury suffered was "due to" (*i.e.* caused by) something other than the vaccine(s) at issue, not exist. As such, the statute does not here appear to contemplate the view of causation adopted by the common law: that there is a plurality, sometimes even a multiplicity of causal factors that may result in a circumstance or event. The statutory language on its face assumes a singularity of cause, as may be illustrated by the following paraphrase, into which the Court inserts the word "also" to amplify the point:

> [A petitioner is entitled to compensation] if the ... court finds ... that the petitioner has demonstrated by a preponderance of the evidence [the prima facie elements, including that the vaccine was both a cause in fact and a substantial factor], and ... that there is not a preponderance of the evidence that the [injury suffered] is [*also*][26] due to [another cause, distinct from the vaccine].

---

[26] To reiterate for clarification: The word "also" is an illustrative addition and does not appear in this portion of the statutory text, nor is the Court here suggesting that it should be added to the statutory text. This illustrative addition merely brings into relief the tension within this text as applied to multiple causative agents.

As illustrated by this paraphrased reading of the statutory text, the second prong of what must be found by the Court, for a petitioner to prevail, is the affirmative absence of preponderant evidence that the injury alleged was due to any other cause, even if such cause was not a superseding cause that overshadowed the vaccine as a causative factor. And, it would seem, use of the conjunction "and" makes this second prong a necessary finding if the Court is to rule in a petitioner's favor.

The Court is sympathetic to Respondent's position. The statute's own terms requires the Court to find the nonexistence of preponderant, affirmative proof of other causes. Although, by force of logic, a proffer by Respondent of preponderant evidence that another cause did exist might conceivably defeat a finding that no such proof existed, it remains somewhat unclear how allocating this burden of proof unto Respondent is not a requirement of a party (Respondent) to *disprove* a negative. *Cf. Walther* at 1150.

On the other hand, in several landmark decisions,[27] most notably in *Shyface*, *supra*, the Federal Circuit has applied a judicial gloss to the statutory text, so as to read it in the context of the

---

[27] For a thorough discussion on this decisional history, including many of the cases cited by the parties in this case, *see Heinzelman v. Secretary of HHS*, No. 07-0001V, 2008 WL 5479123 (Fed. Cl. Spec. Mstr. Dec. 11, 2008):

> The history of relatively older Federal Circuit decisions includes two different lines of cases. In one line of cases, the Federal Circuit uses the term "prima facie" case in the context of cases seeking compensation pursuant to the Vaccine Injury Table. In the other line, the Federal Circuit discusses the burden of ruling out alternative causes in the context of claims that a vaccine actually caused an injury, which are also known as Off-Table cases. Recently, these two lines of cases have blended...
>
> [B]efore 1996, only two Federal Circuit cases contained a holding about alternative causation in the context of an off-Table case. These are *Grant* and *Jay*, which relied upon *Grant*. Other cases, such as *Munn*, *Hellebrand*, and *Hodges*, either did not discuss other potential causes or discussed them in dicta....
>
> The Federal Circuit [in *Shyface*] observed, perhaps with some understatement, that "There is a dearth of precedent discussing the requirements for prima facie causation." The Federal Circuit's use of the term " prima facie causation," arguably created confusion that latter cases are still resolving. Until *Shyface*, the Federal Circuit decisions using the term "prima facie case" were cases seeking compensation pursuant to the Vaccine Injury Table, the prime example being *Whitecotton*.
>
> ...
>
> With regard to how the possible presence of a potential [causal] factor unrelated to the vaccine affects the analysis of off-Table cases, Federal Circuit precedent is not especially clear. More precise guidance, perhaps even a determination en banc, might be helpful. The earliest Federal Circuit case resolving an off-Table claim, *Grant*, separates the determination that the vaccine did cause the petitioner's injury from the determination that an alternative factor did (or did not) cause the injury. The most recent Federal Circuit case for off-Table claims, [*de Bazan*], is consistent with Grant. In [*de Bazan*], the Federal Circuit's description of the respondent's case implies that if the government's evidence did concern a factor unrelated to the vaccine, then the respondent does take up the burden to show the particular agent was "in fact the sole cause" of the injury.
>
> Assuming that the Federal Circuit actually created a distinction between situations in which the government challenged the persuasive value of petitioner's evidence on a particular prong and situations in which the government put forth a particular agent as the cause of petitioner's injury, then the distinction is important.

Heinzelman at *10, 16-17 (internal citations omitted).

common law regarding actual causation, exemplified by the Restatement (2d) of Torts.[28] As explained in that opinion, however, that gloss was based upon the perceived "statutory purpose" of the Vaccine Act, given "[t]he absence of elaboration of the law of causation in the legislative history," once the plain meaning rule had, presumably, been rendered inapplicable by ambiguity.[29] 165 F.3d at 1350-51. The application of this judicial gloss is carried forward in the *Walther* decision, to the affirmative assignment of a procedural burden onto Respondent, encompassing all the matters contained in 42 U.S.C. § 300aa-13(a)(1)(B). Though such assignment may not be a *fait accomplit* required by the statutory prose itself, this Court is nevertheless bound to follow the Federal Circuit's position on this *quodlibet*.[30]

To second-guess now these rules established by judicial gloss is not within the authority of the Undersigned. The Court is bound to apply the law as it may be found. However, it is clear that resolution of this ambiguity is truly outcome-determinative in this case. As in the case of *Herkert*, *supra*, the Court as finder of fact has here found that both the vaccine(s) and the unknown virus were substantial factors in causing Tysheem's transverse myelitis, but for which the disease would not

---

[28] The Federal Circuit quoted sections of the Restatement, *inter alia*:

> [N]egligent conduct is a legal cause of harm to another if
>
> (a) [it] is a substantial factor in bringing about the harm, and
>
> (b) there is no rule of law relieving the actor from liability because of the manner in which his negligence has resulted in the harm.
>
> ...
>
> [N]egligent conduct is not a substantial factor in bringing about harm to another if the harm would have been sustained even if the actor had not been negligent. ... If two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, and each of itself is sufficient to bring about harm to another, the actor's negligence may be found to be a substantial factor in bringing it about.
>
> ...
>
> In order that a negligent actor may be liable for harm resulting to another from his conduct, it is only necessary that it be a legal cause of the harm. It is not necessary that it be *the* cause, using the word "the" as meaning the sole and even the predominant cause.

165 F.3d at 1352, quoting Restatement (2d) of Torts §§ 431-32, 431 cmt. d (emphasis in original).

[29] "The preeminent canon of statutory interpretation requires us to presume that the legislature says in a statute what it means and means in a statute what it says there. Thus, [a court's] inquiry begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004) (internal marks and citations omitted). Longstanding Supreme Court precedent "permit resort to legislative history only when necessary to interpret ambiguous statutory text, as does also the tradition of the common law. Chief Justice Marshall in 1805 stated the principle that definitively resolves this case nearly 200 years later: 'Where a law is plain and unambiguous, whether it be expressed in general or limited terms, the legislature should be intended to mean what they have plainly expressed, and consequently no room is left for construction.'" *Id.* at 187, note 8, quoting *United States v. Fisher*, 2 Cranch 358, 399, 2 L. Ed. 304. *See also* W. Eskridge, P. Frickey, & E. Garrett, LEGISLATION AND STATUTORY INTERPRETATION, App. C (2000); A. Scalia, A MATTER OF INTERPRETATION 18-23 (1997); A. Scalia, "The Rule of Law as a Law of Rules," 56 *U. Chi. L. Rev.* 1175, 1185 (1989).

[30] But see *supra* at note 19.

have stricken Tysheem. Without application of the judicial gloss set forth in *Shyface et al.*, under the statutory interpretation suggested by Respondent, the Petition fails. Applying said gloss, however, establishes that the Petition is entitled to compensation, unless Respondent proffers preponderant proof that a "factor unrelated" was the sole or superseding cause of the injury. Respondent has not argued that, to a preponderance, the unidentified virus (or anything else) was the sole or superseding cause of the transverse myelitis. 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