



Eventually, an evidentiary hearing on the ultimate issue of vaccine causation was convened by the Court *in vivo* in Kansas City, Missouri on 7 January 2009. Hearing Transcript (“Tr.”). Wherein, the Court heard from Petitioner herself, her long-time treating physician, and medical expert witnesses for both parties, Dr. Marcel Kinsbourne, a Pediatric Neurologist, for the Petitioner, and Dr. Thomas Leist, a neurologist specializing in neuro-immunology, for the Respondent. Following those hearings, the parties filed closing briefs with the Court, and the case became ripe for a ruling. On 2 August 2010, the Court convened a hearing to announce its ruling to the parties, which is excerpted in relevant portion and incorporated herein.

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

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

## I. LEGAL STANDARD

It is axiomatic to say that a petitioner bears the burden of proving, by a preponderance of the evidence—which this Court has likened to fifty percent and a feather—that a particular fact occurred or circumstance 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. Sec’y 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. Sec’y 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. Sec’y of HHS*, No. 90-45V, slip op. at 3 (Cl. Ct. Spec. Mstr. March 28, 1991).

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 that she had suffered a “Table” injury, to her 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. Sec’y of HHS*, 956 F. 2d 1144 (Fed. Cir. 1992); *Strother v. Sec’y 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. Sec’y of HHS*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

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

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

*de Bazan v. Sec’y of HHS*, 539 F. 3d 1347, 1352 (Fed. Cir. 2008).

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

As a matter of elucidation, the Undersigned takes note of the following two-part test, which has been vindicated and viewed with approval by the Federal Circuit,<sup>3</sup> and which guides the Court’s practical approach to analyzing the *Althen* elements:

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

*Weeks v. Sec’y 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 Petitioners’ 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. Sec’y 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. Sec’y of HHS*, 165 F. 3d 1344, 1352 (Fed. Cir.1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that petitioner would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*. “[T]he relevant inquiry ...[is]... ‘has the petitioner proven ... that her injury was in fact caused by the ...

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

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

“To prove causation, a petitioner in a Vaccine Act case must show that the vaccine was ‘not only a but-for cause of the injury but also a substantial factor in bringing about the injury.’” *Moberly v. Sec’y of HHS*, \_\_\_ F.3d \_\_\_, 2010 WL 118661 (Fed. Cir. 2010) quoting *Shyface v. Sec’y of HHS*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999); *see also Id.* citing *Walther v. Sec’y of HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007) (for causation analysis in off-Table cases, the Restatement (Second) of Torts applies and ‘the petitioner is treated as the equivalent of the tort plaintiff’). In the watershed case of *Shyface v. Sec’y of HHS*, 165 F. 3d at 1352, the Federal Circuit “adopt[ed] the Restatement [(2d) of Torts] rule for purposes of determining vaccine injury, that an action is the ‘legal cause’ of harm if that action is a ‘substantial factor’ in bringing about the harm, and that the harm would not have occurred but for the action,” and that rule continues to guide the Court today in the instant matter.<sup>4</sup> *Cf. Hargrove v. Sec’y of HHS*, No. 05-0694V, 2009 WL 1220986 \* 39-40 (Fed. Cl. Spec. Mstr. Apr. 14, 2009).

## II. DISCUSSION

The Court’s Bench Ruling was as follows:

[T]his is an actual causation case, not a table case. If we do a review of the testimony of the Petitioner, Petitioner lives on an 84-acre horse ranch. For 20 years, Petitioner was able to keep horses, which required labor to inter alia feed them grain and hay, labor to gather and spread their manure, labor to bale and manipulate the hay in her barn and both dexterity and strength to help in the delivery of foals.

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<sup>4</sup> The mandate of the Federal Circuit in *Shyface* to follow the RESTATEMENT (2D) OF TORTS on the application of actual causation did not indicate how this Court should approach the tectonic shift of the common law into the later Restatement(s). The short answer to this question is that the Federal Circuit incorporated the RESTATEMENT (2D) OF TORTS, and until the Circuit does otherwise to change that gloss, that is the mandatory precedent binding on this Court. By way of more detailed analysis, given the Circuit’s reasoning in *Shyface* for incorporating the Restatement, *i.e.* that Congress contemplated the common law (in its then contemporaneous understanding) within the Vaccine Act draftsmanship, thus presuming the common law as a background legislative intent, it would appear that only the Second Restatement is binding on this Court in matters touching on actual causation, because that is the version in use at the time of the Act’s drafting and passage. Likewise, when the Federal Circuit decided *Shyface* in 1999, the RESTATEMENT (3D) OF TORTS: PRODUCTS LIABILITY had already become available in published form, and yet the Circuit did not choose to incorporate or even reference that Restatement’s provisions at all, notwithstanding the potential corollary to the Program’s focus on causation in the absence of a fault element. Had it done so, a contrary argument could have been made that the Circuit’s reading of congressional intent was a progressing correspondence to whatever Restatement provisions were most current. However, this would seem to correspond to the more dubious “statutory purpose” canon of interpretation. The Court’s reading of *Shyface* leads to a result that the Third Restatement should be viewed at most as persuasive, but not mandatory authority, and is not to be followed where it conflicts with the Second Restatement. Therefore, to the extent the Court cites to the Third Restatement herein, it shall be only to bolster or elaborate citations to other sources.

Involved in other activities ancillary to her husband's public status, she had to lift and maneuver many materials in and out of her trunk and buildings where she displayed them.

At her annual physical exam on 10 November 2005, Petitioner received the flu shot at bar. She had been receiving them annually without prior incident or adverse reaction for the previous seven to 10 years. She testified that she had had no illness or ailment on the day of the vaccine administration. She received the flu shot between 11 a.m. and noon on 10 November 2005.

Now a bit of potential confusion. That night, that is the night she received the injection, the inoculation, her chores were typically strenuous, and she pulled a muscle in her lower middle back towards her side, therefore the Court is assuming in or around her *latissimus dorsi*. That's the Latin.

Petitioner argues that this was not part of her vaccine reaction, but just a wear and tear injury, part of doing physical labor as an aging woman. If it was part of her vaccine injury, which would put onset at around eight hours or so, that would perhaps be too brief for the vaccine to have caused the injury complained of, transverse myelitis.

When she felt pain from the strain on that evening of the 10th, which she described at trial as a "catch" and a "stitch", she saw it as typical and self-treated it with ibuprofen, then slept without incident. She did not see the incident as medically relevant at the time and did not think it worth consulting a doctor.

The next morning while doing chores, she once again felt pain and thought it was just a reactivation or reagravation of the previous night's strain. She consumed two more ibuprofen tablets and took a long shower to soothe the pain only to find, while dressing after the shower, that she could not feel her pants on her waist. That occurred at approximately 11:30 a.m. to 12:00 noon on 11 November, which would put us a hair over 24 hours following vaccination, postvaccinal.

She testified that this was the first time she experienced sensory loss. This new experience was qualitatively different to her and frightened her greatly. In fact, she feared she was experiencing a stroke. Her condition then rapidly deteriorated in a matter of minutes, not hours.

When she went to tell her husband about the sensory loss, that something was seriously wrong, she fell and he had to help her up for her to stand. She described the progression of the numbness as beginning at her waist and rather rapidly moving down her legs such that within 30 minutes it had reached her knees. The numbness was bilateral; that is, it would be more of an indicium of transverse myelitis than a stroke.

Her husband drove her to the hospital, but by the time they arrived, perhaps 30 minutes later, Petitioner had "lost more of the sensation and the use of my legs" and had difficulty extricating herself from the car. By the time she entered the ER, her loss of sensation had extended all the way down to her feet.

She started spacing out and does not recall much of her intake into the ER but for the following: "I remember entering the emergency room, thank you, and I think I was relieved just to get there and I honestly do not remember another thing after I once -- I remember them asking me did you take any drugs and I said ibuprofen. They asked me why. I said because I had a pain in my back or something, but I do not remember anything at all from there on."

She was told of her transverse myelitis diagnosis when she came to. When she was discharged, she couldn't get out of bed on her own, could not go to the bathroom on her own, and she has never been able to resume her previous physical activities on the horse farm.

She has had, as the Court enunciated it, "limited partial recovery." The Court at that hearing:

"THE COURT: And that is your ambulatory and you can control your personal hygienic issues, but you no longer have the stamina? You cannot do the very exceedingly active physical life that you did beforehand?"

"THE WITNESS: Yes, sir. I automatically feel for the arms of a chair because I have no sensation of where my derriere and legs are."

She said further that she has "no sensation of hot or cold or touch."

Her testimony was inconsistent in some ways with medical records on a point raised by Respondent. On cross-examination she stated that she had "never been told" she had degenerative disc disease, though she was aware she had a compression fracture.

Her primary care physician testified a few minutes later that Petitioner has had diagnosed degenerative disc disease for some time. She followed up with a statement, "I never felt pain. I was never immobilized by it, nor did it constrict my activity."

The rest of her preexisting health conditions that Respondent asked about did not seem to be relevant and would not explain the circumstances of 10-11 November 2005, *e.g.*, injury from a horse riding accident, gastric reflux, carpal tunnel syndrome.

Respondent did catch some blatant inconsistencies between her testimony at trial and her affidavit. Her affidavit stated, "During the evening of November 10, 2005, I felt tightness and severe pain in my left side and back." But her trial testimony said it was unremarkable wear-and-tear pain that was handled by ibuprofen.

She explained that it wasn't really "severe" pain that she felt that night, and in fact that may be the case. She did make a distinction between those items. She further explained the history she gave at the ER intake by saying she had been pharmaceutically sedated, at that point probably was not lucid when she gave that history and could remember none of that experience.

The Court gives that a certain amount of tintinnabulation of veracity. She was obviously highly stressed at that point, and to what degree she was pharmaceutically sedated I have no opinion, but I don't doubt that she was stressed out.

Fact witness testimony of the primary care physician, Dr. Perryman: Now, Dr. Perryman's specialty is internal medicine. He has 30 years in practice, has been Petitioner's doctor for 22 years, presumably gaining familiarity with her long-term medical course.

He recounted how he advised her to get a flu shot at her annual checkup and that the symptoms that developed before hospitalization the next day were not at all manifest at the time he saw the Petitioner. He thought the "weakness in her extremities and paresthesias in her body" were vaccine-related. He "knew for a fact" that she's never had those symptoms before he had been her one and only internist.

He stated that Petitioner's current diagnosis, as confirmed by the doctors at the Mayo Clinic, is post-transverse myelitis with residual symptomatology, as well as degenerative disc disease, degenerative joint disease and gastroesophageal reflux disease. He recounted that her diagnosis of TM, that is transverse myelitis, followed within 24 hours of her presentation at the ER and that such diagnosis was confirmed, at least from his perspective.

Petitioner's expert witness, Dr. Marcel Kinsbourne: Dr. Kinsbourne agrees with the transverse myelitis diagnosis. Dr. Kinsbourne agrees that onset occurred at or within 24 hours of vaccination.

Now, his first answer to "can it" is the 1994 IOM report/book, Adverse Events Associated With Childhood Vaccines, of which we are all familiar, "that a series of demyelinating disorders, including transverse myelitis, are biologically plausibly related to a number of vaccines, including influenza."

Secondly on the "can it" issue, he relies on "a number of case reports, published empirical literature and journals, which reported the relationship as the authors concede that between the influenza and transverse myelitis in the cases that they reported."

Also on "can it", he says the epidemiology does not answer the question one way or the other because the condition is so rare and would require an expenditure of

resources on a question that is not that important to the medical field. That's why he says case studies are our best real-world, non-theoretical indicator of "can it".

Explaining the short temporal interval, Dr. Kinsbourne qualified that "if one is to infer temporal relationship from case reports then we will find that the more reports one gets the more the relationship spreads out, so it's not valid to say here are three or four cases and that's their spread and that is it. This is simply something in the distribution."

That means basically that no, it doesn't fit with the range of reported cases, but that's okay because, being such a small sample, it's more likely to have a narrow distribution curve, that is a skinny bell curve.

Second point on the matter of onset timing. He notes, that is Dr. Kinsbourne, the inherent variability of immunology and neurology.

Third defense of the onset timing in the window is reference to an article by Dr. Poser from 1982, which gave the wide range of 24 hours out to two months. Later I will mention a little bit more about Dr. Poser's article from 1982.

Another point regarding "can it" is the connection between flu vaccines and Guillain-Barre syndrome, which is similar to transverse myelitis except that a different part of the nervous system is affected. To state what we know, peripheral nerves are generally associated with the harm in GBS and the spinal cord itself in TM. Dr. Kinsbourne pointed out that the two are so similar it is not unheard of for a patient to have both or some aspects of each in a mixed syndrome.

Dr. Kinsbourne described the process as an inflammatory response to a vaccine, which he believes is due to the vaccine possibly cross-reacting with substances in her spinal cord "upregulating" her immune system, having been previously sensitized by seven to 10 years of flu shots.

From his perspective, he tried to tie the timing interval and the dearth of other possible causes into his general theory by saying, "Given that what happened happened and given that it happened that the onset for the disorder was within 24 hours of the vaccination and given that this is not what we can call a mere temporal interval, it's actually a very important temporal interval because it is backed up with mechanism and plausibility as opposed to being just random, which the word mere implies.

"This is a procedure which is intended to -- allows an immune response, and within 24 hours there was indeed an immune attack on Mrs. Moore's spinal cord and also that the record reflects that no other event in her recent history that could compete as an alternative of causation for which it might have been that caused Mrs. Moore's immune system to react in this way at this time."

Now Dr. Kinsbourne's medical literature. Petitioner's Exhibit 16, the Bakshi article. "Acute transverse myelitis is an inflammatory disorder of the spinal cord that is often associated with an antecedent or intercurrent factor such as infection, collagen vascular disease, multiple sclerosis or ionizing radiation.

"In addition, TM has been reported following vaccinations, including for, amongst others, influenza. Only one patient demonstrating magnetic resonance imaging, MRI, findings in vaccination-associated TM has been described in the literature to date occurring after hepatitis vaccination. This represents the first report of MRI findings in acute transverse myelitis after influenza vaccination."

And Dr. Kinsbourne basically says concerning this article even though it's only one case study and doesn't definitively prove the flu vaccine can cause TM, it is one grain of sand on the scale.

Petitioner's Exhibit 17, the Michael Donaghy textbook. "The majority of patients with transverse myelitis are not systematically ill, and the neurological disorder usually evolves over a few days. Pain at the site of the lesion may be the initial symptom, followed by weakness in the legs and positive sensory symptoms with sphincter involvement." The article lists a lot of different viruses that can trigger this.

Dr. Kinsbourne filed this "to make the point that the triggers of conditions like transverse myelitis are not exclusive and specific, but rather that there is -- there are -- a host of different organisms that on rare occasions can trigger this condition."

Exhibit 18, the Fenichel article, "Following Swine Flu Immunization Program in 1976 Within Two Months, Passively Collected Data," suggested an increase in GBS cases and other neurological symptoms, which was then confirmed by active surveillance of GBS incidence following the flu shot.

It discusses TM as well, stating that TM "reaches its maximal deficit within a few days," that "data concerning a cause-and-effect relationship between immunization and TM is circumstantial and based upon the temporal relationship," and cites another study that "reported two patients with TM following influence immunization" with onset intervals of seven and 29 days.

Kinsbourne's interest in this article is, "Fenichel cites case reports of encephalomyelitis followed in influenza vaccination. Now, encephalomyelitis is not the same as transverse myelitis, but it has in common that there's myelitis. In other words, encephalomyelitis is myelitis plus the brain also being involved, but that's still pertinent to the causation of myelitis, which is part of the condition, and Fenichel again, you know, is a very well-respected author."

Petitioner's Exhibit 19, the Haber article, a study tracking the report of GBS following influenza vaccination, noting a decline in GBS reporting following flu shots since the '96-'97 season.

Kinsbourne's point with this one is "because GBS is so much more frequent and much more prevalent than transverse myelitis, we have much more scientific knowledge of GBS, and our scientific knowledge of GBS includes the fact that influenza vaccinations have repeatedly been shown to have increased the risk of GBS by varying degrees. And my point is that transverse myelitis is very like GBS, only it applies to the spinal cord whereas GBS applies to the peripheral nervous system."

Petitioner's Exhibit 20, abstract of a Dutch case study entitled "Myelopathy Following Three Days After Influenza Vaccination." Citing similarities with Petitioner's course, Dr. Kinsbourne said, "It shows that this has come to medical notice in various parts of the world."

Petitioner's Exhibit 21, the Lerner article, a case report of a guy who suffered optic neuropathy and, despite being on immunosuppressive meds, developed an acute spinal cord syndrome a few days following a flu shot. The introduction cites other neurological incidents following the flu shot, including transverse myelitis.

Dr. Kinsbourne "would put less weight on this one because this patient was immunosuppressed so we don't know the complexity of what was done there, but the fact remains that in whatever state he was in the influenza vaccine is being associated with a myelopathy."

Petitioner's Exhibit 22, the Lasky article, a GBS epidemiology study showing a 1.7 relative risk of GBS if one receives the flu shot, equating to slightly more than one additional case of GBS per million persons getting the flu shot. Dr. Kinsbourne didn't seem to have much to add on that one.

Petitioner's Exhibit 23, the Menkes textbook, discusses the mechanism by which it is generally thought infectious agents trigger demyelinating conditions, molecular mimicry, where certain infectious agents possess antigenic determinants that resemble antigens in the spinal cord, leading to cross-reactive immune response that attacks nerve myelin.

In the case of transverse myelitis, the spinal cord itself is attacked at one level below which the subject loses partial or complete neural function. Dr. Kinsbourne attests that this is the consensus in the field of neurology.

Exhibit 24, the Nakamura article, a case study of two adults with neurologic sequelae following a flu shot. One, the first that is, convulsions that began five days postvaccinal and, number two, paraplegia seven days postvaccinal, diagnosed with

either ADEM or TM. It's myelitis either way, and Dr. Kinsbourne didn't have too much to add to that.

Exhibit 25, the first Poser article. He gives the historical note, "Many vaccinations and viral infections can produce severe and even life-threatening noninfectious reactions. Oddly enough, even today the existence of these reactions, especially to vaccinations, is disputed on the basis of epidemiological studies by public health experts who choose biostatistics over well-founded clinical, neuropathological and experimental data.

"The fact that the pathogenic mechanism that produces the immune response to viral infections and to antiviral vaccines is identical to that of experimental allergic encephalomyelitis, EAE, and neuritis, EAN, seems to have been ignored by those who deny the fact that serious neurological illness may, although it rarely does, result from prophylactic vaccinations.

"This was recognized in 1954 by Miller and Stanton, who stated, 'The occurrence in identical clinical circumstances of radicular polyneuritic, Landy, Guillain-Barre, encephalitic and myelitic syndromes, separately or in combination, strongly suggests a common denominator in the pathogenesis of these various conditions whether they occur after prophylactic inoculation or arise, as they more commonly do, in association with preceding infection.'"

Kinsbourne says he filed the Poser article mainly to include its summary of the Miller and Stanton article, with is voluminous.

Now, Exhibit 26 is the main Poser article. It notes in the abstract that the fuss over GBS in the '76 swine flu cycle caused everyone to pass over the other, less common neurological/demyelinating conditions, which are the focus of the study.

It states, regarding a review of the non GBS case reports following swine flu vaccinations, "The latency between vaccine and onset of illness in the swine influenza group ranged from one to 63 days with a mean of 16.5 days, again slightly different from the influenza vaccine group with a mean latency of 10 days."

Kinsbourne relied heavily on this article and wanted the Court to focus on the study's emphasis on non GBS injuries following the flu shot and presumably and obviously the one-day indication of when that can start to show up.

Exhibit 27, the Reik article or Reik. It's an article really on ADEM and says, "Some systemic features of the postinfectious nervous system disorders also resemble those of human immune complex disease. Transitional cases and occurrence after the same antecedents establish the relationship of ADEM to GBS in which systemic symptoms, immune complex glomerulonephritis and pathologic changes in other

organs similar to those of serum sickness all occur." Kinsbourne says "the point is here made that these conditions are closely related."

Petitioner's Exhibit 28, the Ropper article. "Influenza vaccines over the past 30 years or more have carried a minimal risk of inducing GBS," a concession as opposed to no risk. Kinsbourne did not have much to add to that other than the flu-GBS relationship is the consensus, even if minimized by some.

Petitioner' Exhibit 29, the Adverse Reactions book, discusses the Arthus reaction, inflammatory reaction which is acute, but within hours, six to 12, not minutes. It's not an anaphylactic type reaction, but actually requires the formation of antigen-antibody complexes just like autoimmune demyelinating disorders such as TM, but still can begin within six to 12 hours of the stimulus event.

As to the "did it" portion -- first there is the "can it" and then "did it" -- Kinsbourne pointed out that there is no other identifiable alternate cause for the TM of Petitioner in the medical records, leaving "the influenza vaccine the only viable candidate as a causation that I'm aware of here."

Regarding the involvement of degenerative disc disease, Kinsbourne thinks it's a red herring; that is, a molehill to the mountain of TM, is quite prevalent in the aging population and was not attributed as the culprit for Petitioner's symptoms by any treating doctor.

Furthermore, x-rays did not show any impingement on her spinal cord, which is an immediate threat calling for surgery. Impingement on surrounding nerves is more common and more treatable without surgery. The fact that her treaters did not take immediate action indicates that they did not think her spinal cord was affected by the disc degeneration.

Dr. Kinsbourne considers the first sign of onset being the numbness when Petitioner came out of the shower and could not feel her clothes around her waist, roughly 24 hours postvaccinal. On cross-examination, Respondent challenged Dr. Kinsbourne with the results of a lumbar puncture taken on 13 November, two days after Petitioner's admittance to the hospital, inasmuch as there is no elevated white blood cell count or elevated protein count.

Dr. Kinsbourne explain in response to cross-examination comparing the reactions between the wild flu virus to the flu vaccine, "There are a number of immune responses, and they overlap. Some happen immediately and some happen in a matter of hours and days and weeks.

"Now, of course normally none of them damage another system or we wouldn't be using the vaccination, but that's the enormous variable of the time interval and shows that it's not the virus; it's the host reaction to the virus that is variable, so one isn't, in

neurology, really that surprised if the same provocation causes the same outcome at totally different intervals."

When Respondent pressed Dr. Kinsbourne for his position on how long it would take the body to eradicate the original immune-challenging antigen, he gave greater detail in describing the mechanism thusly, "You get an immune response, you mobilize cells, which produce antibodies and then, as Dr. Leist pointed out, you self-mobilize T-cells, which produce a cellular response of two arms of the immune system, and that is standard and nobody argues about it. At what point in time that mobilization actually removes the invader is really hard to say."

Responding to further questioning on this point, Dr. Kinsbourne said, "The immune response would certainly have to have begun, because it's an immune-mediated process, but that doesn't mean that the immune response would have stopped, would have finished its job on the invader. It might never do so, you know. It might even fail completely to clear the organism such as with herpes virus where the organism stays in the body anyway."

The point of that exchange being the body does not have to eliminate all traces of the immune challenge, whether vaccine or wild virus, in order to mount a reaction such as the autoimmune demyelinating reaction that seems to cause TM.

Respondent tried to pin Dr. Kinsbourne down to having contradicted himself because in another case in which onset was 25 days postvaccinal Dr. Kinsbourne stated the textbook onset interval period of five to 42 days, for which 25 days fell right in the middle.

Dr. Kinsbourne reported herein and responded that he used the "more conservative" textbook interval because timing wasn't an issue in that case, and that's why he took time to justify a one-day interval in this case because there's support for it, even though it's outside the typical window an outlier to the typical bell curve distribution pattern.

Dr. Kinsbourne was persuaded that it could be one day in this Petitioner's case because she had received so many flu shots for so many years in a row such that she could mount an anamnestic response to the vaccine. Dr. Kinsbourne conceded that he did not definitively know that Petitioner had an anamnestic response, but thought that it was quite plausible considering her long history of flu vaccines.

In cross-examination, Respondent honed in on whether Petitioner had experienced an Arthus reaction indicative of the anamnestic response and whether Petitioner had manifested a local reaction at her injection site, which could have indicated the presence of these. Petitioner had no such local reaction.

Later on redirect, Dr. Kinsbourne clarified that, "It's not the case that to have an immune response in the body you have to have visible immune response at the site of the inoculation. Lots of vaccinations are given that are perfectly effective in stimulating the systemic immune system that doesn't have a local effect, and nobody is going to criticize a vaccine because there was no local effect."

Respondent also challenged whether medical literature described the Arthus reaction following a flu vaccine. Dr. Kinsbourne conceded that he knew of no specific article where this was described, but added, "My understanding is that any vaccination can, that this isn't something that's done vaccine to vaccine, that the phenomenon of anamnestic, which is that if you give a provocative agent and it elicits a reaction and you give it again then the likelihood is it will do so in a shorter period of time and that if you give it again it's like even shorter and everybody accepts that. Now, how short is short and showing it separately in each case, I'm not sure that it does that."

When asked whether it is "generally accepted in the medical community that an influenza vaccination can cause an anamnestic reaction," Dr. Kinsbourne replied that "I haven't had occasion to ask people. I would be very surprised if it wasn't, but I would have to speculate."

Also on the Arthus reaction, Respondent pinned down Dr. Kinsbourne to concede that he had "no literature, case reports, epidemiological studies, clinical experience on how the influenza vaccine, the antiproteins, would react to a vascular wall, which is what happens in an anamnestic reaction."

One of Respondent's arguments made in the cross-examination of Dr. Kinsbourne is that "before data can be considered valid, it must be reproducible." Now, that is only true for matters of scientific fact or strong theory. That is certainly not the standard of validity in this program. The Court finds facts upon which it bases its rulings where there is a preponderance of evidence, not only where the evidence is reproducible

Respondent challenged Dr. Kinsbourne's theory of causation via a treater's impressions in a medical record. Petitioner's treating neurologist, Dr. Bettinger, said, "I do think it is an acute inflammation related to an acute event such as a recent viral syndrome. I have difficulty attributing this to being a complication of the flu vaccine, which was given about eight hours beforehand, but it must be kept in mind."

Kinsbourne thinks that such a statement is equivocal inasmuch as she didn't rule out the vaccine or an antecedent viral infection, even though there wasn't an antecedent viral infection.

Respondent pointed out that she told doctors that she had felt tired/exhausted earlier in the week, but Kinsbourne said that that's not good enough to infer a viral infection,

not without a sniffle or nausea or diarrhea or cough. There were no viral syndrome symptoms.

Dr. Kinsbourne did concede that TM can often be idiopathic with no identifiable cause in a significant portion of cases. Dr. Kinsbourne agreed that he could not rule out blind coincidence.

Later on redirect, Dr. Kinsbourne added from that same treater's record that "I think that this is clearly a case of transverse myelitis." And that's also from Dr. Bettinger, and that goes against Respondent's expert's theory. Dr. Kinsbourne does concede that no treating doctors ever settled on a diagnosis that the vaccine was responsible for the TM.

Respondent also challenged Dr. Kinsbourne for not maintaining a clinical practice. He does about 40 percent of his time working on vaccine cases, and the rest is teaching and research.

Respondent's expert, Dr. Thomas Leist, specializes in neuroimmunology, which is the neurology of immunological mediated diseases affecting the central nervous system. He is board certified as a neurologist because there's no board certification for neuroimmunology. He does hold a fellow in neuroimmunology, though. He treats lots of patients, is an associate professor and has done research on the immunology of transverse myelitis.

In a synopsis, Dr. Leist contested A) Whether Petitioner actually suffered from TM considering the absence of white blood cells and proteins in her cerebrospinal flu on spinal tap; B) Whether the flu shot could cause the onset of TM within 24 hours unless there was a pre-prime situation with reactive bodies already in the Petitioner's body that reacted to the flu components within the vaccine; C) Whether there is any evidence of an anamnestic response, that is an Arthus reaction, such as a local reaction at the injection site; and D) Whether the body could have an anamnestic response to a flu vaccine that changes every season.

Now, regarding whether Petitioner actually suffered from TM Dr. Leist said, "There are certain clinical features over here that potentially would raise concern whether transverse myelitis is actually the appropriate diagnosis, Special Mater, because 24 to 36 hours after the initial presentation -- the day of onset, the day after vaccination; that means on 12 November -- she underwent a lumbar puncture which didn't show an increase in protein and it didn't show hypercellularity of white blood cells.

"There would have to be inflammation or some mark of inflammation present, yet the setup of her spinal fluid at that point in time does not show us any inflammation or any markers of inflammation, of acute inflammation."

The incredible rapidity of onset causes him to question both whether the vaccine had anything to do with it or whether it was TM at all. "Her testimony today doesn't affirm the transverse myelitis as much as it raises a potential question because of the shortness of the time interval."

He thinks her history of disc problems in Petitioner's back, coupled with the lack of findings from the spinal tap, totally undermine the TM diagnosis. "Mrs. Moore has an extensive history of changes to her back, of also back injury. She is physically very active. A theoretical possibility also maintains a spinal cord infarct, which would present as such as a rapid onset.

"And so these are other opinions that are there and nothing that was really done by the physicians at the time precludes the ruling out of one or one of the other of these options. For me, the fact that she didn't have clear inflammation in her CSF vitally report that this is a very rapid onset of an event raises a flag. I mean, it indicates to me that perhaps the inflammatory theory needs to be looked at with certain caution, and I think I will also state that in my opinion where I read that 'cannot be established with reasonable certainty.'

"With that I mean there is nothing formally proving that this is transverse myelitis. I don't fault the practitioners for considering this as transverse myelitis, but if we are there and have to say, 'Is it?' then afterwards there's already a paucity of information."

He thinks a spinal cord infarct more likely and consistent with the cerebrospinal fluid results, which causes elevated protein levels, but not within 24 hours. Rather convenient. The elevated protein levels would appear with spinal cord infarct, but only after 48 to 72 hours, during which time no additional spinal taps were performed, so really Dr. Leist has only a negative circumstantial evidence to bolster his theory as there is not affirmative circumstantial evidence to point to.

Of course, as he points out, lumbar punctures are not tests you repeat every day just to check on things, so it's unremarkable that no further punctures were performed during that acute period at the hospital.

His conclusion on transverse myelitis is, "The absence of a white cell count raises in my mind the issue of the presence of an inflammatory response, and that's where my opinion came from that it is a reasonable working hypothesis, but it cannot be proven with certainty that this was in fact transverse myelitis." He added a little later that he "cannot say with reasonable degree of medical probability that she does or does not have transverse myelitis."

The Court hastens to add that an event or circumstance need not be proven with certainty for the Court to include it within its findings of facts, and if he cannot even say with a reasonable degree of medical probability that it was not transverse myelitis

then the challenge he's made to the diagnosis rendered by all the treating physicians that this was TM does not persuade the Court.

Wherefore, the diagnosis of transverse myelitis reached in the medical records and reiterated by Petitioner's treating physician at the hearing, not to mention the Petitioner's expert, stands.

Next on the timing interval, Dr. Leist thought the standard, or as Dr. Kinsbourne termed the classic interval, of five to 42 days was too inclusive. Instead of being the narrower, conservative window that Dr. Kinsbourne perceived, Dr. Leist thought it was too generous to make sure it was inclusive enough.

That means that five days for a reaction is too short "because in order for transverse myelitis to occur I do think that you need to have a cognate P- and T-cell response to ascertain itself, and that normally takes beyond five to seven days. So I will think that the window of five to 42 days probably is already flanking the main incident period by a generous margin by significant days."

The Court queries Dr. Leist whether he disputed the theoretical proposition of flu vaccine-related transverse myelitis. He did not oppose it. "In this very long laundry list of infectious agents that have been temporally associated with transverse myelitis, influenza vaccine belongs in there. I do think that there is a potentiality that the influenza vaccine can cause transverse myelitis."

He did think that such an occurrence would be unbelievably rare because TM is already such a rare condition and its usual triggers, i.e. wild viruses, are live whereas the flu vaccine is killed and less likely to elicit a reaction. He thought that this was the reason that it doesn't show up in epidemiology studies and ultimately why the IOM did not find a causative connection.

The Court also questioned whether there is enough similarity between flu strains in the flu vaccine for the body to remember via the anamnestic response. He answered that "The two viruses would need to have very significantly overlapping characteristics," but vaccine strains between two concurrent years "vary significantly" as a biological necessity.

He brought up an interesting study on this point. "There was a very small study done at one point in geriatric patients to see whether or not they actually produced higher antibody responses if they get immunized every year and one looks solely at the overlap. And in that particular study there was actually a lower antibody response to recurrent antigens so it almost would go in a different direction." That is contradictory to anamnesis.

Dr. Leist could not think of a way that a flu shot could cause transverse myelitis in 24 hours. He said there would have to be an anamnesis or some accelerant. "For

something like this to occur there would have to be an already preestablished response to this vaccine in the body."

So that is why the presence or absence of an Arthus reaction is so important in this case and no local reaction on Petitioner's arm to him means no Arthus reaction, although he did concede Dr. Kinsbourne's point that "not everybody gets local swelling, but the Arthus reaction is not a situation of everybody" and with the Arthus reaction "significant swelling within 24 hours in the arm is an important paradigm."

And from both medical records and Petitioner's fact witness testimony, "there is no indication that there is a location reaction at the site of the vaccine." Therefore, for Dr. Leist "that makes it very difficult for me to assume that there was such a preformed immune response present that would within less than 24 hours cause a central nervous system injury, yet where the antigen actually is it didn't do anything."

Also relating to the Arthus reaction, Dr. Leist expressed his understanding that, "The Arthus reaction in itself needs presence of the antigen." He had not heard within the medical community of the flu vaccine causing an Arthus reaction; said it didn't come up much one way or the other, and yet he could think of no "mechanism by which the influenza vaccination could attach to vascular walls, which would be necessary" to preprime for an Arthus reaction.

To shorten the process though, Dr. Leist did not propose any other potential factor as more likely than not the real cause of the transverse myelitis. However, he did point out several possibilities that were admittedly speculative, but could not be ruled out.

Now the Court's analysis. First, both experts agree that in one form or another a flu vaccine could cause transverse myelitis. They both find to be a plausible theory the situation wherein a flu vaccine's proteins elicit a reaction in the body that attacks a particular pattern of amino acids in the vaccine proteins, but that then turns and attacks the body's own structures, mistaking them for foreign bodies due to a similarity in amino acid pattern.

Second, although Dr. Leist maintained his negation of the transverse myelitis diagnosis, as the Court has noted, the evidence presented does not overcome the presumption afforded to the treating medical records concerning diagnosis.

That every treating physician was adamant that Petitioner suffered from transverse myelitis, including Petitioner's primary care doctor who testified at trial, persuades the Court that Petitioner did more likely than not suffer therefrom. Therefore, the Court finds that Petitioner did suffer from transverse myelitis.

As a point of clarification, the Court notes that it credits Petitioner's testimony for distinguishing the dull muscle ache in Petitioner's latissimus dorsi, which followed

approximately eight hours postvaccinal, from the rapidly-descending numbness and weakness that began about 24 hours postvaccinal. The Court found that account persuasive.

It may or may not be relevant, but perhaps Petitioner's treating neurologist, Dr. Bettinger, might have considered the vaccine as a stronger option if she had calculated onset at 24 hours instead of eight hours. We will never know that. We cannot know that.

Third, then we come to whether flu vaccine-related transverse myelitis could plausibly follow at or within 24 hours of vaccination. Both doctors thought pre-priming was almost a necessity to cause such onset, but whereas Dr. Leist believed a local reaction to be necessarily concomitant with such a so-called Arthus reaction, Dr. Kinsbourne did not believe it to be necessary to manifest a local reaction.

Now, the Court is not absolutely convinced that this issue is central, but amongst the medical literature filed by Petitioner, again Petitioner's Exhibit 26, a Poser article, one well-known and well-respected neurologist authored the article that states a range of one to 60 days plus as a potential onset window.

There is no reference that an Arthus reaction would be necessary to achieve a one-day onset or that a local reaction would be the indicium to watch for. The Court found the medical literature persuasive and relies thereupon to state that a 24 hour onset is plausible, even without the presence of a local reaction at injection site.

Therefore, the Court's mind is satisfied on the question of "can it" inasmuch as the record contains a plausible medical theory that explains how the vaccine in question might reasonably cause the injury suffered.

On the question of "did it", we know that Petitioner did receive a flu vaccine, and the Court has found that she did suffer from transverse myelitis with onset beginning at just under 24 hours after the vaccine administration.

We know that the treating doctors did not identify any possible alternative causes, although they did perform blood tests to find such a cause. Respondent's expert has not raised to the level of more likely than not any potential cause that is exclusive or independent of the vaccine.

Respondent noted and Petitioner's expert conceded that an idiopathic cause or pure chance could also be to blame. However, this cannot be used as a factor unrelated. Section 11(c)(1)(D)(i) of the statutes so indicates.

Given the temporal relationship and the absence of competing causata, the Court finds that the flu vaccine more likely than not did cause Petitioner's transverse myelitis. That is, that Petitioner has demonstrated the logical chain of cause and effect linking the vaccine to Petitioner's injury.

Therefore, this Court finds that Petitioner is entitled to compensation. The parties are strongly urged to begin any damage discussions posthaste.

Tr. at 3-49.

### **III. 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.**

s/ Richard B. Abell

**Richard B. Abell**  
Special Master