

**In the United States Court of Federal Claims**  
**OFFICE OF SPECIAL MASTERS**

No. 08-678V  
Filed: August 3, 2012  
Reissued with redactions: September 25, 2012  
Unpublished

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HEIDI JAGOE, parent of  
M.J., a minor,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

Respondent.

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Transverse myelitis, TM; Diphtheria-tetanus-acellular pertussis, DTaP; Inactivated polio, IPV; Hemophilus influenzae type B, HIB; Pneumococcal conjugate , PCV; Hepatitis B, Hep B, Althen prong three, a medically appropriate time of onset; Crosby v. Sec’y of the Dept. of Health & Human Servs.

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*Ronald Craig Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Petitioner.*  
*Ryan Daniels Pyles, U.S. Department of Justice, Washington, D.C., for Respondent.*

**DECISION ON ENTITLEMENT**<sup>1</sup>

**GOLKIEWICZ**, Special Master.

On September 25, 2008, petitioner filed a Petition pursuant to the National Childhood Vaccine Injury Act of 1986, seeking compensation for neurological injuries allegedly sustained by petitioner’s minor child from five immunizations he received on October 10, 2005. Respondent opposes entitlement to compensation. The outcome of this case hinges upon one essential element of petitioner’s case: whether petitioner is able to show preponderant evidence that onset of her son’s symptoms occurred within a medically appropriate time frame following vaccination. Because petitioner is unable to show onset within a medically appropriate time and this finding is decisive to her case, the undersigned chooses to abbreviate the discussion of other portions of petitioner’s causation evidence.

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<sup>1</sup> This Decision was originally filed on August 3, 2012. On August 17, 2012, petitioner requested redactions. Thereafter, the undersigned granted in part and denied in part petitioner’s request in an Order, filed on August 21, 2012. In this reissued version, the minor child’s name is redacted to initials, the minor’s birth date is omitted and this footnote is changed to reflect the redaction. The remainder of the Decision is unchanged.

It is critical to note that this case was developed parallel to another, very similar case, involving the same petitioner's law firm and the same experts.<sup>2</sup> Crosby v. Sec'y of the Dept. of Health & Human Servs., No. 08-799V, slip op., 2012 WL 2866464, \*1 (Fed. Cl. Spec. Mstr. Jun. 20, 2012), Motion for Reconsideration denied, No. 08-799, slip op. (Fed. Cl. Spec. Mstr. Jul. 19, 2012). Both cases involve a petitioner alleging her infant developed transverse myelitis ("TM")<sup>3</sup> shortly after receipt of childhood immunizations. The issue of what is the medically appropriate timing of onset after vaccination, Althen prong three, is decisive in both cases. Although there were some factual differences, the events surrounding the infants' immunizations and timing of onset were fairly similar. The background scientific evidence presented was the nearly identical. The cases were also filed around the same time in 2008. While not formally connected or processed as related cases, numerous discussions during status conferences included information regarding the application of immunologic evidence to the facts of both this case and Crosby. The testimony given in Crosby greatly affected how this case proceeded and the scientific discussion herein often refers to the Crosby Decision.

In particular, Dr. Byers, the expert employed by petitioner in both cases, gave an opinion herein related to immunology and the issue of appropriate medical timing; this opinion conflicted with testimony offered by the same expert in Crosby. That occurrence is what shaped the process described below. In Crosby, the immunologist testified that 96 hours was the minimum amount of time necessary to produce symptoms of the disorder, unless specific factors were present. The expert testified that those unidentified factors were not present with the Crosby infant. Herein, the same immunologist opined that 36 hours was sufficient time for [M.J.] to manifest TM symptoms, but the immunologist's report does not reliably identify any factors that would allow onset in less than 96 hours. Beyond giving a contradictory opinion in Crosby, the immunologist's placement of onset of symptoms actually conflicted with the medical records and the two neurologists who testified in this case. After being pressed to explain the contradiction or clarify the opinion, petitioner's immunologist withdrew from the case. Subsequently, petitioner notified the undersigned that she would not seek another immunology opinion.

The entire record of this case is considered in coming to this Decision. Ultimately, petitioner declined or was unable to reconcile the immunologist's discordant testimony or offer the opinion of another immunologist that onset of observable symptoms within 24 hours of vaccination was an appropriate time frame to infer vaccine causation. The vast majority of evidence shows onset of [M.J.]'s clinical symptoms within 24 hours and the remaining expert evidence does not support petitioner's allegation that onset of clinical symptoms within 24 hours

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<sup>2</sup> Dr. Rose, the respondent's immunologist in Crosby, was not a witness in this case in light of Dr. Byers' ultimate withdrawal from the case.

<sup>3</sup> Transverse myelitis, or TM, is "an acute demyelinating disorder of the spinal cord that evolves in hours or days." P Ex 12-A, Gerald M. Fenichel, CLINICAL PEDIATRIC NEUROLOGY 264-65 (5th ed. 2005)). "As in adults, acute transverse myelitis in children appears to be a self- and time-limited illness and is generally monophasic. Improvement generally occurs two to 12 weeks after maximal deficit." P Ex 12-H, RMS Riel-Romero, Acute transverse myelitis in a 7-month-old boy after diphtheria-tetanus-pertussis immunization, 44 SPINAL CORD 688 (2006). Notably for this case, the patient referenced in the Riel-Romero article had an upper respiratory infection almost concurrent with vaccination and was admitted to the hospital 17 days after vaccination with leg weakness. P Ex 12-H at 1. The case report suggests the infection and vaccine as possible causes. It also notes several other case reports of TM following vaccination in young children with onset of symptoms ranging from 6 to 21 days after vaccination. Id. at 3.

is medically appropriate. Because petitioner's immunologist has not reliably supported the case and petitioner is not seeking another immunology report, the case is ripe for a denial decision on the grounds that petitioner is unable to show onset of her son's alleged injury occurred within a medically appropriate time frame, as required by Althen v. Sec'y of the Dept. of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005).

### **FACTS**

The most essential portion of the facts in this case regarding the timing issue occurred early on – the day of vaccination through the several days of [M.J.]'s initial hospitalization. Other parts of the medical history are relevant as they provide some additional evidence on timing. Regarding possible vaccine causation, there are opinions of treating physicians in [M.J.]'s medical history.

[M.J.] was born on [redacted]. P Ex 3 at 161-65. He was found to be generally healthy in the time leading to the vaccinations in question. E.g., P Ex 4 at 189, 192-93. He was seen by his pediatrician, Dr. Andringa, for a cold in May 2005. P Ex 4 at 193. Following a set of vaccinations given on August 15, 2005, [M.J.] was seen three days later for a low-grade fever and was assessed as having a viral infection. P Ex 4 at 186-87 (“This appears to be a viral infection. . . . We discussed a shot reaction versus viral. I lean more toward viral because of the length of time but will see him back if he has any further problems.”).

On October 10, 2005, [M.J.] received his six-month immunizations of his third DTaP, IPV, HIB, and PCV and his fourth Hep B vaccination. P Ex 7 at 1; P Ex 4 at 184. It appears the appointment was in the afternoon on October 10 and [M.J.] was assessed as a healthy baby. However, on October 12, the pediatrician noted that he and [M.J.]'s daycare felt [M.J.]'s was flaccid on the day of vaccination, October 10. P Ex 4 at 183 (noting date and time of 10/10/2005 and 4:15 pm); id. at 177 (“At that time, [Monday, October 10,] the physical exam was normal, although he was a little bit flaccid and non-responsive, but the history was great, the physical exam was normal. In hindsight, I said he was a little bit floppy, but that was all. . . . The daycare people said that he was a little bit flaccid but absolutely nothing else.”).

According to petitioner's Affidavit, “[M.J.] was unable to support himself and his body was like a rag doll” the morning following the vaccinations, October 11. P Ex 8 at 2. It was noted that petitioner got her son up that morning, October 11, and he was not himself, was more fussy and irritable. Id. As the morning progressed, petitioner noticed [M.J.] “was not really moving his legs since late yesterday and now today.” Id. For this reason, [M.J.] was seen by his pediatrician. P Ex 4 at 181-83. Petitioner complained that [M.J.] had “not been moving legs since yest[er]day.” P Ex 4 at 183. During this morning exam on October 11, the pediatrician noted [M.J.] “was just perfect” and had a normal physical exam on the preceding day when he received vaccinations. P Ex 4 at 181. At this October 11 exam, the pediatrician laid [M.J.] “on the floor where he usually scoots around and moves a great deal and he just lies there and sort of fusses.” Id. “He is not moving his legs much at all. . . . He is not moving either leg. There is some quivering or tremor-like movements in the leg, but that is all. No trauma. No falls, no accidents of any kind that anybody knows about. No fever. No cough or cold. Just no other physical symptoms.” Id. “He just does not seem to want to move his lower extremities. He

used to stand a lot being held. He does not want to stand.” Id. The doctor notes that [M.J.] “was crying and very fussy and just not himself” the day before and spit up on the morning of October 11. During the physical exam, many systems were evaluated as normal and there was “No crying. No fussiness. No discomfort. Moves both lower extremities. No pain. No discomfort. He is very content and happy. I really worked the legs/hips hard. Absolutely normal.” Id. at 181-82. “He does not want to stand. He seems to be somewhat flaccid, even the upper extremities seem a little bit more flaccid than usual.” Id. at 182. The pediatrician’s “Impression/Plan” was “[w]ithout a proven cause and the history has only been for at the most 18 hours and there is no fever, we are going to wait and watch and see what happens.” Id. Blood was taken for diagnostics but results were not available during the visit. Petitioner averred [M.J.] did not improve throughout the day, remained flaccid and became increasingly fussy. P Ex 8 at 2; P MSJ at 3.

Later in the day on October 11, petitioner took her child to the emergency room with a complaint of “difficulty in walking.” P Ex 3 at 152. In the physician’s form, the “C.C.” or chief complaint was noted as “Rxn to immunization.” P Ex 3 at 153. “Pt received immunizations last [night]. Since pt has lost muscle control. Mother reports pt unable to grasp. ‘Pt not acting himself.’” Id. Decreased muscle strength and leaking urine were noted, existing for “x 1 day,” as well as decreased muscle tone throughout and that [M.J.] was not using his legs. Id. at 154-55. He was discharged home and it was recommended that [M.J.] have a follow-up the next morning. Id. at 155.

Early the next morning, October 12, [M.J.] was seen by his pediatrician again. P Ex 4 at 177. At this exam, the pediatrician commented that [M.J.] was “a little bit flaccid and non-responsive” but otherwise normal at the October 10 vaccination visit. Id. “In hindsight, I said he was a little bit floppy, but that was all.” Id. Also, he noted that petitioner thought [M.J.] was “a little just not quite himself” on October 10 and that “[t]he daycare people said that he was a little bit flaccid but absolutely nothing else.” Id. This observation, of flaccidity on October 11, the day of vaccination, was not noted in the contemporaneous record. The pediatrician recounted the October 11 visit when petitioner had complained [M.J.] was not himself following the vaccination and the normal exam except that [M.J.] was not moving his lower extremities and could not support himself. Id. He noted that the evaluation in the emergency room was normal but that they had also noticed [M.J.] was flaccid. Id. Examination showed that the upper extremities were flaccid along with the lower extremities. P Ex 4 at 177. At this point, less than two days after vaccination, [M.J.] was admitted to the hospital.

The pediatrician’s admission note mentioned [M.J.] was not himself on the day of vaccination and that he thought the child was a bit flaccid during the exam and not moving well. P Ex 3 at 77. The record also indicated that a lessening of movement was noted on October 10 and [M.J.] was more flaccid the next morning. Id. The pediatrician recounted the flaccidity in the lower extremities, the urinary symptoms, the irritability and an otherwise normal exam on October 11. Id. This record also stated, “I am very impressed with how flaccid he is.” Id. at 78. “There is no movement [in the lower legs] whatsoever.” Id. The pediatrician noted there was some weakness on exam on October 11 but it had advanced and there was no resistance in the body when [M.J.] was stood up and held under his arms; “He just slid right through my hands. This is not what he had earlier at 4 months and 2 months. It is not what he had on Tuesday,

although I did think there was some weakness.” Id. The pediatrician continued, “[t]here is no doubt that there is a 36-hour history of going from absolutely normal motor skill to a very flaccid individual, certainly first the lower extremities and now the upper extremities.” Id. at 79. Tests were ordered and a pediatric neurologist was involved in the case. Id.

A resident, Dr. Hackman, dictated another record on October 12 that describes the events leading up to hospitalization. P Ex 3 at 80. “A 6-month-old male with flaccid lower extremities since yesterday.” Id. The resident noted [M.J.] was fussy, with rosy cheeks and an occasional cough on October 8 and that petitioner thought he was teething at that time. Id. The doctor also noted [M.J.] was still fussy and seemed uncomfortable breastfeeding on October 10. Id. The resident specifically recorded the parents’ observation that [M.J.] was “a bit more weak” approximately four hours after his immunizations and that he would not stand on October 11. Id. Dr. Hackman related that the flaccidity became more pronounced and urine was “just ‘dribbling out’” later in the day on October 11. Id. “They were seen by Dr. Andringa today with new upper extremity weakness, a weak grip, and not using his hands and fingers much. No bowel movements since Saturday but did have a bowel movement after rectal temperature upon admission . . . (? involuntary stooling). He had a good urine stream with a forceful arch when he was weighed.” P Ex 3 at 80. On exam, the resident found [M.J.] to be “unable to sit without support . . . poor muscle tone in lower extremities. Won’t bear weight on lower extremities. . . . Decreased muscle tone is also noted in the upper extremities but lower extremities are notably worse.” Id. at 81. The record reiterated, “[s]ymptom onset was about 4 hrs after immunizations but it appears he was not acting right prior to the immunizations.” Id. (emphasis added).

A note from Dr. Andringa, the pediatrician, on October 13 noted [M.J.] was “[a]dmitted for progressive hypotonia; got immunizations **3 hr before start.**” P Ex 3 at 90 (emphasis added). A physician’s note by a Dr. Burrow on the morning of October 13 notes, “[d]oing somewhat better this a.m. Moving his arms more than yesterday . . . moving legs more than yesterday, but not as much as usual . . .” Id. at 91.

The pediatric neurologist, Dr. Doescher, saw [M.J.] on October 13. In the recitation of the history it was noted that “**onset of these symptoms occurred somewhat acutely on 10/11/2005.**” P Ex 3 at 82 (emphasis added). “**He received [vaccinations, and] [f]our hours later, the patient had weakness of his bilateral lower extremities.**” Id. (emphasis added). “On 10/12/2005, the patient also had worse lower extremity hypotonia and the family describes poor coordination of his upper extremities bilaterally.” Id. [M.J.] was described as being unable to support his weight or maintain a good sitting position, roll over from front to back, and he had reduced spontaneous movements. Id. The neurologist noted the first MRI of [M.J.]’s brain was normal but, upon review, he saw “questionable fullness in the cervical cord with some subtle signal change. . . . There is also questionable low-lying cerebellar tonsil as an incidental finding.” Id. at 83. He also noted, “[cerebrospinal fluid examination] notes white blood cell count of 15 with 66 monocytes and 33 lymphs, RBCs 1, glucose 54, protein 43.” Id. “On motor examination, he does have reduced tone bilaterally. . . . He has reduced spontaneous movements. He does react to tactile stimulation. . . . He has no voluntary motor movements.” Id. The assessment was [M.J.] suffered from “an upper motor neuron lesion.” Id. Another MRI was ordered of his cervical spinal cord and the decision was made to follow [M.J.] clinically. Id.

On October 14, a note from Dr. Andringa recorded [M.J.] “continues to improve. More arm movement, more head movement and better affect. More resistance in legs but won’t stand.” P Ex 3 at 94. Dr. Burrow noted [M.J.] as being “mildly improved” and to consider the possibility of [M.J.] being discharged. Id. at 95.

A pediatric neurosurgery consultation occurred on October 15 with Dr. Iskandar. P Ex 3 at 85. The note recorded immunizations given on October 10 and that “[i]t seems that it was not until Wednesday on 10/12, that the parents truly detected a change in his lower extremity function although there was a question the day before.” Id. (emphasis added). The neurosurgeon noted an MRI showed “at least 6 mm of tonsillar herniation. The tonsils were somewhat constricted at the foramen magnum because of a relatively small size of the foramen magnum. There was questionable signal change in the upper to mid-cervical spinal cord that was not confirmed on the repeat MRI scan.” Id. The neurosurgeon did note under “Review of Systems” “[s]ignificant for possible URI symptoms or teething just preceding vaccination and the onset of symptoms.” Id. “[M]ild to moderate truncal hypotonia, significant lower extremity hypotonia, and mild to moderate upper extremity hypotonia” were noted. Id. at 86. “He does not have a good grasp in either hand. He has very poor motor function in the lower extremities.” Id. The neurosurgeon stated he could not detect any hyperreflexia on exam but that this was significant in the exam done by Dr. Doescher. Id.

The “Impression” was that [M.J.] had:

a sudden onset of quadriparesis greater in the lower than the upper extremities. I agree that there must have been a cervical spinal cord problem. The differential diagnosis does include transverse myelitis from various etiologies infectious or inflammatory or other. The presence of a Chiari<sup>4</sup> type I malformation is somewhat curious to me. Although the Chiari is unlikely to be causing these symptoms (since Chiari malformations rarely ever present acutely), the tonsillar ectopia is relatively significant in that there is significant constriction of the tonsils at the foramen magnum. Therefore, I could not completely rule out the possibility that the Chiari could have caused enough stenosis at the craniocervical junction to cause a minor neck movement/trauma to result in a contusion in the cervical spinal cord. . . . I explained to the family that Chiari malformations are relatively benign and that these may remain asymptomatic or may cause gradual onset of symptoms over time, but rarely a sudden devastating injury such as this one. . . . However, the fact that there is significant tonsillar ectopia in the setting of a myelopathy makes it reasonable to offer the patient a craniocervical decompression in a couple of months. . . . **However, I would still emphasize that this situation is more likely related to a transverse myelitis than a Chiari malformation and I would strongly recommend continued follow-up with Dr. Doescher for not only evaluating his neurologic condition but also to follow up on the CSF study and in particular, various possible viral etiologies. . . . Again, even though the Chiari is less likely to be the etiology in this case,**

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<sup>4</sup> A Chiari or Arnold-Chiari malformation is “herniation of the cerebellar tonsils and vermis through the foramen magnum into the spinal canal.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1113 (31st ed. 2007).

**there is enough risk here that I would recommend decompression in a couple months.**

P Ex 3 at 86-87 (emphasis added). [M.J.] showed mild improvement and was discharged from the hospital on October 15, 2005. Id. at 100.

Petitioner described that, despite being discharged, [M.J.] continued to suffer serious symptoms and was “a totally different baby.” P Ex 8 at 3. A visit to Dr. Doescher confirmed this on October 18. P Ex 4 at 174-75. “He continues to have poor truncal tone and does not sit or roll like he once did. He still does not support his weight. He has not had significant return to spontaneous movements of his lower extremities.” P Ex 4 at 174. Dr. Doescher noted mild improvement in muscle tone of the lower extremities and much less hyperreflexia on [M.J.]’s right side. Id. at 175. The Assessment noted, “[p]atient is a six-month-old male with upper motor neuron findings concerning for differential of Chiari malformation, with upper cervical cord compromise vs. myelopathy related to immunization such as transverse myelitis. Overall, his condition is stable and somewhat improving.” Id. An MRI on the next day was noted to be “suspicious for myelitis.” Id. at 364. Further, the report noted, “[t]here is a Chiari I malformation, but the subtle cord edema is probably not caused by the Chiari I malformation, since there is no significant compression of the cord caused by the low-lying cerebellar tonsils.” Id. (emphasis added). Another visit with Dr. Doescher on October 21, the doctor noted that the MRI findings could support either a diagnosis of myelitis, as well as “symptomatic Chiari malformation and possibly pre syrinx development.” P Ex 4 at 167. This record noted a three to four hour onset of symptoms following vaccination. Id. Also, this and other records noted a family history significant for Chiari malformations. Id. At this time, Chiari malformation decompression was recommended by Drs. Doescher and Iskandar. Id.; P Ex 5 at 229.

A visit to Dr. Iskandar on October 27 confirmed [M.J.]’s slow improvement in some areas and further testing was ordered. P Ex 5 at 228-29. Dr. Iskandar noted, “[o]n reviewing the MRI scans, it seems evident that the patient has crowding at the foramen magnum from the Chiari malformation and an obvious T2 signal abnormality starting that the foramen magnum going all the way to the midcervical region.” Id. at 228. A nurse’s intake note accompanying Dr. Iskandar’s report noted the reason for the visit as an evaluation for “transverse myelitis [secondary to] immunizations; Chiari malformation.” Id. at 230. The parent’s “New Patient Questionnaire” filled out by one of [M.J.]’s parents noted, “Diagnosis of Chiari Type 1 malformation.” Id. at 232. The note also states that [M.J.] was flaccid “**the next day**” after his 6-month immunizations. Id. (emphasis added).

On November 1, 2005, Dr. Doescher reevaluated [M.J.], noting in the history that [M.J.] was being seen for concerns of symptoms due to an “upper neuron lesion **likely due to Chiari I malformation . . .**” P Ex 4 at 162 (emphasis added). His improvement continued and he was almost able to support a sitting position. Id. at 163. The doctor noted that [M.J.] suffered from a “**likely Chiari malformation. This is more likely an atypical presentation of Chiari malformation compared to an atypical transverse myelitis in a very short time or a reaction from his immunizations.**” Id. (emphasis added).

Medical testing was performed on November 3 at the University of Wisconsin Hospital. P Ex 5 at 130. The record noted [M.J.] “developed hypotonia and loss of developmental milestones the day after his 6 month health supervision visit. . . . received his regular 6 month vaccines at that visit. **The very next day he developed weakness in all extremities.**” Id. (emphasis added). “[M.J.] was admitted in October . . . where MRI showed Chiari I malformation and possibly a ‘presyrinx’ in the spinal column.” Id.

The decompression surgery to treat the Chiari I malformation occurred on November 23, 2005. P Ex 5 at 8-9. “Because of the possibility that the Chiari malformation could have been part of the etiology of the upper cervical spine problem, we elected to decompress the foramen magnum.” Id. at 8. Surgery notes recorded the observation that [M.J.]’s “tonsils were deformed and pressing against the brain stem.” P Ex 5 at 8. No complications were encountered, id. at 9, and [M.J.] was stable following surgery. Id. at 343, 351.

On January 4, 2006, [M.J.] was seen by his pediatrician, Dr. Andringa, who noted [M.J.] received “his 6-month shots **and that day and the next couple of days he developed a marked progressive hypotonia.**” P Ex 4 at 147 (emphasis added). The pediatrician noted that he called the “Center for Adverse Reactions” and [M.J.]’s condition was not a reported complication of the vaccines. Id. During this visit, the influenza vaccine was mentioned and the parents expressed the desire that [M.J.] not have the vaccination. Id. The pediatrician recorded,

I agree with them 100%. Problem will come at 1 year of age. When he gets his other immunizations. Right now the parents are against any more immunizations. I can certainly understand that. This is 1 patient who I may not push immunizations, but will discuss it at 1 year of age and go over in great detail. Even though I think it would be reasonable to give, I think with the very dramatic hypotonia he had even giving 1 shot at a time may be questionable. We will discuss this in great detail, but if the parents are not in favor of it I will certainly agree with their concerns.

P Ex 4 at 147-48.

On February 20, 2006, a follow-up with Dr. Iskandar noted improvement in [M.J.] following the decompression surgery. P Ex 5 at 13. On March 13, 2006, [M.J.] was seen by Dr. McLeish for evaluation of his therapy needs. P Ex 5 at 16. Dr. McLeish noted that [M.J.] had “flaccid upper extremities and lower extremities **the day after his 6-month immunizations.**” Id. (emphasis added). It is also noted that “[a]t this point, his mother indicates that she is not planning to have him receive any additional immunizations but would be interested in talking to one of the pediatric infectious disease specialists, so I will try to help facilitate a referral.” Id. In the “Impression,” Dr. McLeish noted that she would “confer with Dr. Iskandar about this. It is unclear whether it was a Chiari or indeed possibly transverse myelitis.” Id. at 17. Petitioner notes in her affidavit that Dr. McLeish calls [M.J.] her “‘mystery patient’ because it is uncertain what is causing his gross motor delays.” P Ex 8 at 6.

On April 5, 2006, [M.J.] saw his pediatrician, Dr. Andringa, for upper respiratory symptoms. P Ex 4 at 130. The pediatrician noted that [M.J.] “may be allergic to Pneumococcal

vaccine and Pediarix. This is because he had a horrendous neurological hypotonia following those immunizations.” Id. It was noted that “[m]otor-wise, he looks fantastic. He is using all 4 extremities so much better and Mother says he is back to normal.” Id. at 131.

On June 15, 2006, [M.J.] was evaluated by Dr. Conway, a pediatric infectious disease specialist. P Ex 5 at 22-26. The doctor noted, “I was asked to see him in regards to possible involvement of immunizations with his neurologic issues and discussion about future plans for future immunizations.” P Ex 5 at 22. In the recitation of the history, Dr. Conway noted [M.J.] was fussy on the day his vaccinations were given in the afternoon. Id. “He remained fussy throughout the night and then the next day, was noted to have poor motor function, primarily of his legs, but also arms.” Id. “He was seen at a local emergency room and was thought to have pain and fussiness related to the immunizations and was discharged home, but later returned then with increasing concerns and at that time, was noted to have some hypotonia and was admitted.” Id. at 22-23. The exam was largely normal with the exception of decreased strength and tone in [M.J.]’s legs and a difficulty in eliciting deep tendon reflexes. Id. at 23-24. Dr. Conway reviewed the diagnostics of [M.J.]’s original hospitalization and noted, “[t]here were no comments about changes in the white matter consistent with either Guillain-Barré or transverse myelitis.” Id. Despite this, TM was still considered a possibility in the differential diagnosis and Dr. Conway noted [M.J.]’s CSF studies “would suggest the possibility” of a viral infection associated with TM. Id. at 24. “I think that if there is insufficient evidence for his neurological findings to be attributed to the Chiari, then transverse myelitis secondary to some infectious etiology is the most likely diagnosis.” Id. at 25 Dr. Conway notes that the tests for the “most likely pathogens that may cause” TM were not performed. Id. **“Overall, I think that it is unlikely that [M.J.]’s initial problems at 6 months or his continued problems are related to immunizations.”** P Ex 5 at 26 (emphasis added). Dr. Conway continued by recommending [M.J.] receive further immunization but separating some in time to watch for signs of any reaction. Id. **“Although temporally the vaccine association is interesting, I think there is very little to suggest or support involvement with this neurologic event.”** Id. (emphasis added).

In December 2006, [M.J.] saw Dr. Andringa, his pediatrician, again and the doctor noted [M.J.] had a “severe reaction to the immunizations and maybe had a transverse myelitis, but nobody is quite sure.” P Ex 4 at 52. Another note from Dr. Andringa on October 22, 2007, stated, “[t]his young man was doing just fine in his life when he was found to have **marked hypotonia within 24 hours after getting his immunizations.**” P Ex 4 at 20 (emphasis added).

[M.J.] was seen by Dr. Hsu with the University of Wisconsin Hospital on August 5, 2008. P Ex 11 at 5-8. The record notes [M.J.] was fussy during the evening following vaccination and “was found to have no bowel or bladder control, and was very weak in both the arms and the legs” by the next morning. Id. at 5. Dr. Hsu noted that [M.J.]’s parents specifically asked if [M.J.]’s condition was TM after vaccination. Id. at 6. Under Impression, Dr. Hsu opined that [M.J.]’s “clinical history is consistent with his symptoms being due to the Chiari I malformation . . .” Id. Dr. Hsu considered TM after vaccination and stated that “this can happen, although it is uncommon.” Id.

However, this post vaccination syndrome occurs at least these 2 weeks after vaccination because that is how long it takes the immune system to rev up and then attack the spinal cord or other parts of the nervous system. Thus the history of abrupt onset of symptoms on the same day of vaccination suggests the symptoms were not due to the vaccinations.

Id. at 7. Other screenings were set up to determine if there was another underlying cause of [M.J.]’s continued hypotonia. Id. at 7-8.

In her affidavit created in 2008, petitioner noted that [M.J.] continues to have significant difficulties with his lower extremities, relies heavily on his upper body strength for movement and complains of pain in his left leg. P Ex 8 at 6.

### **EXPERT EVIDENCE**

Testimony given in the Crosby case developed the issues of timing of the onset of clinical symptoms. As stated previously, the way these two cases proceeded affected the other due to the subjects being discussed and the experts utilized. Petitioner’s major stumbling block was that her expert neurologist candidly admitted at Hearing that he was unable to opine regarding the appropriate timing of onset, noting an immunologist would be the proper expert to discuss the immune processes and the accompanying time frames. Despite attempts to provide literature that showed onset of clinical symptoms within 24 was appropriate, the neurologist could not offer the preponderant evidence necessary. Unfortunately, petitioner’s immunologist was equally unhelpful.

To give a reader some context, the undersigned provides this lay description of the complex immunologic processes discussed. When a person encounters an antigen, such as a bacteria or a vaccine, the innate immune response is the “first responder.” One’s innate immune system is the body’s defense that we are born with intact. It provides a general, non-specific response to foreign materials and also works to communicate information about the invader to the body and the eventual adaptive immune response. As discussed by Dr. Byers in her report, a person can have symptoms of the innate response and these are usually transient, inconsequential symptoms such as a low grade fever. The adaptive immune response, as the name suggests, is the specific or tailored response one’s body creates as it encounters antigens. Receipt of a vaccination is intended to trigger this system so one’s body “learns” to handle these antigens when a person is exposed to the virus itself. When one’s adaptive immune response learns to fight an antigen, it is found that the adaptive response can sometimes go awry and attack one’s own cells. This constitutes an autoimmune response, where the adaptive immune response targets self-antigens. The attack causes cellular damage and eventually manifests with symptoms. This is one the theories offered in this and other cases alleging vaccinations have caused myriad demyelinating disorders. See Crosby v. Sec’y of the Dept. of Health & Human Servs., 2012 WL 2866464, \*5-22 (Fed. Cl. Spec. Mstr. Jun. 20, 2012); Contreras v. Sec’y of the Dept. of Health & Human Servs., No. 05-626V, 2012 WL 1441315, \*8-24 (Fed. Cl. Spec. Mstr. Apr. 2012), appeal docketed, No. 05-626V (Fed. Cl. May 4, 2012); P Ex 12-H at 4 (describing the autoimmune response resulting in TM); P Ex 12-C, website of MayoClinic.com regarding Transverse Myelitis; P Ex 12-D, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES

(“IOM”), IMMUNIZATION SAFETY REVIEW; HEPATITIS B VACCINE AND DEMYELINATING NEUROLOGICAL DISORDERS (2002). See also A Body Basics Article: Immune System, [www.kidshealth.org/parent/general/body\\_basics/immune.html](http://www.kidshealth.org/parent/general/body_basics/immune.html) (last visited Jul. 27, 2012)(offering a general, background description of the immune system).<sup>5</sup> Although some steps in the processes of the innate and adaptive responses overlap in time, it is generally discussed that the innate immune response precedes the adaptive immune response. In fact, many of the tasks handled by the innate immune response are preparatory for the adaptive response.

In this case, as in Crosby, the undersigned makes no finding but assumes petitioner can support the theory that vaccinations can trigger the demyelinating injury. The issue herein is whether a vaccination can trigger the adaptive immune response and the adaptive response can cause enough cellular damage to produce clinically observed symptoms all within 24 hours.<sup>6</sup>

Because this decision hinges on one aspect of the case, timing and the third prong of Althen, a discussion of the evidence relating to the first and second prongs of Althen is not had. For the reader’s education, a more thorough discussion of the background medical evidence relating to the alleged medical theory can be found in Crosby v. Sec’y of the Dept. of Health & Human Servs., 2012 WL 2866464, \*5-22 (Fed. Cl. Spec. Mstr. Jun. 20, 2012); see also Contreras v. Sec’y of the Dept. of Health & Human Servs., No. 05-626V, 2012 WL 1441315, \*8-24 (Fed. Cl. Spec. Mstr. Apr. 2012), appeal docketed, No. 05-626V (Fed. Cl. May 4, 2012). No finding is

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<sup>5</sup> This internet site information was not entered into the record. It is only referenced to provide background to a reader unfamiliar with the immune system.

<sup>6</sup> In Crosby, the undersigned often found petitioner’s experts to be equivocating regarding what the appropriate minimum time would be for manifestation of the adaptive immune response that theoretically causes the TM versus what the appropriate minimum time would be for manifestation of the clinical TM symptoms. As discussed in Crosby:

Before discussing the experts’ opinions and testimony, the undersigned points out a critical distinction of which a reader must be aware. The experts discuss two concepts: a) an adaptive . . . or an autoimmune response [within the body] that is evident at first only by measurement of antibodies in a patient and b) the development of symptoms of an injury caused by that autoimmune or adaptive immune response, signs that actual damage is occurring in a patient. The former would be measured by antibodies circulating in a person’s system. The latter would be the symptoms, such as the inability to use one’s legs with TM, that a person experiences or observes. It was stressed that these are two phases separated by some amount of time . . . . One must first develop the immune response before one sees the symptoms of injury from that response. In order for the symptoms of the autoimmune injury to manifest, the autoimmune or adaptive immune response must have developed, proliferated, traveled to the site of injury and had sufficient time to cause enough damage that the injury manifests symptoms. The undersigned found that the experts’ references to these two stages, particularly the references by petitioner’s experts [Drs. Renfro and Byers], to be confusing and lax in regard to which process they referred throughout the Hearing.

Crosby, 2012 WL 2866464, \*5. As in Crosby, it is unnecessary – and arguably inappropriate considering the state of the evidence herein – to make a finding on what the appropriate minimum time for onset of TM symptoms following vaccination would be. For purposes of this case, the finding that a period of time less 24 hours from vaccination to manifestation of symptoms is not medically appropriate is sufficient to decide causation.

made regarding the first two prongs of Althen as it is unnecessary to this Decision. Only expert evidence regarding prong three of Althen is discussed in-depth in this section.

#### A. Dr. Renfroe's Opinion

Dr. Renfroe is a pediatric neurologist and is board certified by the American Board of Psychiatry and Neurology with special training in the care of children. P Ex 13; Hr'g Tr. at 7-11. He is a clinical assistant professor, a teaching position, at Florida State University, School of Medicine. Hr'g Tr. at 8-9. Dr. Renfroe primarily sees pediatric patients. Hr'g Tr. at 9-10. He is also a published author. Hr'g Tr. at 10; P Ex 13. On his CV, Dr. Renfroe is listed as the President and founder of the Child Neurology Center of Northwest Florida. P Ex 13. Dr. Renfroe was accepted as an expert for petitioner in pediatric neurology without objection. Hr'g Tr. at 11.

Dr. Renfroe's report begins with a recitation of the events surrounding [M.J.]'s October 10 vaccinations. P Ex 12 at 1-3. Dr. Renfroe noted decreased muscle tone and an inability to support weight on October 11 during the pediatrician's exam and significant "weakness, and hypotonia in both arms and legs" on October 12, when [M.J.] was hospitalized. P Ex 12 at 2. Dr. Renfroe discussed the MRIs performed, noting subtle signal changes in the October 12 MRI that were suspicious for myelitis and a normal MRI on October 14. Later in the report, he noted the pediatrician's record of weakness on October 11 and documentation on October 12 of "marked deterioration during the preceding 24 hours." P Ex 12 at 4.

In this initial report, Dr. Renfroe discussed Chiari malformations, blood supply to the spine and transverse myelitis generally. P Ex 12 at 3-4. Dr. Renfroe's opinion continued, "[M.J.] . . . experienced an acute event with onset hours after receiving multiple immunizations . . . ." P Ex 12 at 4 (emphasis added). He stated the findings were most consistent with TM. Complications with the Chiari malformation would result in sensory loss in addition to paralysis, id.; this, preservation of sensation being indicative of TM, was contested by the government's expert. The report noted, "rapid onset of [TM] **might** occur in a child who had prior exposure to vaccines then received another challenge." P Ex 12 at 5 (emphasis added).<sup>7</sup> No further information was given in this report regarding what might be a medically-appropriate time for onset of TM due to vaccination.<sup>8</sup>

<sup>7</sup> This idea – that previous exposure to vaccines causes subsequent responses to be quicker and/or robust – is referenced as "primed" or "priming" herein.

<sup>8</sup> Along with his original report, Dr. Renfroe supplied literature in support of his opinions. Several articles discuss TM generally. See P Ex 12-A, Gerald M. Fenichel, CLINICAL PEDIATRIC NEUROLOGY 264-65 (5th ed. 2005)(describing TM generally and noting that "no evidence supports" the belief that "a prior infectious illness or immunization causes transverse myelitis"); P Ex 12-C, Mayo Clinic staff, Transverse Myelitis, <http://www.mayoclinic.com/health/transverse-myelitis/ds00854/dsection=causes> (last visited Jul. 27, 2012; current site has changes from the exhibit submitted by petitioner)(describing TM generally); P Ex 12-D, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES ("IOM"), IMMUNIZATION SAFETY REVIEW; HEPATITIS B VACCINE AND DEMYELINATING NEUROLOGICAL DISORDERS (2002)(describing TM and noting vaccination for rabies one "of the factors that may contribute to its development"). Petitioner's Exhibit 12-B presents the anatomy of the spine. P Ex 12-B, Raymond D. Adams, MD, and Maurice Victor, MD, PRINCIPLES OF NEUROLOGY (4th ed. 1991). The remainder of the exhibits submitted with Dr. Renfroe's first opinion are case reports describing TM or other demyelinating conditions following vaccination; however, these articles do not support onset of clinical symptoms

During the Hearing in March 2010, Dr. Renfroe admitted that [M.J.]’s presentation with symptoms of TM were “out of the norm” in regard to the medically appropriate time frame for developing TM from vaccinations. Hr’g Tr. at 25-26. When asked if onset was within an appropriate time frame, Dr. Renfroe stated, “So, it is not – it does not fit with what – we wouldn’t be here if he was in the time frame that was the norm.” Hr’g Tr. at 26. Dr. Renfroe refocused the discussion on whether it was possible to present with TM in a time period shorter than expected and noted this discussion was an **immunologic** issue. Id. (emphasis added). Given his interpretation of the medical literature he reviewed, Dr. Renfroe felt [M.J.] suffered a “complement cascade that can result in a severe acute response . . . .” Id. Dr. Renfroe admitted the complement cascade is a very complex concept and qualified his interpretation with, “**I’m not an immunologist. I just want to underscore that.**” Hr’g Tr. at 27 (emphasis added). He characterized the complement cascade as a domino effect of negative immune responses that can result in “dramatically amplify[ing] an immune response . . . on an acute basis. . . . It can be a rapid response.” Hr’g Tr. at 27-28. Dr. Renfroe discussed this concept in reference to an anaphylactic reaction to peanuts but admitted these were not the same type of immune responses. Id. at 28. Dr. Sladky, respondent’s expert, confirmed this in his testimony, noting that an anaphylactic reaction to peanuts is a very different reaction from an autoimmune process that causes inflammation in the spinal cord. Hr’g Tr. at 104-05.

Again explaining he is not an immunologist, Dr. Renfroe noted that he felt [M.J.]’s system was primed to these vaccines as he received them in Augusts 2005. Hr’g Tr. at 29-30. When asked how quickly a response can occur, Dr. Renfroe noted that rat studies found a protein response to stimulus within one day. Hr’g Tr. 31. Notably, there was no discussion of whether a “protein response” amounts to observable symptoms. When pressed about timing, Dr. Renfroe noted that onset of the neurological symptoms likely began **within eight hours after vaccination**. Hr’g Tr. at 32-36 (emphasis not in the original). Later, Dr. Renfroe referenced onset of [M.J.]’s TM to be approximately 12 hours. Hr’g Tr. at 61-62. At this point, Dr. Renfroe admitted, “I don’t understand immunology well enough to know if it’s possible to have that acute a response.” Hr’g Tr. at 36. “I do know it’s not common. I know it’s not – it’s not recorded.” Id. The undersigned followed up by asking, “[n]ow listening to what you just stated, you are **not** offering an opinion as to whether or not the timeframe in this case is appropriate, temporally appropriate? Medically appropriate?” Hr’g Tr. at 38 (emphasis added). Dr. Renfroe responded, “I think that’s a valid statement. **It is just beyond my expertise.**” Id. (emphasis added).

During cross-examination, Dr. Renfroe opined that the first symptom of [M.J.]’s neurologic condition was fussiness, Hr’g Tr. at 39-40, and the first “major symptom” to a layperson would be floppiness or paralysis. Hr’g Tr. at 40; see also Hr’g Tr. at 54 (“Q: Can

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within 24 hours of vaccination. P Ex 12-E, F. Tezzon, et al., Acute radiculomyelitis after antitetanus vaccination, 15 ITAL J. NEUROL SCI. 191 (1994)(describing a patient with symptom onset three weeks following vaccination); P Ex 12-F, S. Lim, et al., Transverse Myelitis after measles and rubella vaccination, 40 J PAEDIATR. CHILD HEALTH 583 (2004)(describing a patient with symptom onset 16 days following vaccination); F. Karaali-Savrun, et al., Hepatitis B vaccine related-myelitis?, 8 EUROPEAN J OF NEUROLOGY 711 (2001)(describing four patients with symptom onset of six weeks, four weeks, three weeks, and three months following each patient’s receipt of vaccinations); RMS Riel-Romero, Acute Transverse Myelitis in a 7-month-old boy after diphtheria-tetanus-pertussis immunization, 44 SPINAL CORD 688 (2006)(describing a patient with symptom onset approximately 17 days following vaccination).

flaccidness be the presenting clinical onset of transverse myelitis? A: Yes.”). Respondent’s counsel referenced the pediatrician’s note from October 12, which noted [M.J.] not moving his legs on October 11, and Dr. Renfroe agreed that [M.J.] had experienced the onset of TM symptoms on October 11. Hr’g Tr. at 57-58. When asked if Dr. Renfroe could differentiate fussiness seen in [M.J.] before the vaccination from that seen after vaccination, Dr. Renfroe referenced [M.J.]’s rough night following vaccination. Hr’g Tr. at 41-42. Ultimately, when walked through medical records referencing the days preceding vaccination, Dr. Renfroe agreed that [M.J.] had “something preceding immunizations.” Hr’g Tr. at 55-61. Respondent’s counsel asked, if the histories taken by Drs. Hackman and Andringa were accurate for flaccidity preceding vaccination, “why wasn’t that the start of [M.J.]’s transverse myelitis?” Hr’g Tr. at 63. Dr. Renfroe responded, “[i]t is possible.” *Id.* Dr. Renfroe noted that he was relying on [M.J.]’s legs not moving the morning following vaccination as the “dramatic change.” Hr’g Tr. at 42-43; see also Hr’g Tr. at 63 (“It’s what happened later that was the definite[ symptom].”).

Dr. Renfroe was recalled following Dr. Sladky’s testimony. Hr’g Tr. at 149-66. At this point, Dr. Renfroe stated medical literature existed to support onset of TM symptoms in fewer than five days, again stressing he was **not an immunologist**. Hr’g Tr. at 152-54 (emphasis not in the original). He specifically noted “sub 24 hour evidence of this anaphylactoid response to complement stimulation in the spine.” Hr’g Tr. at 154. When pressed about his opinion on timing, Dr. Renfroe stated he could support his opinion about such a reaction with literature that had not been previously entered into evidence. Hr’g Tr. at 156-57. At this point, Dr. Renfroe’s opinion about the type of process allegedly occurring in [M.J.] became confused. “I have an opinion that – and I’m not sure that it’s autoimmune. It may be a diffuse aggressive immune reaction.” Hr’g Tr. at 157. “Can you develop a transverse myelitis in three to [four] hours, there seems to be literature that supports that as a possibility.” *Id.* Clarifying, Dr. Renfroe stated he could submit literature to support a rapid immune response in the spine. Hr’g Tr. at 157-58. Notably, the doctor did not state literature would support onset of observable symptoms in a three to four hour period after exposure. However, this discussion prompted the filing of Dr. Renfroe’s supplemental report and accompanying literature after the Hearing.

In his supplemental report, filed after the March 2010 Hearing, Dr. Renfroe addressed timing specifically. P Ex 15, filed May 10, 2010. Dr. Renfroe discussed the idea of priming, where a person is exposed to an antigen once to elicit an immune response and a subsequent exposure to the same antigen “may result in a rapid, acute immune response.” P Ex 15 at 1. He stated the timing of a “pathologic response is poorly understood” and studies document evidence of a central nervous system response as early as 18 hours after exposure but “most studies do not attempt to document an immune response prior to 3-5 days.” *Id.* Ultimately, Dr. Renfroe opined based upon the supplied literature that “immune responses can and do occur quickly. However, **an immunologist is better qualified to delineate the factors which dictate why some patients fall outside the standard bell shaped curve in the onset of their immune disorder.**” *Id.* at 2. (emphasis added). Ultimately, this supplemental opinion failed to substantiate Dr. Renfroe’s hearing testimony that an autoimmune disorder caused by vaccination could present with clinical symptoms in less than 24 hours. The literature submitted with this supplemental report was rebutted by Dr. Sladky as noted in the next section. Dr. Renfroe did not exhibit an in-depth understanding of immunology, which he freely conceded. His testimony was not found to be persuasive.

**B. Dr. Sladky's Opinion**

Dr. Sladky is also a pediatric neurologist and board certified by the American Board of Pediatrics, the American Board of Psychiatry and Neurology with Special Competence in Child Neurology, and the American Board of Electrodiagnostic Medicine. R Ex A-1. He has two associate professor appointments with the University of Pennsylvania, School of Medicine, and two professor appointments at Emory University, School of Medicine, where he is also Chief of the Division of Pediatric Neurology. R Ex A-1. He is also the Director of the Neuromuscular Clinic at Children's Hospital of Philadelphia. Id. The vast majority of his patients are children. Hr'g Tr. at 88-89. Dr. Sladky is also a published author and describes his research interests as "[p]eripheral nerve, peripheral nerve disease, specifically Guillain-Barré disease." Id. at 89; R Ex A-1. Dr. Sladky was accepted as an expert in pediatric neurology without objection. Id. Dr. Sladky proved to be a very persuasive expert witness.

Dr. Sladky's opinion, as did the others, began with a review of [M.J.]'s history. Dr. Sladky acknowledges that at the time of [M.J.]'s initial hospitalization, his treating physicians appeared to attribute [M.J.]'s problems more likely to TM. R Ex A at 2. However, Dr. Sladky disagreed with Dr. Renfroe regarding the preservation of sensation eliminating the Chiari malformation as causative. Id. He stated that "some degree of sensory abnormality is anticipated in either scenario and is certainly not a *sine qua non* for a diagnosis of Chiari malformation." Id. at 3. Ultimately though, Dr. Sladky could not distinguish which potential injury [M.J.] sustained. Id.

Regardless of the underlying condition, Dr. Sladky agreed with the treating physician, Dr. Hsu, who specifically ruled out vaccine causation based on the onset of symptoms in mere hours after vaccination. R Ex A at 3. Based on evidence from the Institute of Medicine ("IOM"), Dr. Sladky opined an autoimmune demyelinating injury, such as TM, would manifest within five days at the earliest, assuming vaccines could even cause TM. Id. at 3-4; R Ex A-2, Institute of Medicine, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINE, EVIDENCE BEARING ON CAUSALITY, 45 (1994)("a conservative estimate of the limits of the latencies . . . is considered to be from 5 days to 6 weeks"). Dr. Sladky felt this estimation was broader than what occurs in reality. Id. at 4. Dr. Sladky considered onset of weakness and hypotonia to be the first symptoms of [M.J.]'s neurological problem. Id. Dr. Sladky also noted that in one third to one half of the cases of TM, no antecedent event or infection can be found. Id.

In his testimony during the March 2010 Hearing, Dr. Sladky confirmed that "an equally good case can be made for" either transverse myelitis or complication of the Chiari malformation. Hr'g Tr. at 90-92; Hr'g Tr. at 92-93. Dr. Sladky explained that, when reviewing medical records, he often relies on the most contemporaneous records and always trusts the pediatric resident. Hr'g Tr. at 92-93. In this case, the resident noted onset of weakness four hours after vaccination. Hr'g Tr. at 93. Dr. Sladky considered this time frame, four hours after vaccination, as onset of [M.J.]'s TM and noted this was too soon to be vaccine related. Id.

In discussing TM and the timing involved, Dr. Sladky referenced the experimental model used to investigate the disorder, experimental allergic encephalomyelitis ("EAE"). Hr'g Tr. at

107-10. With EAE, an anti-myelin autoimmune response is created in an animal model. Hr’g Tr. at 108. Regarding the normal time course in an unprimed animal, Dr. Sladky explained:

If you look at those studies, and there have been hundreds, animals are well until roughly 10 to 14 days [after exposure]. And then, they develop a fairly stereotypical illness. They get a flaccid ta[il]. They then get weak hind limbs. And in the more severe cases, they will get . . . four limb weakness, and can get generalized paralysis and die. But, animals don’t get symptoms within four hours or within six hours. . . . Now, there have been efforts to see what does it take to make EAE. . . . The quickest model . . . of EAE that I’ve seen occurs within about five days . . . . [m]y point is only, that do what you will, you can’t cause clinical symptoms in under about four to five days.

Hr’g Tr. at 109-10.<sup>9</sup> Dr. Sladky then described the numerous steps that must occur to cause TM in the human body following vaccination, assuming vaccinations can cause TM. Hr’g Tr. at 112-115. Dr. Sladky stressed that many steps the immune system is taking cannot be perceived; “It’s not until a part of the brain doesn’t work that we know that the brain has been attacked by the immune system.” Hr’g Tr. at 115. In Dr. Sladky’s opinion, there is no way the immune system could mount an attack on the central nervous system and show symptoms of TM within 24 hours. Hr’g Tr. at 115-16. The process of causing the type of damage seen in TM takes “thousands and thousands, millions of cells . . . working together to cause enough gross damage so that . . . a clinically identifiable lack of function, or alteration of function occurs.” Hr’g Tr. at 119. Even assuming a person is primed by previous immunizations, there remain many steps that must occur to have perceivable damage. Hr’g Tr. at 120-22.

During cross examination, Dr. Sladky agreed when petitioner’s counsel asked if the immune phenomenon of complement cascade can be activated faster than five days. Hr’g Tr. at 138. During redirect, respondent’s counsel asked if this faster activation affected Dr. Sladky’s opinion that TM symptoms could not occur within one day. Hr’g Tr. at 142-43. Dr. Sladky explained that it did not; “complement fixation is one of the later phenomenon in the immunological process. . . . So, the premonitory steps that we talked about earlier . . . all have to take place before that happens.” Hr’g Tr. at 143.

When questioned by the undersigned regarding an early symptom [M.J.] experienced, being unable or unwilling to bear weight, Dr. Renfroe noted that “just feeling bad, you know, doesn’t make you unable to bear weight . . . .” Hr’g Tr. at 146.

Following the Hearing and Dr. Renfroe’s supplemental report, Dr. Sladky filed a responsive supplemental report. R Ex B, filed Jun. 9, 2010. Dr. Sladky’s response reviewed the literature relied upon by Dr. Renfroe in his supplemental report regarding timing and, for the most part, noting the articles did not shed light upon the timing between exposure to an antigen and development of clinical symptoms of an autoimmune attack on the spinal cord. P Ex B at 1-3. “[I]t is difficult to appreciate that any of the articles cited in Dr. Renfroe’s report have direct bearing on the question of the timing of the interval between the initial immunological stimulus

<sup>9</sup> See Crosby, 2012 WL 2866464, \*21 (describing in-depth how one EAE model is manipulated to produce symptoms and the time frames in which symptoms occur).

and subsequent evolution of symptoms of transverse myelitis.” P Ex B at 3. “The exception to that statement may be the paper by Gordon, et al., which demonstrated that the onset of a second episode of EAE could be accelerated to begin just a week after the inciting stimulus but not nearly to with 24 hours of the antecedent event.” Id. Ultimately, Dr. Sladky stated, “[d]espite considerable efforts in scores of laboratories over decades, however, there are no reports of an interval from inciting stimulus to onset of neurological manifestations of EAE in less than about 5 days.” Id. at 4. “The exquisitely sensitive governance necessary to control this process requires an irreducible finite period of time. The contention, therefore, that an immune stimulus can elicit full blown symptoms of transverse myelitis within 24 hours is, in my view, untenable.” Id.

### C. Dr. Byers’ Opinion

In her expert report, Dr. Byers presents her opinion as “a supplement report to that of Dr. Renfroe.” P Ex 18 at 1. She states, “I have been asked to provide literature on the time between infection and/or vaccination and the onset of transverse myelitis, and to opine on the etiology of the paralysis in this child.” P Ex 18 at 4. Dr. Byers opined regarding the immunology portion of this case for petitioner.

Dr. Byers is board certified in Internal Medicine. P Ex 18 at 2. Her CV characterizes her as an “internist . . . [and] medical toxicologist,” with experience conducting “[b]asic and clinical research [on] cancer and tumor immunology, bone marrow transplantation, immunodermatology, allergy and autoimmune diseases, HIV disease, and pharmacotoxicology and immunotoxicology.” P Ex 17. She has a PhD in immunology. P Ex 17. Because of her withdrawal from this case, Dr. Byers experience and credentials were not further explored in this case. Notably, in the Crosby case, it was pointed out that Dr. Byers is not a neurologist and she relied upon Dr. Renfroe regarding the neurology information and opinions in Crosby. Crosby, 2012 WL 2866464, \*10.

Dr. Byers discusses the history of the case and the medical history involved, acknowledging the undersigned’s Order that questioned Dr. Renfroe on the appropriate medical timing given the theory offered. P Ex 18; Order, filed Dec. 21, 2010. Dr. Byers’ stated, “I have been asked to review . . . [evidence in this case] to form an opinion as to the length of time that elapsed between the set of vaccines given on October 10, 2005 and symptoms of [TM] which began in the child. The key symptom(s) of TM is paralysis.” P Ex 18 at 1. Essentially, Dr. Byers opined the changes seen in [M.J.] in the first 36 hour after vaccination were the result of his innate immune response to the vaccinations and not symptoms of the adaptive immune response causing [M.J.]’s TM. For this opinion, Dr. Byers relies upon: literature discussing the transient side effects seen following childhood vaccinations; characterizing the changes seen by the parents and pediatrician on October 11 in [M.J.]’s movement as a mere reluctance to move because he was generally not feeling well; her interpretation of the pediatrician’s note regarding the 36 hour progression to paralysis after vaccination as the TM symptoms beginning around 36 hours; and the normal MRI when [M.J.] was initially hospitalized in contrast to the subtle abnormality seen on an MRI nine days later. P Ex 18 at 4-7. Dr. Byers dismisses notes of flaccidity and the lack of spontaneous movement in [M.J.]’s legs. Her opinion regarding onset of [M.J.]’s symptoms appears to focus on a finding of paralysis, noting, “even the pediatrician . . .

who was called in when the child was hospitalized felt the symptoms of paralysis did not begin until about 36 hours after vaccination.” P Ex 18 at 4. Dr. Byers finds there was no evidence of paralysis in the exam performed the day after vaccination. Id. This reliance on the “36 hour” time frame appears to be a mischaracterization of Dr. Andringa’s note and is discussed below. Notably, the expert neurologists, including petitioner’s expert, Dr. Renfroe, placed the onset of TM symptoms well within a 24 hour period by relying on symptoms of fussiness, flaccidity and lack of spontaneous leg movement – not the 36 hour period Dr. Byers assumed.

Following this report, a supplemental report was requested from Dr. Byers to reconcile her opinion in this case that an onset of TM within 36 hours was appropriate when she had testified to the contrary in Crosby – that 96 hours, the time necessary for the adaptive immune system to produce onset of TM, was the minimum and “stretching the envelope.” Order, filed May 19, 2011; Crosby, 2012 WL 2866464, \*16. Specifically in Crosby, Dr. Byers agreed that “onset within 24 hours of vaccination would not support vaccine causation” in that case.” Crosby, 2012 WL 2866464, \*37 (citing Transcript of Hearing at 108, Crosby v. Sec’y of the Dept. of Health & Human Servs., No. 08-799V (May 10-11, 2011)). Although the first Status Report thereafter noted a date petitioner intended to file Dr. Byers’ supplemental report, P Status Report, filed May 31, 2011, petitioner filed a Motion for an Extension of Time on July 28, 2011, noting Dr. Byers could no longer serve as an expert in this case and requesting time to submit the report of another immunologist. As noted previously, petitioner informed the court during a Status Conference on August 9, 2011, that she would not seek another expert immunology report. Order, filed Aug. 9, 2011. In her briefs concerning her Motion for Summary Judgment, petitioner continues to rely upon Dr. Byers’ report over respondent’s stringent objections.

Given her withdrawal from this case, respondent and the undersigned had no opportunity to examine Dr. Byers regarding her opinions. The undersigned does not quibble with the portion of Dr. Byers’ report regarding nonspecific symptoms following vaccination – these symptoms, such as fussiness or mild fever, are usually transient, not serious, and not uncommonly seen in some children following vaccination – that are effects of the innate immune response. However, several problems stand out upon review of Dr. Byers’ report and the way in which she characterizes the specific facts in the case.

First, Dr. Byers discusses the fever [M.J.] had following his August 2005 vaccinations without acknowledging or discussing the treating physician’s note that the fever was likely due to a viral illness. P Ex 18 at 3; but see P Ex 4 at 186-87. Second, Dr. Byers omits the references to flaccidity on the day of vaccination by the treating physician and the day care, and again by the pediatrician on October 11, the morning following vaccination. P Ex 4 at 181-83. Third, the doctor somewhat mischaracterizes the symptoms seen in the emergency room on October 11 as [M.J.] being “reluctant to stand, and moaned with movement.” The record actually notes “decreased muscle tone . . . won’t support [weight] on legs, decreased movement of head” and the ER recording to the possibility of Guillain-Barré Syndrome and a recommended neurology consult. P Ex 18 at 3; but see P Ex 3 at 155. Even prior to the submission of Dr. Byers’ report, Dr. Sladky testified that the description of events on October 11 and 12 were more than merely a child feeling ill. Hr’g Tr. at 146. Fourth, although Dr. Byers correctly quotes the pediatrician as noting a “36 hour history of going from absolutely normal . . . to a very flaccid individual,” she appears to misconstrue the pediatrician’s discussion, stating the pediatrician did not feel

symptoms of paralysis began until 36 hours after vaccination. P Ex 18 at 4; but see P Ex 3 at 77-79. Further on this point, Dr. Byers did not acknowledge the admission note that discussed weakness seen on exam on October 11 and how that had progressed to no resistance the next day or the report of losing urinary control. P Ex 3 at 78, 80. Fifth, Dr. Byers characterizes the symptoms [M.J.] suffered following prior vaccinations as “the same reaction” as the symptoms [M.J.] suffered after the vaccinations in questions here given on October 10, 2005. P Ex 18 at 4. The records show [M.J.] had a rash reported by the mother and was fussy and febrile following the August 2005 vaccinations. P Ex 4 at 185-87. On the visit to the pediatrician after the October 2005 vaccinations, [M.J.] was indeed fussy but he was afebrile, no rash was noted, he was not moving his legs since the previous day and the pediatrician noted some flaccidity in his extremities. P Ex 4 at 181-83. The two episodes do not appear similar except for [M.J.]’s fussiness. Finally, Dr. Byers lists numerous instances of nonspecific responses to vaccinations, including fever which is repeatedly referenced, but fails again to acknowledge [M.J.] was afebrile when the observations of flaccidity and decreased movement were made. P Ex 18 at 5.

Additionally, Dr. Byers’ opinion does not acknowledge testimony given by petitioner’s own expert neurologist, Dr. Renfroe. Dr. Byers characterized the first MRI performed as being normal. Dr. Renfroe testified that changes were seen in the initial MRI and the follow-up MRI several days later that “showed a diffuse inflammatory process within the spine.” Hr’g Tr. at 12-13. The initial MRI was performed at approximately 1:33 pm on October 12, 2005, within about 48 hours of vaccination. P Ex 3 at 105. Although this MRI was initially read as normal, P Ex 3 at 155, the treating neurologist noted “questionable fullness” in the spinal cord and evidence of the Chiari malformation. P Ex 3 at 73, 83. Regarding this MRI, the doctor noted “there is concern over cervical spinal cord lesion, which might explain his lower greater than upper extremity weakness and hypotonia . . . .” Id. Dr. Byers’ opinion ignored this evidence that the initial MRI on October 12 was re-read to show signs of inflammation, which was relied upon by treating doctors and Dr. Renfroe, and only acknowledged the abnormal MRI on October 19, 2005. P Ex 18 at 5. Dr. Byers also omitted reference to the lumbar puncture, which was performed on October 13 and relied upon by Dr. Renfroe to show inflammatory process in the cerebral spinal fluid. P Ex 18; Hr’g Tr. at 13-14; Hr’g Tr. at 80. Again, the undersigned notes that Dr. Byers is not a neurologist and in Crosby specifically deferred to Dr. Renfroe regarding the neurological evidence. Dr. Byers ventured far outside her stated expertise in the report filed herein.

Finally, and most importantly, Dr. Byers’ initial opinion in this case supported vaccine causation for an onset that was 36 hours after vaccination. This was in conflict with testimony Dr. Byers gave in Crosby. When ordered to reconcile this information, Dr. Byers failed to do so. Based upon these problems, the undersigned does not find Dr. Byers’ report persuasive or reliable when considering the body of evidence as a whole and accordingly gave virtually no weight to her opinion.

### **PROCEDURAL HISTORY AND PROCEDURAL ISSUES**

On September 25, 2008, petitioner filed a Petition pursuant to the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§ 300aa-10 et seq. (2006)<sup>10</sup> (“Act” or “Program”). The Petition seeks compensation for neurological injuries sustained by petitioner’s minor child allegedly due to his immunizations received on October 10, 2005. Pet. at ¶ 1. The original Petition did not describe the injuries the child suffered. On December 1, 2008, petitioner filed medical records and her Amended Petition for Vaccine Compensation (“Petition” or “Pet. at ”).<sup>11</sup> Notice of Filing on Compact Disc, Dec. 8, 2012. Respondent filed her Rule 4(c) Report on January 30, 2009 (“R4 at ”). Respondent’s Rule 4(c) Report recommended against vaccine compensation and, among other disputed issues, challenged whether petitioner met the Althen<sup>12</sup> prongs by preponderant evidence. R4 at 9-10. Respondent also noted a potential alternative cause to the child’s injury, the Chiari malformation, and the fact that several medical records discussed symptoms being present at and slightly before immunization. R4 at 10. Petitioner subsequently filed an expert report neurologist Dr. J. Ben Renfroe. P Exhibit (“P Ex ”) 12. Respondent filed a competing expert report from neurologist Dr. John Sladky. R Ex A.

A Hearing was held on March 19, 2010, wherein testimony from these neurologists was taken. At Hearing and following the testimony of Dr. Renfroe, respondent moved to dismiss the Petitioner based on the inability of Dr. Renfroe to provide preponderant evidence regarding the medical-appropriateness of the onset timing in this case. Transcript of March 19, 2010 Hearing (“Hr’g Tr. ”) at 86-87. The undersigned acknowledged the reasonableness of respondent’s motion to dismiss but chose to continue with the testimony of Dr. Sladky. Hr’g Tr. at 87. After recalling Dr. Renfroe, petitioner elicited testimony from him that literature existed that would substantiate the short time period, less than one day, until onset of the child’s TM. Hr’g Tr. 152-65.

Respondent renewed the motion to dismiss on the record following testimony from Dr. Sladky; for the motion, respondent noted the issues of onset and appropriate timing, as well as the potential alternate cause to the child’s injury. Hr’g Tr. at 167. Petitioner noted the standard for a motion to dismiss and pointed out that expert testimony, diagnostics and treating physicians supported petitioner’s allegation that the child suffered from TM. Hr’g Tr. at 168-69. Petitioner also noted literature her expert neurologist discussed that shows immune reactions have the potential for occurring rather quickly. Id. After a brief discussion, the undersigned noted agreement with petitioner regarding the likelihood of success on a motion to dismiss regarding the potential alternative cause. However, the undersigned issued a stern warning to petitioner regarding the sufficiency of her evidence relating to Althen prong III, the medically appropriate timing for the alleged injury. Hr’g Tr. at 170-72. The undersigned noted that review of Dr. Renfroe’s testimony would show contradictory statements regarding the medically appropriate timing, which would ultimately detract from the persuasiveness of this evidence. Hr’g Tr. at

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<sup>10</sup> This Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (2006). Hereafter, individual section references will be to 42 U.S.C. §§ 300aa of the Act.

<sup>11</sup> References herein to the “Petition” will refer to petitioner’s Amended Petition for Vaccine Compensation, filed on December 1, 2008.

<sup>12</sup> Althen v. Sec’y of the Dept. of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

170-72. Also, based upon Dr. Renfroe's repeated assertion that he is not qualified to interpret the immunologic evidence, the undersigned cautioned petitioner that unreasonable efforts to have her expert opine in areas he was not qualified in would not be compensated. Hr'g Tr. at 170-72. Respondent further objected to allowing petitioner to submit evidence that was not in the record at the time of the Hearing. Hr'g Tr. at 172-73.

Following the Hearing, an Order issued allowing petitioner to file additional medical literature in support of her position that the timing for the injury was medically-appropriate. Order, filed Mar. 25, 2010. On May 10, 2010, petitioner filed a supplemental report from Dr. Renfroe and medical literature. P Ex 15, filed May 10, 2010; P Exs 15(A-F), filed May 10, 2010. The supplemental report did not provide support for onset of TM within four to five hours after immunization, as was required of petitioner. P Ex 15; Order, filed Mar. 25, 2010 ("The undersigned is allowing petitioner an opportunity to supplement the record with the medical literature referenced at the Hearing, along with a supplemental report from Dr. Renfroe, explaining how the literature supports an onset of an immunological response within three to four hours after immunization, consistent with the opinions and testimony he has already given.").

On June 9, 2010, respondent filed a Renewed Motion to Dismiss and a supplemental response from Dr. Sladky. R Notice of Filing and Renewed Motion to Dismiss, filed Jun. 9, 2010; R Ex B, filed Jun. 9, 2010. Respondent characterized petitioner's supplemental expert report as speculative and pointed out the fact that the newly-submitted literature failed to support such a brief time to onset "no matter how much the immune system is manipulated to guarantee a resultant autoimmune disease." R Renewed Motion to Dismiss at 2. Dr. Sladky's supplemental report discussed the literature submitted by petitioner and how the articles were irrelevant or failed to support petitioner's position that the timing in her case is appropriate for vaccine causation. R Ex B.

A status conference was held on June 22, 2010, wherein petitioner requested the opportunity to file a response to respondent's Motion to Dismiss and an expert immunology report to address the third prong of Althen. Order, filed Jun. 22, 2010. Respondent objected to the filing of an immunology report. Id. Petitioner then filed a response to respondent's Motion to Dismiss, as well as a Motion to Submit the Expert Report of an Immunologist. P Oppositions to the Respondent's Renewed Motion to Dismiss and Motion to Submit the Expert Report of an Immunologist, filed Jul. 22, 2010 ("While he does not believe this evidence is necessary to his *prima facie* case, to expedite resolution of his case, [M.J.] respectfully requests permission to submit the medical expert report of an immunologist."). Respondent filed a response on August 6, 2010, and petitioner replied on August 13, 2010. R Response to Petitioner's Motion to Submit the Expert Report of an Immunologist and Reply to Petitioner's Opposition to Respondent's Renewed Motion to Dismiss, filed Aug. 6, 2010; P Reply to the Respondent's Response to Petitioner's Motion to Submit the Expert Report of an Immunologist, filed Aug. 13, 2010.

On December 21, 2010, the undersigned issued an Order denying the Motion to Dismiss and allowing the petitioner an opportunity to file an immunologist's report. Order, filed Dec. 21, 2010. The Order denied respondent's Renewed Motion to Dismiss in order to allow petitioner the "second chance" to support the timing portion of her case.

[T]he question that remains unanswered is whether the child would have manifested neurological symptoms within three to four hours of the vaccination when examined under petitioner's theory of causation. Contrary to petitioner's legal posturing, the undersigned is not requiring scientific certainty, but is requiring reliable support for a medically appropriate time frame for petitioner's theory. See, e.g., de Bazan, 539 F.3d 1347; Althen, 418 F.3d 1274. To date, petitioner has presented speculation from an expert who has repeatedly stated that he is unqualified to discuss the matter.

Order at 5, filed Dec. 21, 2010.

Petitioner filed the expert report of Dr. Vera Byers on March 21, 2011. P Ex 16, Unsigned Report of Dr. Byers, filed Mar. 21, 2011. The signed report of Dr. Byers and accompanying medical literature was filed on March 28, 2011. P Ex 18, filed Mar. 28, 2011; P Exs 18(A-T), filed Mar. 28, 2011. Similar to the Crosby case, Dr. Byers took the position that the symptoms the child suffered in the first 36 hours after vaccination were caused by his innate immune response and not his adaptive immune response responsible for his TM. P Ex 18 at 4; Crosby, 2012 WL 2866464, \*8-10. This was contrary to the testimony given by petitioner's other expert, Dr. Renfroe, a neurologist. Dr. Byers actually opines that "neurological abnormalities" were recognized 36 hours after vaccination; this is presumably the point at which Dr. Byers places onset of the child's TM symptoms. P Ex 18 at 6. Dr. Byers bases this on a medical record wherein a treating physician states, "[t]here is no doubt that there is a 36 hour history of going from absolutely normal motor skill to a very flaccid individual . . . ." P Ex 18 at 5 (citing P Ex 3, 77-79).

A status conference was held after petitioner filed Dr. Byers' report wherein it was noted that Dr. Byers testified in the Crosby case that the minimal amount of time necessary for a vaccination to cause an autoimmune response was 96 hours; this was in contrast to her opinion in this case that 36 hours was sufficient time. Crosby, 2012 WL 2866464, \*16; Order, filed May 19, 2011. Thus, an Order was issued stating, "[u]ltimately, reconciliation and/or explication of the differences between Dr. Byers' opinion in this case and her testimony in the similar case regarding an appropriate time to onset of TM is required . . . ." Order at 2, filed May 19, 2010. Petitioner filed a Motion for Extension of Time on July 18, 2011, noting that "Dr. Byers has informed petitioner's counsel that she is no longer able to serve as a medical expert in this case" and requesting time to retain another immunologist. P Motion for Extension of Time, filed Jul. 18, 2011. No reasoning was given for Dr. Byers' withdrawal from the case. Respondent filed her objection to the Motion on July 22, 2011, and again requested the case be dismissed. R Response to Motion for Extension of Time, filed Jul. 22, 2010.

During a status conference on August 9, 2011, "[p]etitioner reported that a report from another immunologist will not be sought and requested thirty days to inform the court of how petitioner intends to proceed." Order, filed Aug. 9, 2011. Petitioner filed a Motion for Summary Judgment on September 22, 2011, requesting "a ruling on the existing record" regarding entitlement to compensation. P Motion for Summary Judgment ("P MSJ"), filed Sep. 22, 2011. Petitioner's Motion for Summary Judgment relied upon Dr. Byers' opinions despite the fact that

Dr. Byers could no longer serve as a medical expert “due to personal reasons.” P MSJ at 22, 30-33. Petitioner also incorporated portions of testimony from the Crosby case in support of entitlement in this case. P MSJ at 34-35.

Respondent filed her Objection to Petitioner’s Motion for Summary Judgment and Motion to Strike the Deficient Report of Vera Byers, M.D., on October 21, 2011. R Objection to Petitioner’s Motion for Summary Judgment and Motion to Strike the Deficient Report of Vera Byers, M.D. (“R Objection to MSJ”), on Oct. 21, 2011. Due to the fact that “Dr. Byers has made herself unavailable to remedy the deficiencies in her report or for cross-examination, petitioner should not be allowed to rely on Dr. Byers’ report and accompanying references . . . .” R Objection to MSJ at 20. Respondent requested striking Dr. Byers’ report or alternatively being able to rely upon respondent’s expert immunologist in the similar case. R Objection to MSJ at 20. Respondent notes that reliance upon her immunology expert in the similar case is only a partial remedy since Dr. Byers made additional assertions in this case. R Objection to MSJ at 20.

Lastly, petitioner filed her Reply to the Respondent’s Objection to Petitioner’s Motion for Summary Judgment and Motion to Strike the Report of Dr. Vera Byers on November 4, 2011. P Reply to the Respondent’s Objection to Petitioner’s Motion for Summary Judgment and Motion to Strike the Report of Dr. Vera Byers (“P Reply”), filed November 4, 2011.

#### **A. Petitioner’s Motion for Summary Judgment**

Petitioner styled her Motion as a “Motion for Summary Judgment” but further characterized it as petitioner moving “for a ruling on the existing record that he is entitled to compensation.” P MSJ at 1-2. Petitioner’s Motion does not address the standards for a Motion for Summary Judgment but rather reads as a post-Hearing brief discussing petitioner’s position on the causation issues herein. Respondent’s Response does discuss the standard for a Motion for Summary Judgment and her position that such a procedure is not appropriate. R Objection to P MSJ at 4-6. Respondent’s Response also counters petitioner’s position regarding causation. Id. at 11-21. Specifically, respondent points to four issues that require weighing of evidence and foreclose the appropriateness of a motion for summary judgment. Id. at 5-6 (noting conflict regarding the actual onset of [M.J.]’s injury, the diagnosis of [M.J.]’s injury, and petitioner’s evidence as it regards the causation elements of Althen).

Regarding the issues respondent finds to be inappropriate, respondent first notes that there is evidence that [M.J.] suffered the onset of his neurological injury prior to receiving vaccinations on October 10. R Objection to P MSJ at 5. Regarding this, the pediatrician noted that daycare personnel observed [M.J.] as being “a little bit flaccid” just prior to vaccination and the pediatrician’s own exam on October 10 showed [M.J.] to be somewhat flaccid in hindsight on the day vaccines were given, according to his exam note on October 12. P Ex 4 at 177 (“In hindsight, I said he was a little bit floppy, but that was all.”).

Respondent also notes the complication of [M.J.]’s Chiari malformation as a possible alternative explanation for the symptoms. Petitioner fails to address the role of the Chiari malformation in her Motion for Summary Judgment or her Reply filed on November 4, 2011. Reviewing the record, there is tension between the treating physicians’ opinions on whether the Chiari malformation played a role in [M.J.]’s injury. As noted previously, respondent’s expert

neurologist opined a good case could be made for either diagnosis, TM or a symptomatic Chiari malformation. This does not appear to be a clear cut issue in this record.

Respondent's third and fourth issues deal with petitioner's evidence under the causation standards set forth in Althen. R Objection to P MSJ at 5-6. Respondent argues petitioner has failed to: evidence [M.J.]'s vaccines "can cause" the alleged injury; show [M.J.]'s vaccines actually "did cause" the alleged injury; and demonstrate onset within 24 hours was medically appropriate for vaccine causation.

Petitioner's Reply argues that these points are not material facts but it is "the interpretation and significance of those facts" that are at issue. P Reply at 3.

The Court of Federal Claims Rule 56 states:

A party may move for summary judgment, identifying each claim or defense – or the part of each claim or defense – on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.

RCFC 56(a) (2011). Determination of whether a genuine issue of material fact exists is to be made by considering "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." DIRECTV Group, Inc. v. U.S., 670 F.3d 1370 (Fed. Cir. 2012)(quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986)). "Summary judgment is appropriate when, drawing all justifiable inferences in the non-movant's favor, there exists no genuine issue of material fact and the movant is entitled to judgment as a matter of law." Toshiba Corp. v. Imation Corp., 681 F.3d 1358, 1361 (Fed. Cir. 2012)(citing Fed.R.Civ.P. 56; Anderson v. Liberty Lobby, Inc., 477 U.S. at 255). "A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Toshiba Corp., 681 F.3d at 1361 (citing Anderson, 477 U.S. at 248). Therefore, the undersigned should grant petitioner's Motion for Summary Judgment only if it is established there is no genuine issue of material fact relating to vaccine-causation of [M.J.]'s alleged injury.

The undersigned reviewed all of the evidence and the arguments the parties have offered to date, including testimony regarding timing from the Crosby case, and agrees with respondent that petitioner's Motion for Summary Judgment is not appropriate. As is easily seen from the documentary evidence and expert testimony, there is a great deal of contention and competing evidence regarding most, if not all, of petitioner's case. Viewing the evidence with inferences drawn in respondent's favor, petitioner's Motion for Summary Judgment fails.

Following the withdrawal of Dr. Byers and prior to her Motion for Summary Judgment, petitioner requested time to retain another immunologist and file this immunologist's expert report. P Motion for an Extension of Time, filed July 18, 2011. Respondent objected. During a subsequent status conference, petitioner informed the court that she would not seek another expert immunology opinion and was granted time to determine how to proceed. Petitioner's Motion for Summary Judgment was the culmination of that time.

The undersigned notes that petitioner's claim has survived multiple reasonable Motions to Dismiss, surviving only because the undersigned was inclined to grant petitioner time to substantiate the significant deficiency in her case: appropriate timing of onset. Cite Hr'g Tr. at 86-87, 167-73; R Motion to Dismiss, filed Jun. 9, 2010; Order Denying Motion to Dismiss, filed Dec. 21, 2010. Petitioner's Motion for Summary Judgment requested a ruling regarding causation. And in light of petitioner's intention to not seek another immunology opinion and the copious evidence and briefing already presented, the undersigned finds a ruling on causation appropriate at this time. **Petitioner's Motion for Summary Judgment is denied and a ruling on the record follows the discussion of respondent's Motion to Strike.**

## **B. Respondent's Motion to Strike the Report of Dr. Vera Byers**

Due to the fact that Dr. Byers withdrew from the case for unspecified reasons, respondent moved to strike Dr. Byers' report. R Objection to P MSJ at 20-21. Dr. Byers' testimony was sought to contend with the timing of onset of the alleged injury. See Order, filed Dec. 21, 2010. Although the ultimate benefit to petitioner's case is dubious at best, the undersigned errs on the side of inclusivity and will allow petitioner retain the opinion and accompanying literature from Dr. Byers. **Respondent's Motion to Strike the Deficient Report of Vera Byers, M.D. is denied.**<sup>13</sup>

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<sup>13</sup> Considering the undersigned is allowing Dr. Byers report to remain in the record, the question arises of how to utilize the medical literature submitted with her report. Reviewing these articles, P Exs 18 A-T, the undersigned observes that several are of questionable use in this case. Many references describe general information not necessarily relevant to the specific controversy in this case. See P Ex 18-T, Lisa J. Wood, et al., The Cancer Chemotherapy Drug Etoposide (VP-16) Induces Proinflammatory Cytokine Production and Sickness Behavior-like Symptoms in a Mouse Model of Cancer Chemotherapy-Related Symptoms, 8-2 BIOLOGICAL RESEARCH FOR NURSING 157 (2006)(discussing chemotherapy-related side effects and whether a particular chemotherapy drug can induce inflammatory cytokine production in mice); P Ex 18-E, Jens Gaab, et al., Stress-induced changes in LPS-induced pro-inflammatory cytokine production in chronic fatigue syndrome, 30 PSYCHONEUROENDOCRINOLOGY 188 (2005)(evaluating the "production of pro-inflammatory cytokines before and after a standardized psychosocial stress test in [chronic fatigue syndrome] patients and healthy controls . . . ."); P Ex 18-B, M.R. Amel Kashipaz, et al., Normal production of inflammatory cytokines in chronic fatigue and fibromyalgia syndromes determined by INTRACELLULAR cytokine staining in short-term cultured blood mononuclear cells, 132 CLIN EXP IMMUNOL 360 (2003)(employing "intracellular cytokine staining and flow cytometric analysis to facilitate the detection of cytokine production" in analyzing patients with chronic fatigue syndrome and fibromyalgia syndrome); P Ex 18-F, Göran K. Hansson, et al., Innate and Adaptive Immunity in the Pathogenesis of Atherosclerosis, 91(4) CIRCULATION RESEARCH 281 (2002)(discussing the innate and adaptive immune responses as they pertain to the development of atherosclerosis); P Ex 18-R, Annamaria Vezzani, PhD, and Tallie Z. Baram, MD, PhD, New Roles for Interleukin-1 Beta in the Mechanisms of Epilepsy, 7(2) EPILEPSY CURRENTS 45 (2007)(examining the role of IL-1  $\beta$  in epileptogenesis in mature and developing rodent brain); P Ex 18-C, Ruth M. Barrientos, et al., Time course of hippocampal IL-1  $\beta$  and memor consolidation impairments in aging rats following peripheral infection, 23 BRAIN, BEHAVIOR, AND IMMUNITY 45 (2009)(examining "whether the effects of aging on *E. coli*-induced increases in IL-1  $\beta$  and memory impairments could be explained by decreased clearance of *E. coli*"); P Ex 18-N, INFLAMMATORY BOWEL DISEASE: FROM BENCH TO BEDSIDE, 235 (2d ed. 2003)(discussing systemic response seen with ulcerative colitis or Crohn's disease and the associated cytokines). A few of the articles do not support petitioner's arguments regarding the appropriate timing, which was a major challenge to petitioner's case and why Dr. Byers' opinion was obtained. See P Ex 18-J, Min Young Kim, MD, and Eun Sook Suk, MD, A case of acute transverse myelitis following chickenpox, 52-3 KOREAN JOURNAL OF PEDIATRICS 380 (2009)(discussing onset of TM 18 days after suffering chickenpox); P Ex 18-D, D F D'Costa, et al., Transverse myelitis following cholera, typhoid and polio vaccination, 83 JOURNAL OF THE ROYAL SOCIETY OF MEDICINE 653 (1990)(reporting TM following the typhoid, cholera and oral polio vaccinations, with onset of neurological symptoms 36 hours after vaccination and after the

Regarding Dr. Byers' testimony in Crosby, respondent's view is that petitioner is misconstruing Dr. Byers' testimony. In her Motion for Summary Judgment, petitioner notes that Dr. Byers testified that at least four days was required to produce an **adaptive immune response** in an individual who was primed by prior vaccination, which was in generally in agreement with respondent's expert neurologist and immunologist in Crosby. P MSJ at 34-35; see also Transcript of Hearing at 87-88, Crosby v. Sec'y of the Dept. of Health & Human Servs., No. 08-799V (May 10-11, 2011)("Q: Is four days, in your opinion an appropriate timeframe for an adaptive immune response to have developed in this child? A: It is stretching the envelope but yes it is still consistent with the development of an adaptive immune response."). The undersigned notes that four days was the time Dr. Byers agreed an **adaptive immune response** would develop but this testimony did not differentiate between the immune response and the presentation of symptoms from that immune response. Also in petitioner's Motion for Summary Judgment, petitioner cites Dr. Byers' testimony that "given the appropriate 'clinical circumstances,' an individual could manifest an adaptive immune response in shorter than four (4) days." P MSJ at 35. However, in Crosby, Dr. Byers did not specify what these "appropriate clinical circumstances" would be but noted they were not present in the Crosby child. Petitioner, citing Dr. Byers' report, avers [M.J.] is a child with such "appropriate clinical circumstances" to develop "**symptoms** of TM in shorter than four (4) days." Beyond unsupported supposition regarding [M.J.]'s Chiari malformation, about which Dr. Byers was not qualified to testify, the undersigned does not find in Dr. Byers' opinion what appropriate "clinical circumstances" affected [M.J.] to make onset within 36 hours after vaccination medically appropriate. Dr. Byers did not address the appropriate "clinical circumstances" in her report and, due to her withdrawal from the case, did not testify to the same. It is thus unknown what the appropriate "clinical circumstances" are and whether they would reliably abbreviate the four day period to onset that Dr. Byers characterizes as already "pushing the envelope." What the court is left with are lawyers' arguments, which are not proof.

Because she finds petitioner to be mischaracterizing this testimony from Crosby, respondent requested to be able to rely on the expert testimony of her immunologist in the Crosby case, Dr. Rose. The undersigned, in fact, reviewed the general information about the adaptive immune response and its timing, information learned from both Dr. Byers and Dr. Rose in Crosby, in deciding this case. Specific case-specific conclusions, however, cannot be applied to [M.J.]'s case since Dr. Rose's testimony was not taken regarding [M.J.]'s case. Regarding testimony on timing, the only conflict with the background scientific information between Dr. Byers' testimony in the Crosby case and her opinion herein was that she opined here that onset

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patient was suffering an upper respiratory infection and pharyngitis for five weeks prior and a fever on the day of vaccination). One article notes onset of TM following vaccinations by days or years, is a review of case reports, and does not investigate causation or other potential causes; particularly, the article is not specific about whether the measured time frame pertains to the first symptoms of TM or the diagnosis of TM. P Ex 18-A, N. Agmon-Levin, et al., Transverse myelitis and vaccines: a multi-analysis, 18 LUPUS 1198 (2009)(noting TM following vaccination in 37 cases, with onset ranging from two days after vaccination – in two cases with rabies, cholera, typhoid and/or oral polio vaccinations – to nine years – in one case after vaccination with the oral polio vaccination). After review of these articles of medical literature, the undersigned finds nothing in them that supports the idea that clinical symptoms of an adaptive immune response attacking one's own tissue could manifest with clinical symptoms within 24 hours. As such, these articles are unpersuasive or irrelevant. In the final analysis, the undersigned did not find Dr. Byers involvement in this case particularly helpful.

of symptoms within 36 hours of vaccination would be appropriate for vaccine causation whereas she stated onset of an adaptive immune response in less than 96 hours would be “pushing the envelope” in the Crosby case and required certain, unidentified “clinical circumstances.”<sup>14</sup> Moreover, Dr. Byers never stated what the “appropriate clinical circumstances” hypothesized in Crosby might be and did not identify these in this case regarding [M.J.]’s clinical circumstances.

As respondent finds that petitioner is misconstruing the above-discussed portion Dr. Byers’ testimony from Crosby, she requests admission of the Crosby Hearing Transcript if the undersigned does not strike the expert report of Dr. Byers. Petitioner does not object to the inclusion of the Transcript from Crosby. P Reply at 3-4. This is not an unreasonable request. **However, in light of the thorough recitation of expert evidence in the Decision in Crosby, filed on June 20, 2012, the undersigned does not find admission of the transcript necessary.** The relevant portions are reviewed here.

The portion of Dr. Byers’ testimony in Crosby cited by petitioner *sub judice* was offered while Dr. Byers was being cross-examined by respondent’s counsel and is as follows.

Q: And so, correct me if I’m wrong, but this is a sentence that I believe you are giving testimony on. And that sentence was, talking about the adaptive immune response, “it can be hastened if the host has previously encountered the same agent, i.e. been primed, but initiation of the adaptive immune system still requires at least 96 hours.” Now, in that context wasn’t it your testimony that that is pushing the envelope?

...

A: Yes. It is – if it was any earlier than that I think you would have to very carefully look at the clinical circumstances before you could make an opinion that anything earlier than four days was appropriate.

Transcript of Hearing at 106-07, Crosby v. Sec’y of the Dept. of Health & Human Servs., No. 08-799V (May 10-11, 2011). Dr. Byers had characterized onset of TM within four days of vaccination as “stretching the envelope” earlier in her Crosby testimony. Crosby, 2012 WL 2866464, \*16; Transcript of Hearing at 87-88, Crosby v. Sec’y of the Dept. of Health & Human Servs., No. 08-799V (May 10-11, 2011). It bears repeating that Dr. Byers did **not** specify what “clinical circumstances” would have to be present to have onset in less than four days during her testimony in Crosby, only that those circumstances were not present in the Crosby child. Dr. Byers has also not specified what those circumstances would be for [M.J.] in this case.

As in Crosby, the undersigned recalls another demyelinating-type case in which Dr. Byers testified before the undersigned that five days after vaccination was “a little bit too soon for a T-cell response to come up and actually start producing damage” even though the petitioner had received the same vaccine in the past and was presumably primed. Rego v. Sec’y of the

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<sup>14</sup> The undersigned notes that Dr. Rose **did not** give the opinion that onset of clinical symptoms at 96 hours after vaccination was medically appropriate to find a causal relationship. Dr. Rose’s opinion was that 96 hours was the minimum time necessary to develop an adaptive immune response and that it would take several days thereafter for clinical symptoms to arise. In her Crosby testimony, Dr. Byers was unclear and at times appeared to accept that onset of symptoms after 96 hours was appropriate.

Dept. of Health & Human Servs., No. 04-1734, 2008 WL 1990844 (Fed. Cl. Spec. Mstr. 2008). But again, Dr. Byers testified that onset within 24 hours of vaccination was not plausible.

Dr. Rose in the Crosby case, on the other hand, was resolute that initiation of the adaptive immune response, even in a primed individual, would take four days and manifestation of clinical symptoms would not happen for a time after that response had developed. “The clinical manifestation of the autoimmune response, the ‘visible’ signs and symptoms, **‘can be a few days, 4, 5, or 6 days after the autoimmune response is evident.’**” Crosby, 2012 WL 2866464, \*20 (quoting Transcript of Hearing at 186, Crosby v. Sec’y of the Dept. of Health & Human Servs., No. 08-799V (May 10-11, 2011))(emphasis in the Crosby Decision); see also Contreras v. Sec’y of the Dept. of Health & Human Servs., No. 05-626V, 2012 WL 1441315, \*8-24 (Fed. Cl. Spec. Mstr. Apr. 2012)(discussing generally the time necessary for an adaptive immune response to arise and cause damage, such as the symptoms of TM), appeal docketed, No. 05-626V (Fed. Cl. May 4, 2012). This notion is consistent with the testimony of other experts the undersigned has heard from in this program, including Dr. Byers herself in the Rego case.

This inquiry is moot though. With a finding that [M.J.]’s symptoms of TM started well within 24 hours of vaccination, these appropriate “clinical circumstances” become irrelevant given that Dr. Byers agreed “that onset within 24 hours of vaccination would not support vaccine causation . . . .” Crosby, 2012 WL 2866464, \*37 (citing Transcript of Hearing at 108, Crosby v. Sec’y of the Dept. of Health & Human Servs., No. 08-799V (May 10-11, 2011)).

## **DISCUSSION REGARDING CAUSATION**

### **Legal Standard for Causation**

In Vaccine Act cases, causation can be established either through the statutorily prescribed presumption of causation or by proving causation in-fact. For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions, which create a rebuttable presumption that the vaccine caused the injury or condition if they are found to occur within a prescribed time period. §14(a); 42 C.F.R. § 100.3. This case present a cause-in-fact or so-called “off-Table” case.

According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.<sup>15</sup> To demonstrate entitlement to compensation in a causation in-fact case, petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused or significantly aggravated the injury alleged. See, e.g., Grant v. Sec’y of Dept. of Health & Human Servs., 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992); Bunting v. Sec’y of Dept. of Health & Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Sec’y of Dept. of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); see also §§11(c)(1)(C)(ii)(I) and (II). To prevail, petitioner must produce “preponderant evidence both

<sup>15</sup> A preponderance of the evidence standard requires a trier of fact to “believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact’s existence.” In re Winship, 397 U.S. 358, 371-72 (1970)(Harlan, J. concurring)(quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

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 Health and Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing Shyface v. Sec’y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999)). The vaccination “must be a ‘substantial factor’” in bringing about the injury, but “it need not be the sole factor or even the predominant factor.” Id. at 1357 (quoting Shyface, 165 F.3d at 1352-53).

In Althen v. Sec’y of Dept. of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit explained that petitioner’s burden is to produce “preponderant evidence” demonstrating: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury.”

The evidence relating to these three prongs “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford, 451 F.3d at 1355. Petitioner must provide a “reputable medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” Moberly v. Sec’y of Dept. of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2005); Broekelschen v. Sec’y of the Dept. of Health & Human Servs., 618 F.3d 1339, 1350 (Fed. Cir. 2010), reh’g en banc denied (Dec. 8, 2010). Petitioners do not satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating “inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation”)); Hodges v. Sec’y of the Dept. of Health & Human Servs., 9 F.3d 958, 960 (Fed. Cir. 1993). Also, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

Petitioners must support their proposed causation theory with a “sound and reliable medical or scientific explanation.” Knudsen v. Sec’y of the Dept. of Health & Human Servs., 35 F. 3d 543, 548 (Fed. Cir. 1994).<sup>16</sup> As the Federal Circuit reiterated:

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<sup>16</sup> The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Sec’y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). See also Cedillo v. Sec’y of Dept. of Health & Human Servs., 617 F.3d 1328, 1338-39 (Fed. Cir. 2010)(approving the use of the Daubert factors in examining the reliability of expert testimony); Moberly v. Sec’y of Dept. of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010)(citing Daubert; approving of the use of the Daubert factors in determining expert reliability). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert’s opinion. Id. In other words, the “testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.” Id. Factors relevant to that determination may include, but are not limited to:

Although Althen and Capizzano make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. See Daubert, 509 U.S. at 593-97, 113 S.Ct. 2786 (noting that one factor in assessing the reliability of expert testimony is whether the theory espoused enjoys general acceptance within a relevant scientific community). . . . Althen makes clear that a claimant's theory of causation must be supported by a "reputable medical or scientific explanation." 418 F.3d at 1278.

Andreu v. Sec'y of Dept. of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); see also Grant, 956 F.2d at 1148 ("A reputable or scientific explanation must support this logical sequence of cause and effect."). The Federal Circuit further explained in Andreu:

The assessment of whether a proffered theory of causation is "reputable" can involve assessment of the relevant scientific data. Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard . . .

Andreu, 569 F.3d at 1380 (citing Bunting, 931 F.2d 867, 873 (Fed. Cir. 1991)). Proving causation in-fact by proving the Althen standards requires preponderant proof of each of the three prongs. de Bazan v. Sec'y of the Dept. of Health & Human Servs., 539 F.3d 1347, 1351-

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

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

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert, 509 U.S. at 593. However, the Supreme Court has provided guidance to the lower courts in determining the reliability of a novel proposition:

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

Id. at 593-94; see Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274,1280 (Fed. Cir. 2005)("the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."); see also, Gall v. Sec'y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL 1179611, at \*8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

52 (Fed. Cir. 2008); Moberly, 592 F.3d at 1315, 1322; Caves v. Sec’y of the Dept. of Health & Human Servs., 100 Fed. Cl. 119, 132 (Fed. Cl. 2011) aff’d per curiam, No. 2011-5108, 463 F. App’x 932, 2012 WL 858402 (Fed. Cir. Feb. 14, 2012).

A finding that petitioners established their *prima facie* burden does not end the inquiry. The Act provides that a petitioner may not receive compensation “if the court finds by a preponderance of the evidence on the record as a whole ‘that the illness, disability, injury, condition, or death described in the petition is due to **factors unrelated to the administration of the vaccine** described in the petition.’” Knudsen, 35 F.3d at 547 (citing §13(a)(1)(B))(emphasis in original); Walther v. Sec’y of the Dept. of Health and Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007)(“[W]e conclude that the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes when the other evidence on causation is sufficient to establish a *prima facie* case.”). Since the undersigned finds that petitioner has not provided preponderant evidence on vaccine causation, a factor unrelated analysis is unnecessary.

As stated previously a discussion of the evidence relating to the first and second prongs of Althen is unnecessary because, assuming petitioner would have prevailed under these two prongs, petitioner’s case fails under the third prong of Althen.

### Appropriate Diagnosis

Petitioner avers [M.J.] suffered from TM as a consequence of the vaccinations he received on October 10, 2005. There is no contention by petitioner that the vaccination caused or exacerbated any condition related to [M.J.]’s Arnold-Chiari I malformation.<sup>17</sup> Reviewing the medical records, it is unclear whether many of the treating physicians were convinced of the condition from which [M.J.] suffered. See, e.g., P Ex 3 at 73 (“He was seen by Dr. Iskandar . . . who felt that his presentation was somewhat unusual for a Chiari malformation, and felt that a concurrent transverse myelitis would be more consistent with his symptoms.”). The exceptions are pediatrician, Dr. Andringa, who consistently noted a vaccine reaction, and Drs. Hsu and Conway, both of whom ruled out vaccine causation and/or attributed [M.J.]’s problems to the Chiari malformation. Other injuries were considered in [M.J.]’s differential diagnosis, such as meningitis, but those conditions only appear sporadically in the record and were usually accompanied by reasons they were unlikely.

[M.J.]’s pediatrician appeared reasonably convinced that [M.J.]’s neurological problem resulted from a vaccine reaction; however, the pediatrician does not always identify the injury, only referring to it generically as an allergy or reaction. He repeatedly remarked on the dramatic reaction or injury following immunization. See, e.g., P Ex 4 at 147-48 (expressing agreement with the parents’ desire to not vaccinate [M.J.]); P Ex 4 at 130 (“may be allergic to

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<sup>17</sup> Although not a neurologist, Dr. Byers offered speculation that “antigen-antibody complexes . . . could have been trapped in the foramen magnum which was unusually small in this child, producing a vasculitis of the small vessels to the cord as it passed through the bony hole at the base of the skull, resulting in TM.” P Ex 18 at 7. The undersigned notes this possibility was not discussed by either expert neurologist, nor was it evident in the medical records. As stated previously, Dr. Byers is not a neurologist and previously deferred to Dr. Renfroe regarding the neurology portions of petitioner’s case in Crosby. Also, since Dr. Byers withdrew from this case, there was no opportunity to explore this portion of her opinion. Naturally, this evidence is unpersuasive and not relied upon in this Decision.

Pneumococcal vaccine and Pediarix . . . because he had a horrendous neurological hypotonia following those immunizations.”); P Ex 4 at 52 (“severe reaction to immunizations and maybe had a transverse myelitis, but nobody is quite sure.”).

[M.J.]’s treating pediatric neurologist, Dr. Doescher, did not express such definite conclusions. P Ex 4 at 167 (discussing the possibility of TM or a “symptomatic Chiari malformation and possibly pre syrinx development”). Later in the history, Dr. Doescher stated [M.J.] suffered from “a likely Chiari malformation . . . more likely [than] . . . an atypical transverse myelitis in a very short time or a reaction from his immunizations.” P Ex 4 at 163. Dr. Conway, a pediatric infectious disease specialist to whom [M.J.] was sent specifically to discuss the immunizations, was doubtful of a relationship to the vaccinations. He expressed the belief that the diagnostics possibly showed a viral infection related to the TM if the symptoms could not be explained by the Chiari malformation. P Ex 5 at 22-26. He recommended continuing with vaccinations but to separate them, allowing for time to watch for any signs of a reaction. Id. at 26. His conclusion was, “[a]lthough temporally the vaccine association is interesting, I think there is very little to suggest or support involvement with this neurologic event.” Id. The pediatric neurosurgeon records noted both TM secondary to immunization and the Chiari malformation and admits decompression surgery was performed “because of the possibility that the Chiari malformation could have been part of the etiology of the upper cervical spine problem . . . .” P Ex 5 at 8-9. Dr. Hsu discounted a vaccine-caused injury altogether, specifically because the onset was too soon after vaccination. P Ex 11 at 5-8.

Additionally, petitioner’s expert neurologist, Dr. Renfroe, opined to the diagnosis of TM, or a similar spinal lesion caused by an autoimmune process. Dr. Renfroe cited the treating physician records and the preservation of sensation for the reason he felt transverse myelitis was the injury. See Hr’g Tr. at 14 (“In my opinion, and it appears in the opinion of the physicians that were caring for the child, the primary differential diagnosis was Guillain-Barré versus transverse myelitis . . . .”). As noted, the government disagrees that preservation of sensation is dispositive of this issue. Dr. Renfroe characterized the Chiari malformation as an “incidental note” that the neurosurgeon found to be “not clinically significant.” Hr’g Tr. at 14-15. Reviewing the neurosurgeon’s note, Dr. Renfroe did voice some skepticism about the Chiari malformation being causative because of the acute onset of [M.J.]’s problem. P Ex 3 at 86-87. However, the neurosurgeon also noted that he “could not completely rule out the possibility that the Chiari could have caused enough stenosis at the craniocervical junction to cause a minor neck movement/trauma to result in a contusion in the cervical spinal cord.” Id. Because of the significant “tonsillar ectopia,” the neurosurgeon recommended decompression surgery that occurred in November 2005 but stated that he felt the condition was more likely related to transverse myelitis. Id. “Even though the Chiari is less likely to be the etiology in this case, there is enough risk here that I would recommend decompression in a couple months.” Id.

Respondent’s expert neurologist testified candidly that he was uncertain regarding the cause of [M.J.]’s neurological injury. Hr’g Tr. at 90-92. “[I]n retrospect, I’m not sure that I can separate the two quite clearly.” Hr’g Tr. at 92.

Impressions of the treating physicians are highly relevant with regard to this issue. Capizzano v. Sec’y of the Dept. of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir.

2006). Both transverse myelitis and the Chiari malformation are discussed following [M.J.]’s initial ordeal. Reviewing the medical records, the evidence does not definitively set forth what injury [M.J.]’s physicians felt he suffered. However, as my former colleague explained, the preponderant standard is proof akin to 50% and a feather. See, e.g., Whitener v. Sec’y of the Dept. of Health & Human Servs., No. 06–0477V, 2009 WL 3007380 \*1 (Fed. Cl. Spec. Mstr. Sep. 2, 2009). Although an extremely close call in this case, the undersigned finds petitioner has shown by preponderant evidence that her son suffered from the neurological injury, transverse myelitis, she alleges with support from the medical records and the expert testimony.

### **Time of Onset of the Alleged Injury**

Unlike the factual scenario in the Crosby case,<sup>18</sup> this case does not present the same level of uncertainty regarding the onset of [M.J.]’s symptoms of transverse myelitis. Herein, there are numerous, consistent notes that [M.J.]’s leg symptoms began within one day of vaccination. The majority of references discuss [M.J.]’s leg symptoms being noted by his parents the morning after his vaccinations, which were given the prior afternoon, and some records even reference onset of weakness within three to four hours after vaccination. P Ex 8; P Ex 4 at 20, 147, 167, 177, 181-83; P Ex 3 at 77-91, 152-155; P Ex 5 at 16, 22-26, 130, 232. However, as respondent points out, there were at least two notes that suggest [M.J.]’s hypotonia was already present at the time of vaccination.<sup>19</sup> P Ex 4 at 177; P Ex 3 at 77; R Response to P MSJ at 5, 7, 16.

In the undersigned’s review of the medical records, references to flaccidity or weakness prior to vaccination are in the minority. Further, they were not in contemporaneously created records but were either an afterthought by the pediatrician or part of the history given by the family to medical personnel. The majority of the evidence describes onset of the symptoms of weakness or loss of spontaneous movement in [M.J.]’s legs within four to 24 hours after vaccination. The undersigned accepts Dr. Renfroe’s discussion of the events following vaccination as it appears consistent with the majority of the medical records. Dr. Renfroe relied on the notes of [M.J.]’s fussiness on the evening of vaccination and his loss of spontaneous movement the next morning for placing onset. P Ex 12 at 4; Hr’g Tr. at 32-42, 57-58, 61-63. Use of these descriptions in the medical records comports with what it appears the treating

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<sup>18</sup> In some medical histories given at the time and in the petitioner’s affidavit, the Crosby parents described a very dramatic change in their child the day following vaccination, similar to what is seen herein. Crosby, 2012 WL 2866464, \*2-5. The medical records, however, appeared somewhat less clear; specifically, it was noted that the child in Crosby was not seen by a neurologist or hospitalized until seven days after vaccination. Id. Also, a treating physician record of the initial examination the day after vaccination was not dictated until approximately three weeks after the exam. Id. at 2-3. Petitioner and her experts in Crosby zeroed in on this late-dictated exam note to call into question the treating physician’s accuracy in recollecting the neurological symptoms observed within 24 hours of vaccinations. E.g., Crosby, 2012 WL 2866464, \*2-5, 9. Such a problem with the medical records is not present in the case *sub judice*. Petitioner’s experts in Crosby also focused on other non-specific symptoms the child was experiencing during the first few days after vaccination, characterizing the symptoms noted in the first few days to be related to an innate immune response – as opposed to the adaptive immune response that ultimately lead to the transverse myelitis. This last point is similar to Dr. Byers’ opinion in this case.

<sup>19</sup> Although it was briefly touched upon during cross examination of Dr. Renfroe, petitioner has not presented evidence or argument that [M.J.]’s injury was significantly aggravated by the vaccinations he received on October 10, 2005. Dr. Renfroe’s opinion on this was that there was little data on whether a vaccine could exacerbate an already-present immune response to cause TM but that he suspected it was possible. Hr’g Tr. at 47-48.

physicians were seeing and what the family was reporting. Dr. Sladky agreed that onset was less than 24 hours after vaccination, possibly as early as four hours after vaccination. R Ex A at 3; Hr'g Tr. at 93.<sup>20</sup>

In light of this evidence, the undersigned finds that onset of [M.J.]'s clinical symptoms occurred well within 24 hours of vaccination based upon a preponderance of the evidence.

### **Althen Prong Three – A medically appropriate onset of symptoms**

The third prong of Althen is the “showing of a proximate temporal relationship between the vaccination and injury.” In de Bazan v. Sec’y of the Dept. of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008), the Federal Circuit explained that “the 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.” Id. (citing Pafford, 451 F.3d 1352, 1358; Althen, 418 F.3d at 1281). “Merely showing that injury occurred after administration of a vaccine is insufficient.” Veryzer v. Sec’y of the Dept. of Health & Human Servs., 100 Fed. Cl. 344, 356 (Fed. Cl. 2011), appeal docketed, No. 12-5034 (Fed. Cir. Jan. 3, 2012).

In de Bazan, the Federal Circuit observed the “unusual situation” in which “the basis for the special master’s finding that [petitioner] had failed to prove a proximate temporal relationship was that the onset of her [injury] was too early to be attributable to the vaccine.” De Bazan, 539 F.3d at 1352 (affirming the original decision of the special master that found time to onset of ADEM symptoms after vaccination too soon to be related to the vaccine). “Usually, a petitioner’s failure to satisfy the proximate temporal prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause.” Id. (citing Pafford, 451 F.3d at 1358). “But we see no reason to distinguish between cases in which onset is too soon and cases in which onset is too late; in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked.” de Bazan, 539 F.3d at 1352. Other cases have also found that onset too soon after vaccination can be fatal to a Petition. See, e.g., Doe/11 v. Sec’y of the Dept. of Health & Human Servs., 87 Fed. Cl. 1 (Fed. Cl. 2009)(finding death occurred too soon after vaccination to be caused by vaccination), aff’d, 601 F.3d 1349 (Fed. Cir. 2010); Donica v. Sec’y of the Dept. of Health & Human Servs., No. 08-625V, 2010 WL 3735707 (Fed. Cl. Spec. Mstr. 2010)(finding onset of alleged injury within two hours of vaccination was not a medically appropriate time frame for vaccine causation).

It is under this third prong of Althen where petitioner’s case fails. “While a petitioner may be able to show a literal temporal association, the petitioner herein is unable to show a medically-accepted temporal relationship between the vaccination and the alleged injury given

<sup>20</sup> Dr. Byers’ was the only expert opinion to find onset of TM symptoms outside of 24 hours. Dr. Byers’ placed onset of TM symptoms approximately 36 hours after vaccination based on her seemingly flawed interpretation of a treater’s note regarding the injury’s history. P Ex 18 at 5 (citing P Ex 3, 77-79)(“There is no doubt that there is a 36 hour history of going from absolutely normal motor skill to a very flaccid individual . . .”). Dr. Byers’ is not a neurologist, disagreed with the opinions of the expert neurologists testifying herein and apparently with the treating physicians regarding the timing of onset, and was unavailable to further explain this opinion. This opinion regarding onset is contrary to the other evidence and is thus unhelpful and not persuasive.

the evidence and testimony submitted by both sides.” Crosby, 2012 WL 2866464, \*36 (citing Pafford, 451 F.3d at 1358; see also de Bazan, 539 F.3d at 1352; Veryzer v. Sec’y of the Dept. of Health & Human Servs., No. 06-522V, 2011 WL 1935813, \*23-24 (Fed. Cl. Spec. Mstr. 2011)(finding petitioner had not established a medically appropriate time frame between vaccination and onset of injury), aff’d, 100 Fed. Cl. at 356 (Fed. Cl. 2011), appeal docketed, No. 12-5034 (Fed. Cir. Jan. 3, 2012)).

Based upon the medical records and the testimony of the two expert neurologists, the undersigned found onset of [M.J.]’s observable TM symptoms occurred in less than 24 after vaccination. Because of this finding, the temporal relationship is not medically appropriate for the injury to be caused by [M.J.]’s vaccinations. Petitioner is simply unable to show preponderant evidence that 24 hours is a medically appropriate time for onset of clinical TM symptoms caused by the theory alleged.

Dr. Renfroe pointed out numerous times that he was not qualified to testify on this point and identified an immunologist as the appropriate expert. When Dr. Renfroe sought literature to support onset the day following vaccination, he was unable to find supporting literature and Dr. Sladky rebutted the literature that was provided. Dr. Byers, opining as an expert in immunology, disagreed with the medical record evidence and the testimony of the expert neurologists regarding onset of [M.J.]’s TM symptoms. Dr. Byers also did not provide testimony or support for onset of clinical symptoms within 24 hours being medically appropriate. The best petitioner could gain from Dr. Byers’ opinions in this case and in Crosby is her unsupported opinions that onset of clinical symptoms in less than four days might occur with fulfillment of certain unidentified factors. What these factors are in this case were not presented. In fact, Dr. Byers has not stated with any particularity what the factors are generally or specifically to this case. Also, Dr. Byer’s presumably opines that a 36 hour onset of symptoms in this case is appropriate. However, even this opinion is questionable and contradicted by both testifying neurologists and by the medical record evidence submitted in this case. See supra pp. 17-20. Following her withdrawal from this case, Dr. Byers could not be questioned about her opinion in this case or her contradictory opinion rendered in Crosby. Petitioner’s opted not to seek the opinion of another immunologist. Order, filed Aug. 9, 2011.

Examining the evidence, petitioner presented the unpersuasive and arguably unreliable opinion by Dr. Byers that onset of clinical symptoms 36 hours after vaccination is appropriate to infer vaccine causation. Given the undersigned’s finding that symptoms began within 24 hours of vaccination, this does not assist petitioner in meeting her burden. Petitioner also offered the opinion of Dr. Renfroe who opined that [M.J.]’s TM symptoms began in well under 24 hours but could only offer his unsupported belief this brief onset period was appropriate for vaccine causation. By his own admission, Dr. Renfroe was unqualified to offer opinions on the immunological timing issues presented in this case. Arguably, petitioner also has implied support for timing from Dr. Andringa, [M.J.]’s pediatrician, who was treating [M.J.] at the time the injury occurred and repeatedly references a vaccine reaction in [M.J.]’s subsequent medical records. P Ex 4 at 52, 130, 147-48. Early on in [M.J.]’s treatment, Dr. Doescher also pondered whether a vaccine related myelopathy was the source of [M.J.]’s injury. P Ex 4 at 175. Statements from treating physicians may be relied upon in the Vaccine Program. See, e.g., Andreu v. Sec’y of the Dept. of Health & Human Servs., 569 F.3d 1367, 1375-77 (Fed. Cir.

2009)(discussing the role of treating physician testimony); Capizzano v. Sec’y of the Dept. of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006)(finding the lower court “erred in not considering the opinions of the treating physicians who concluded that the vaccine was the cause of [petitioner]’s injury.”) Egan v. Sec’y of the Dept. of Health & Human Servs., No. 05-1032V, 2009 WL 1440240 (Fed. Cl. Spec. Mstr. 2009)(relying on treating physician opinion that vaccination was *not* a likely cause of the alleged injury).

However, as aptly stated in Snyder v. Sec’y of the Dept. of Health & Human Servs., 88 Fed. Cl. 706, 746 n. 67 (Fed. Cl. 2009), “there is nothing in Andreu that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted.” Dr. Andringa’s records do not discuss why he opines there was a vaccine reaction and appear to be based upon the close temporal relationship. Additionally, examination of [M.J.]’s medical records shows several other treating physicians who dismissed the vaccine as being the likely causative factor. See P Ex 5 at 22-26 (noting evaluation by Dr. Conway regarding vaccine involvement and his opinion that [M.J.]’s problems were unlikely to be related to his vaccination); P Ex 11 at 5-8 (noting evaluation by Dr. Hsu who dismissed vaccine causation specifically because the abrupt onset of symptoms was too soon). Dr. Doescher himself appeared to change his opinion as soon as November 2005 that [M.J.] more likely suffered from an “atypical presentation of Chiari malformation compared to an atypical transverse myelitis in a very short time or a reaction from his immunizations.” P Ex 4 at 163.

Also in evidence, respondent offered persuasive testimony from Dr. Sladky that 24 hours was an implausibly short period of time in which to develop symptoms of TM. Dr. Sladky supported his opinion by reference to evidence from the IOM. R Ex A-2 (discussing the theoretical minimum amount of time for onset of a demyelinating injury is five days). Although it is difficult to show a negative – that onset of symptoms within 24 hours is not possible – none of medical literature supplied by petitioner supported vaccine causation when onset of symptoms occurred in less than 24 hours. And although case reports rarely rise to the level of showing a causal link, the case reports discussed within petitioner’s medical literature all demonstrate an onset of greater than 24 hours. See supra pp. 12-13 n. 8, pp. 25-26 n. 13. The undersigned also considered the testimony in Crosby given by Dr. Rose, who testified consistently and persuasively in that case, *and* also by Dr. Byers that onset of TM symptoms in less than 24 hours after vaccination was not appropriate to implicate the vaccines. See supra pp. 26-28; Crosby, 2012 WL 2866464, \*8, 11, 20, 36-37. Further supporting the respondent’s case, as noted above, are the records of several treating physicians who discounted the vaccinations’ involvement; one treating physician in particular, Dr. Hsu, dismissed the vaccination because onset was so soon after vaccination. P Ex 11 at 5-8. In summary, petitioner has not presented preponderant evidence that such a rapid onset of clinical symptoms is medically appropriate to find the vaccinations [M.J.] received were causative of his injuries. In fact, there is evidence in this case and Dr. Byers’ testimony in other Vaccine Act cases that onset of symptoms of a demyelinating condition in less than 24 hours is affirmatively an inappropriate time frame to infer vaccine causation.

As petitioner communicated to the undersigned, she will not seek the opinion of another immunologist. In light of this, a ruling on the record regarding entitlement is appropriate.

Petitioner has failed to satisfy her burden under Althen prong three to show onset occurred within a medically appropriate time frame.

As noted in Crosby, “[t]he issue – how much time it takes to develop symptoms of an autoimmune demyelinating injury – has been examined frequently in the Program.” Crosby, 2012 WL 2866464, \*37 (citing e.g., Contreras, 2012 WL 1441315 (denying compensation because a one-day onset of TM following vaccination is insufficient to show causation), appeal docketed, No. 05-626V (Fed. Cl. May 4, 2012); Veryzer, 2001 WL 1935813, \*23-24 (finding onset of demyelination or toxicity within hours of receiving a vaccination not medically appropriate), aff’d, 100 Fed. Cl. 244 (Fed. Cl. 2011), appeal docketed, No. 2012-5034 (Fed. Cir. Jan. 3, 2012)). “It is likely to continue to be a critical issue as many demyelinating injuries are alleged under the Act.” 2012 WL 2866464, \*37. As in this case and Crosby,

care is not always taken by the parties or experts to differentiate between onset of the autoimmune response and onset of symptoms of the injury in discussing the medically appropriate time of injury onset. Review of the expert evidence in this case and discussions in other cases demonstrates the issue of an appropriate time frame for actual symptoms to appear deserves careful attention to distinguishing between what Dr. Rose says are two different time frames – the time necessary for a measurable adaptive immune response in the body and the time required to manifest clinical symptoms when that adaptive immune response causes injury in the body.

Id. However, preponderant evidence in this case shows the onset of TM symptoms within less than 24 hours of vaccination is simply not a medically appropriate time frame in which to ascribe causation to [M.J.]’s vaccinations.<sup>21</sup>

### CONCLUSION

In light of the overwhelming evidence, onset of [M.J.]’s alleged injury occurred within less than 24 hours following vaccination. The opinions of Dr. Renfroe and Dr. Byers do not support petitioner’s burden of showing onset was within a medically appropriate time following immunization, Althen, prong three. First, Dr. Byers interprets the factual evidence herein to determine onset of symptoms in a manner contrary to the medical records and both testifying neurologists. The remainder of Dr. Byers opinion, albeit unsupported, approves of onset of clinical TM symptoms within 36 hours after vaccination as medically appropriate. This opinion is contrary to her opinion in other cases and this contradiction was not resolved or addressed. More to the point, Dr. Byers testified in Crosby that onset of TM symptoms within 24 hours of vaccination is not a medically appropriate time frame. Petitioner’s other expert, Dr. Renfroe, admittedly lacked the expertise to opine on the medically appropriate time frame and was unable to provide medical literature to support vaccine causation with onset of clinical symptoms in less

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<sup>21</sup> Petitioner in Crosby filed a Motion for Reconsideration on July 11, 2012. The undersigned denied this Motion on July 19, 2012. In her Motion, the Crosby petitioner requested a finding by the undersigned regarding what is the appropriate minimum time for onset of TM symptoms following vaccination. As was the case in Crosby, the evidence here only shows that onset within 24 hours is implausible. A further finding is not necessary and is unwarranted given the state of the evidence.

than 24 hours. Petitioner was unable to show preponderant evidence that onset of clinical symptoms within 24 hours of vaccination is medically appropriate to infer vaccine causation.

**As such, petitioner fails to carry her burden and her claim is denied.** The Clerk of the Court is directed to enter judgment accordingly.

**IT IS SO ORDERED.**

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