In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 02-0738V

Filed: 20 July 2007

BAILEY BANKS, by his father KENNETH BANKS,	*	
Petitioner,	*	**PUBLISHED**
v.	*	Non-autistic developmental delay; Acute Disseminated Encephalomyelitis; Expert Credibility; Evidentiary Reliability; Scientific Validity; Burden of Proof; Causation in Fact; Proximate Causation
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael G. McLaren, Esq., Black & McLaren, Memphis, Tennessee, for Petitioner;
Alexis B. Babcock, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT RULING[1]

ABELL, Special Master:

On 26 June 2002, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2] alleging that, as a result of the MMR vaccination received on 14 March 2000, his child, Bailey, suffered a seizure and Acute Disseminated

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

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

Encephalomyelitis ("ADEM"),[3] which led to Pervasive Developmental Delay ("PDD"),[4] a condition from which he continues to suffer (the "Petition"). By the terms of the Petition itself, Petitioner brought this action under an actual causation theory of recovery, as the seizure was alleged to have occurred on 30 March 2000, sixteen days after the vaccination date, and outside of the time periods set on the Table. Petition at 2.

This petition was reassigned to my chambers on 22 December 2004. Eventually, a telephonic evidentiary hearing on the ultimate issue of entitlement for compensation was held on 1 June 2006. Hearing Transcript ("Tr.") at 1. Whereupon, the Court heard from medical expert witnesses for both parties: Dr. Ivan Lopez for the Petitioner and Dr. John MacDonald for the Respondent. Subsequent to that hearing, the parties filed closing briefs with the Court, and the case is now ripe for a ruling.

As a preliminary matter, the Court notes that Petitioner has satisfied the pleading requisites found in § 300aa-11(b) and (c) of the statute, by showing that: (1) he is a valid legal representative of the injured party, Bailey Banks; (2) the vaccine at issue is set forth in the Vaccine Injury Table (42 C.F.R. § 100.3); (3) the vaccine was administered in the United States or one of its territories; (4) no one has previously collected an award or settlement of a civil action for damages arising from

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[3] Acute disseminated encephalomyelitis (ADEM) is "an acute or subacute encephalomyelitis or infiltration and demyelination; it occurs most commonly following an acute viral infection, especially measles, but may occur without a recognizable antecedent....It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system. Clinical manifestations include fever, headache, vomiting, and drowsiness progressing to lethargy and coma; tremor, seizures, and paralysis may also occur; mortality ranges from 5 to 20 per cent; many survivors have residual neurological deficits." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 610.

[4] Pervasive Developmental Delay describes a class of conditions, and it is apparent from the record that the parties and the medical records are referring to Pervasive Developmental Disorder Not Otherwise Specified ("PDD-NOS"):

> Pervasive Developmental Disorder, Not Otherwise Specified (PDD-NOS) is a 'subthreshold' condition in which some - but not all - features of autism or another explicitly identified Pervasive Developmental Disorder are identified. PDD-NOS is often incorrectly referred to as simply "PDD." The term PDD refers to the class of conditions to which autism belongs. PDD is NOT itself a diagnosis, while PDD-NOS IS a diagnosis. The term Pervasive Developmental Disorder - Not Otherwise Specified (PDD-NOS; also referred to as "atypical personality development," "atypical PDD," or "atypical autism") is included in DSM-IV to encompass cases where there is marked impairment of social interaction, communication, and/or stereotyped behavior patterns or interest, but when full features for autism or another explicitly defined PDD are not met.
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> It should be emphasized that this "subthreshold" category is thus defined implicitly, that is, no specific guidelines for diagnosis are provided. While deficits in peer relations and unusual sensitivities are typically noted, social skills are less impaired than in classical autism. The lack of definition(s) for this relatively heterogeneous group of children presents problems for research on this condition. The limited available evidence suggest that children with PDD-NOS probably come to professional attention rather later than is the case with autistic children, and that intellectual deficits are less common.

The Yale Child Study Center's Developmental Disabilities Clinic Webpage, article on PDD-NOS, available at http://www.med.yale.edu/chldstdy/autism/pddnos.html. See also DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDER, (4th ed. 2000) at 69 *et seq*. In the interest of consistency, the Court will follow the convention adhered to by the medical records and by the parties in this case, and this condition will be referred to herein as "PDD".

the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 300aa-16(a) requirement that the petition be timely filed has been met. On these matters, Respondent tenders no dispute.

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

I. FACTUAL RECORD

Despite their accord on certain factual predicates contained in Bailey's medical records, there is, unsurprisingly, a pronounced conflict between the parties as to the following issues: whether a biologically plausible link exists between ADEM and pervasive developmental delay (PDD) in a direct chain of causation, whether Bailey did in fact suffer from ADEM, and ultimately whether the administration of the MMR vaccine to Bailey actually caused ADEM which would then cause PDD that currently besets Bailey today. Considering these disputes and the Court's commission to resolve them, it behooves the Court to explain the legal standard by which factual findings are made.

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

This Court is authorized by statute to render findings of fact and conclusions of law, and to grant compensation upon petitions that are substantiated by medical records and/or by medical opinion. §§ 12(d)(3)(A)(i) and 13(a)(1).

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

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

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

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

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

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

A. Medical Records

The Court turns first to the recorded facts drawn from the sources offered by the parties in this case. There is no dispute regarding the following facts, which are referenced to one degree on another in both parties' closing briefs:

1. Bailey Banks was born 26 October 1998. Petitioner's Exhibit ("Pet. Ex.") 2, 3. Bailey's development before his vaccination (both before and after birth) was normal and healthy. Pet. Ex. 1, 5, and 11.

2. At Bailey's fifteenth month check-up on 14 March 2000, no health concerns were noted, and he received the MMR vaccination at issue, his first. Pet. Ex. 11 at 2, Pet. Ex. 5 at 25.

3. Bailey then experienced a seizure 16 days later, on 30 March 2000, during which Bailey's mother witnessed his eyes rolling back and him choking, and he was taken to the Emergency Room. Pet. Ex. 4 at 5, 16, 52-54. At the Emergency Room, Bailey was found to be afebrile and irritable and to have vomited three times. Id. at 52. The treating doctor at the time characterized Bailey's condition as "new onset seizure" and Bailey was admitted to the hospital for observation, where he remained apparently healthy for the remainder of his stay there. Id. at 4, 14, 53.

4. The following day, on 31 March 2007, an MRI scan was taken of Bailey's brain, which was interpreted by the treating radiologist, Bret Sleight, M.D., as "most consistent with a demyelinating process of immune etiology such as may be seen with ADEM or perhaps post-vaccination." Pet. Ex. 4 at 36-37.

5. Bailey then underwent, on 10 April 2000, a full neurological examination, administered by another neurologist, Bryan Philbrook, M.D. Pet. Ex. 5 at 40-42.

The examination revealed "slight left esotropia"[5] and "gait and coordination [that was] extremely immature in that his gait was wide based. There was also some hyperextension of both knees noted with poor balance and frequent falling." Id. Based on these observations, Dr. Philbrook concluded that Bailey suffered from "mild gross motor developmental delay" and strabismus,[6] and recommended further lab tests, ophthalmology consultation and physical therapy evaluation of Bailey's gait. Id. Dr. Philbrook also noted his medical opinion that "[w]e reviewed the patient's MRI and felt that moderate hypomyelination was more likely than a demyelinating process like ADEM, but cannot rule out the latter with certainty." Id.

6. An EEG performed while Bailey slept on 5 May 2000 was unremarkable. Id. at 3. Also, a brain MRI performed on 5 January 2001 evidenced in the same results as the MRI performed on 31 March 2000, with no significant changes since then. Id. at 16-18, 24.

7. On 22 January 2001 Bailey was examined by another neurologist, Frank Berenson, M.D., who noted that Bailey was suffering from global developmental delays, which included features associated with pervasive developmental delay. Id. at 46-48. His conclusion was based on his examination of Bailey, in which he observed that Bailey continued to assume a toddling gait, speech delays, and social interactive difficulties (e.g., poor eye contact and biting), despite suffering no additional seizures since the one suffered on 30 March 2000. Id. Dr. Berenson noted some cognitive progress since Bailey's last neurology visit, including speaking up to ten words, better comprehension, following simple directions, and identifying individual body parts. Id. at 46. Additionally, Bailey's motor skills had improved such that Bailey assisted with dressing and drank from a cup. Id. However, he added that "[s]ocially there continues to be difficulty. His eye contact is variable. He has limited to no imaginary pretend play. He continues to bite excessively...." Id. Furthermore, even though Bailey remained alert during the visit, his speech development was found to be delayed. Id. Lastly, Bailey continued to walk with a "somewhat toddling gait" that Dr. Berenson described as "somewhat puppet-like" in appearance. Id.

Beyond the medical records mentioned above, Petitioner's brief references several others, engendered between 2001 and the present, that support the claim that Bailey continued to display neurological developmental delays requiring therapeutic services. Petitioner's Closing Brief at 4-7. Only by 24 September 2002, in a "Speech and Language Evaluation" report, were there clear signs of unequivocal improvement: Despite a severe language delay, some of Bailey's linguistic, social and cognitive elements for further development seemed emergent. Pet. Ex. 11 at 16-17.

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[5] Esotropia is "strabismus in which there is manifest deviation of the visual axis of an eye toward that of the other eye," also known as "cross-eye". DORLAND'S, supra, at 644.

[6] Strabismus is "deviation of the eye which the patient cannot overcome," wherein "[t]he visual axes assume a position relative to each other different from that required by the physiological conditions." DORLAND'S, supra, at 1766.

Among the physicians treating Bailey, a neurologist named Dr. Ivan Lopez personally examined Bailey and diagnosed Bailey as follows:

> This patient has developmental delay probably secondary to an episode of acute demyelinating encephalomyelitis that he had at 18 months of age after the vaccine. He certainly does not ___ [sic] for autism because over here we can find a specific reason for his condition and this is not just coming up with no reason.

Pet. Ex. 44 at 2. As Petitioner's testifying expert witness, Dr. Lopez maintained, reiterated, and elaborated upon this threshhold diagnosis.

Dr. Lopez's diagnosis appears to conflict with the diagnosis given by Bailey's pediatrician on 20 May 2004, who saddled Bailey's condition with the generalized term "autism";[7] however, that pediatrician later acknowledged that use of the term autism was used merely as a simplification for non-medical school personnel, and that pervasive developmental delay "is the correct [i.e. technical] diagnosis." Pet Ex. 35. Another pediatrician's diagnosis noted that Bailey's condition "seems to be a global developmental delay with autistic features as opposed to an actual autistic spectrum disorder." Pet. Ex. 30 at 4.

B. Expert Testimony at the Entitlement Hearing

1. Ivan Lopez

Dr. Ivan Lopez is certified by the American Board of Psychiatry and Neurology in the field of Neurology, with specific subspecialty in the area of Child Neurology, and has been since 2000. Transcript ("Tr.") at 18. It is Dr. Lopez's professional medical opinion that "Bailey's neurological deficit stem[s] from the vaccine he received on March 14, 2000." Tr. at 29.

Dr. Lopez explained to the Court that ADEM occurs when a subject "has been exposed to a foreign protein, in this case [the] vaccine," which causes the body to produce antibodies (specifically T-cells), such that the body's antibodies "turn against [the myelin sheathing covering the nerves] and destroy it." Tr. at 30.

Dr. Lopez explained the clinical indicia that Bailey exhibited, indicia that support a diagnosis of ADEM. He mentioned ataxia,[8] stating that "ataxia is one of the symptoms or signs of ADEM,

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[7] "An autism spectrum disorder is a brain disorder affecting a person's ability to communicate, form relationships, and/or respond appropriately to the environment. Such disorders sometimes result in death. The 'spectrum' of such disorders includes relatively high-functioning persons with speech and language intact, as well as persons who are mentally retarded, mute, or with serious language delays. Symptoms may include, but are not limited to, avoidance of eye contact, seeming 'deafness,' abrupt loss of language, unawareness of environment, physical abusiveness, inaccessibility, fixation, bizarre behavior, 'flapping,' repetitive and/or obsessive behavior, insensitivity to pain, social withdrawal, and extreme sensitivity to sounds, textures, tastes, smells, and light." Autism General Order # 1, (Fed. Cl. Spec. Mstr. Jul. 3, 2002), quoting National Institute of Mental Health, Publication 97-4023.

[8] Ataxia is a "failure of muscular coordination; irregularity of muscular action." DORLAND'S, supra, at 170.

but...it's not specific for ADEM." Tr. at 36. The same can be said, according to the doctor, for vomiting and irritability. Id.

Dr. Lopez then discussed the medical records created around the time of Bailey's seizure. He explained that Dr. Sleight's MRI notations were consistent with a diagnosis of ADEM, as were also the MRI films themselves, which Dr. Lopez himself personally examined in preparations for this case. Tr. at 37. He elaborated further, explaining that, using the "T2 technique" of analysis, the MRI showed an increased signal, indicating that "the white matter in between the ventricles of the brain and the cortex" had taken on a more "whitish" appearance than is normal, and such a result is consistent with ADEM. Id.

Dr. Lopez explained further to the Court that ADEM is a "monophasic condition," meaning that "it only appears once." Tr. at 38. He noted during direct examination that, in like manner, Bailey "only had one episode of acute neurological deficits" as well, which were "followed by the sequela of this condition" (i.e., the PDD).

Direct examination of Dr. Lopez concluded with addressing potential alternative diagnoses and explanations for Bailey's condition. Considering Respondent's Expert's proffered hypothesis, that of a glucose disorder or a glucose deficiency, he gave three reasons for his disagreement: (1) that Bailey would have shown evidence of such a disorder in his first few months, not in the second year of his life; (2) that those suffering from glucose transporter 1 deficiency have microcephaly,[9] a condition which Bailey does not have; and (3) that glucose transporter 1 deficiency is an "autosomal dominant"[10] disease, such that one of Bailey's parents would necessarily have the condition as well, which they do not. Tr. at 40-41.

Moving on to the alternative hypothesis/diagnosis of autism, Dr. Lopez distinguishes autism as a more generalized condition without a known etiology, and contrasted it to Bailey's condition, which he says is clearly attributable to demyelination based on neuroimaging evidence. Tr. at 41-42. Dr. Lopez also differentiated Bailey's condition from autism, because Bailey has been affected in more than one developmental skill area; he clarified by stating that Bailey has "induced pervasive developmental delay...due to ADEM." Tr. at 32. He noted that the conflation of designations resulted from a medical convention created for the sake of explanation to laymen, but that the two are not properly interchangeable, but actually quite distinct. Id. Speaking more directly, Dr. Lopez stated that "Bailey does not have autism because he has a reason for his deficits." Tr. at 42.

Dr. Lopez finished his direct examination testimony by averring that his opinion testimony in support of the Petition was given "to a reasonable degree of medical certainty." Id.

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[9] Microcephaly is an "abnormal smallness of the head, usually associated with mental retardation." DORLAND'S, supra, at 1151.

[10] An autosome is "any ordinary paired chromosome that is alike in males and females, as distinguished from sex chromosomes." DORLAND'S, supra, at 183. Diseases that are autosomal dominant are those in which a genetic disorder need only be present in, and passed on from, one parent, in order for a child to inherit the disease. See Medline Plus website (a service of the National Library of Medicine and the National Institutes of Health), available at http://www.nlm.nih.gov/medlineplus/ency/article/002049.htm.

On cross-examination, Dr. Lopez acknowledged that ADEM cannot be diagnosed based solely on a radiographic reading, but must be correlated with supportive clinical findings. Tr. at 45. However, he took issue with Respondent's line of questioning regarding whether the correlative symptoms must necessarily precede onset of ADEM, opining that "oftentimes those symptoms precede the onset of the disease, but it's not a must," and that "if [Bailey] hadn't thrown up three times," it would not change his medical opinion and diagnosis. Tr. at 47. He stipulated that "prior to the seizure it appeared that Bailey was healthy," and that, hypothetically, Bailey's three vomiting bouts could have resulted just from the afebrile seizure. Tr. at 49.

Responding to questions posed by the Respondent, Dr. Lopez noted that the other treating neurologists in the medical records did not diagnose Bailey with ADEM. Tr. at 60-61. Dr. Philbrook "felt" hypomyelination was more likely than ADEM, a demyelinating condition, Doctors Berenson and Pearlman could not ascertain or simply did not state an etiology, and in December of 2004 Dr. Trasmonte noted a prior diagnosis of Bailey's condition as pervasive developmental delay, without concluding whether Bailey had suffered from either hypomyelination or demyelination. Tr. at 52-60. However, Dr. Lopez was quick to add:

> [J]ust because this neurologist didn't say specifically that Bailey has ADEM doesn't mean that he doesn't. As a matter of fact, it is not saying that he doesn't have ADEM. All of them are saying that he has pervasive developmental delay, to which I agree, and they just leave it right there.

Tr. at 60.

As to the alternative diagnosis of autism, Respondent questioned Dr. Lopez whether Dr. Kartzinel's assessment of Bailey's condition was autism (see Pet. Ex. 7 at 8), and Dr. Lopez agreed.[11]

On Redirect Examination, Dr. Lopez agreed that, despite several neurological examinations, no one heretofore has made a definitive diagnosis of Bailey's condition other than PDD, but that both radiologists–Doctors Sleight and Barnes–concluded from studying the MRI films that they were consistent with a finding of ADEM. Tr. at 63-64.

2. John MacDonald

Dr. John MacDonald is a pediatric neurologist and has been board certified in neurology with special competence in child neurology since 1980. Tr. at 67-68. Due to the nature of his work, he stated that he sees patients with ADEM on a fairly regular basis, considering the rarity of the affliction. Tr. at 68-69. After perusing the Record in this case, Dr. MacDonald offered his opinion, to a reasonable degree of medical certainty, that Bailey's current neurological symptoms are not related to the MMR vaccine administered on 14 March 2000. Tr. at 71.

[11] The Court notes that the same medical record as was referenced by Respondent also states that Bailey "had good use of words up until he had a seizure" and that, "MRI studies, separated by 9 months[,] suggest post vaccinal injury...." Pet. Ex. 7 at 8.

After first addressing why this Petition does not qualify for one of the conditions entitled to a statutory presumption, Dr. MacDonald stated that unprovoked, afebrile seizures like the one that Bailey suffered are "relatively common" and that "[t]he vast majority of these are of unknown cause." Tr. at 72-73. He disagrees with Dr. Lopez's opinion that Bailey suffers from ADEM, but agrees that ADEM "is typically a monophasic illness," which appears "relatively quickly" and then peaks after two days. Tr. at 73. He describes the progress of the illness thusly:

> The child is generally quite sick with several symptoms. Seizures may be included, but most of the symptoms are much more physically dramatic -- paralysis, ataxia, coma.
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> Then as the picture evolves, you do the brain scan and it typically does show some changes, and then it runs its course. Most of these children are, if you suspect that diagnosis, are treated with high doses of intravenous steroids for at least three days. Many will make a partial improvement.
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> But it's an acute onset disorder of the central nervous system that presents several symptoms over several days. The children are generally quite ill, and it just does not -- in my experience and reading the literature -- a single isolated seizure in which the patient recovers immediately is not hardly an acute let alone a disseminated encephalomyelitis.

Tr. at 73-74. Also, Dr. MacDonald confirmed what had been heard throughout the proceeding, that doctors do not diagnose ADEM based solely upon MRI results. Tr. at 74

When questioned by the Court regarding his opinion on "what could have initiated the seizure," Dr. MacDonald noted that he does have some thoughts on the topic, but that they do not relate to ADEM, and that he sees no relationship to the administration of the MMR vaccine. Tr. at 74. His perspective is that the seizure's temporal proximity to the vaccine administration was purely happenstance, and "does not directly relate to the vaccine at all." Tr. at 74-75. When the Court inquired further, on whether there was a relationship between the seizure and the diagnosed PDD, Dr. MacDonald responded that "[s]eizures in general, isolated seizures can be seen in patients with PDD, but they are usually not the presenting symptoms," after noting that that is "a more difficult question." Tr. at 75.

Moving back into direct examination, Dr. MacDonald agreed that, but for the single seizure, Bailey did not present with "the multiplicity of signs and symptoms that we associate with the typical ADEM case." Tr. at 75-76. He ruled out the presence of ataxia at the time of the seizure, citing the physical examination statement upon discharge was "totally normal." Tr. at 76. However, he conceded that Dr. Philbrook had noted in his findings that "[Bailey's] gait was somewhat immature, wide based," but he believes that this circumstance is attributable to being a young child of a toddler's age, when children learn to walk. Id. He went further, stating, "Ataxia during ADEM comes immediately with the onset. It doesn't show up later." Id. He distinguished ataxia from what he believes to be merely "delays in...fine and gross motor [skills],...neurological signs, coordination issues [which caused Bailey] to have an odd gait," which, he avers, "occurs in about 15 percent of the normal population." Tr. at 77. Continuing further, he did state that such a condition is "common

in people with PDD." Id. He also agreed that Dr. Philbrook did not diagnose ataxia in his analysis. Id.

Moving on to Bailey's MRI scans, Dr. MacDonald does not think that they are consistent with a diagnosis of ADEM, because they both "look pretty clear," and indicate a consistent, bilateral white matter abnormality, whereas, he said, "ADEM tends to be much more asymmetric." Tr. at 77-78. He elaborated further that MRI scans typically "improve dramatically" following ADEM (however, some occasionally deteriorate), but, at any rate, "they change over time." Tr. at 78. He opined that "the fact that they are unchanged really over years to me is more typical for the hypomyelination," adding that the issues apparent in the MRI scans, "in and of themselves are nonspecific." Id. He went on to explain the difference between demyelination and hypomyelination: where the former indicates the loss of myelin which had previously existed, the latter expresses the circumstance where there is a slowed development or accrual of myelin over the nerve fibers. Tr. at 79.

Dr. MacDonald next addressed his postulated theory to describe Bailey's injury: glucose transporter 1 deficiency. When he first examined Bailey's records, he became concerned because the glucose levels in Bailey's spinal fluids were "quite low" at a value of 26. Tr. at 79-80. He admitted that he is "always looking for rare disorders," expressing that, when he suspects "a rare but treatable condition," he feels it is his duty "to pursue that vigorously." Id. He explained this rare deficiency as one where there is a critical shortage of important transporter enzymes that are responsible for bringing metabolic fuel (glucose) to the brain, across the blood-brain barrier, due to a genetic abnormality. Tr. at 80. He described the effect of this deficiency, saying, "all the initial cases presented with epilepsy in the first months of life, and a progressive neurological deterioration unless they were treated," adding that "there are milder forms," in that "[s]ome do not even have epilepsy...[but] only changes in their mental status." Id. He summarized his opinion by saying, "[W]hen I look at this picture, this is a problem with glucose metabolism of the brain," which could be responsible for "pervasive developmental disorder, which is a global brain dysfunction of neurons...". Tr. at 81. He disputed the earlier argument of Dr. Lopez, regarding whether this condition is "autosomal dominant": "Well, in a subtle sense it is [autosomal dominant], but there are at least 30 mutations of the genes; the parents can carry it but don't have to express it." Tr. at 82.

Regarding the medical records that indicated that Bailey was or is autistic, Dr. MacDonald said, "I think he falls into that autistic spectrum pervasive developmental disorder category, and that seems to be fairly consistent." Tr. at 84. He noted, however, that a majority of people "use these terms somewhat interchangeably." Id.

When questioned about the existence of medical literature which establishes a "relationship between MMR and autism or PDD," Dr. MacDonald indicated his thought that "all the medical literature is negative in that regard." Tr. at 85. Also, he referenced a dearth of known literature to explain why he sees no connection between ADEM and PDD:

> I can find no literature relating ADEM to autism or pervasive developmental disorder, and by its nature ADEM is a primary demyelinating disorder of the nervous system....PDD is a problem with the neurons, not the white matter of the brain, so it

> doesn't make sense that autistic children would have had a demyelinating disorder before. In fact, MRI scans [that] have been done repeatedly in children with PDD/autism don't show demyelination, so there is no connection. Even if one believes the child has ADEM, there is no connection to the diagnosis of PDD.

Tr. at 85-86.

When questioned by the Court on the existence of "one overarching etiology for Bailey's condition," Dr. MacDonald again referenced his proffered theory of glucose deficiency, but ultimately concluded that "Bailey falls into the large group of children with autism/PDD in which by our current evidence-based medicine we rarely can make a specific diagnosis." Tr. at 86.

Turning to cross-examination, Dr. MacDonald admitted that, in describing Bailey's post-seizure, toddling gait, Dr. Philbrook had expressed that "the gait and coordination were 'extremely immature.'" Tr. at 90. When asked if ataxia is definitionally a "lack of coordination," he clarified that ataxia manifests as a "pronounced instability of gait that's not age-appropriate." Tr. at 90-91.

When asked during cross-examination, Dr. MacDonald agreed that Dr. Sleight had analyzed the MRI scan results as "most consistent with a demyelinating process of immune etiology such as may be seen with ADEM," but he disagreed with this conclusion, admitting such disagreement was a necessary element of his ultimate conclusion in opposition to the Petition. Tr. at 91-92. However, later in cross-examination, Dr. MacDonald agreed that the IOM has reported a demonstrable biological plausibility for a causal relationship between the measles vaccine and demyelinating diseases, of which ADEM is one. Tr. at 101-02.

When questioned regarding his theory of hypomyelination due to a glucose transporter deficiency, Dr. MacDonald thought it would be likely that a scan performed several months before the seizure would have manifested the same results, but admitted that there was no indication in any of Bailey's medical records that there was anything irregular with his health until after the seizure. Tr. at 98-99. He added that he assumed that the hypomyelination process was present for some time before Bailey received the vaccine, but said "there is no way to know that." Tr. at 99. He agreed that "until the seizure there is [sic] no medical records or factual findings that indicate Bailey had any problems whatsoever." Id. What this means is that, if Bailey suffered from hypomyelination before the vaccination, it would not be the cause of those conditions afflicting Bailey immediately after the seizure, which could have resulted entirely from some other cause. Tr. at 99-100. Lastly on the theory of glucose transporter deficiency, Dr. MacDonald agreed with the Court's characterization of his opinion on this topic: "He sees this as something that has to be looked at as a possible, not necessarily a probable diagnosis, but that he is not holding this out by a preponderance of the evidence more likely than not." Tr. at 101.

The Court asked Dr. MacDonald whether he would advise the Respondent to concede if, in fact, the diagnosis of ADEM was indisputable, to which he responded (a) that he is aware of no supportive medical literature that indicates ADEM leading to the pervasive developmental delays from which Bailey suffers; (b) that symptoms of ADEM are felt immediately, and do not aggravate with the passage of time; and (c) that ADEM affects motor ability and/or control, and would not have rendered the effects to Bailey's mental status seen in the facts of this case. Tr. at 104.

3. Ivan Lopez

Dr. Lopez was recalled by the Court *sua sponte* to offer more testimony on his opinion in support of the Petition. Tr. at 107. The Court specifically asked Dr. Lopez to explain the causative, logical link between the disputed occurrence ADEM and the undisputed PDD from which Bailey now suffers. Id. Dr. Lopez conceded that "the majority of patients with ADEM improve significantly," but added that "the exception to this rule is when patients have been exposed to measles, just like in the case of MMR vaccine," in which case "sequela may occur in up to 50 percent of patients." Tr. at 107-08. He elaborated that such sequela potentially include "mental syndromes such as PDD and others, focal deficits, [and hemiparesis]," and opined that "up to 50 percent of patients...who have had ADEM will show[,] as a consequence of this monophasic condition[,] PDD." Tr. at 108.

C. Post-Hearing Submissions

At the conclusion of the hearing, Petitioner was adjured to file certain additional supportive materials with the expectation that another hearing might be necessary to give both parties' experts an opportunity to comment thereupon. Whereupon, Petitioner filed the treating records completed pursuant to Bailey's visit with Dr. Ivan Lopez, followed by certain medical literature texts and a supplemental expert opinion report from Dr. Lopez. These were followed by a supplemental expert opinion report from Dr. MacDonald, followed by more medical literature from Petitioner, followed by yet another medical expert report from Dr. MacDonald, and followed finally with more medical literature from Petitioner. After these several filings, the parties agreed that a further hearing would be unnecessary, and opted instead to address any outstanding issues in closing briefs. Wherefore, the Court set a briefing schedule, which has since run its course, and this case is ripe for a ruling on the issue of entitlement.

II. Ultimate Findings of Fact

A. The Parties' Arguments

Petitioner argues that the MMR vaccination Bailey received 14 March 2000 initiated a bout of ADEM, which led acutely to Bailey's seizure and eventually caused pervasive developmental delay that affects Bailey to this day.

Petitioner references an article from 2000, filed as Pet. Ex. 26, which seems to contradict statements made by Respondent's expert. That study notes that ADEM can follow measles infections, and mentions that the "most common presenting feature" is ataxia, followed by (*inter alia*) hemiparesis. Pet. Ex. 26 at 1310. It states:

> Although regarded as a monophasic condition, a characteristic feature of ADEM is the evolution of symptoms and signs over time. Ten children in this series deteriorated after admission to the hospital, with many developing new neurologic signs. Ataxia was usually present at the outset and did not develop later in the

> illness....Although ADEM is typically described as a monophasic illness lasting from 2 to 4 weeks, relapses have been reported.

Id. at 1310-11. Also, of particular note, the article later states that "MRI is highly sensitive in detecting white matter abnormalities and is the investigation of choice in ADEM." Id. at 1311.

Petitioner also cites in their Brief to an article of older vintage which, discussing ADEM, states:

> Patients may recover completely or be left with residual symptoms, which may be mild or severe. There may be only slight motor disturbances or pronounced spastic paraplegia and impairment of sphincter control. In children[,] recovery from the acute stage is sometimes followed by a permanent disorder of behavior, mental retardation or epilepsy.

Pet. Ex. 27 at 530.

Citing to Doctor Lopez's initial expert report, Petitioner seeks to establish a biologically plausible temporal connection between vaccination and the seizure and a means of showing the injury suffered:

> ADEM most commonly occurs in 3 to 15 days following vaccinations....The onset may be abrupt with seizures or less explosive with residual behavioral abnormalities, dementia, or motor deficits....Brain magnetic resonance imaging (MRI) generally reveals extensive abnormalities of white matter compatible with demyelination.

Pet. Ex. 18 at 1.

Likewise, Petitioner adds comments from the expert report of Dr. Patrick Barnes, a radiologist, who, in reviewing several of Bailey's CT and MRI scans concluded that, "These findings, although not specific, are most consistent with a post-viral or post-vaccinal encephalopathy (e.g., Acute Disseminated Encephalomyelitis - ADEM)," but added that, "Such findings must be correlated with the clinical findings." Pet. Ex. 16. Petitioner argues that Dr. Barnes' opinion supporting ADEM, coupled with the treating opinions of Dr. Lopez and Dr. Sleight all support this explanation, and that, in order to hold Dr. MacDonald's contrary view, one must negate or ignore the professional opinions of these three doctors. Pet. Closing Brief at 12. Petitioner then argues in detail as to why the facts support a finding of ADEM. Stipulating that ADEM is monophasic, Petitioner notes that Bailey's condition was not multi-episodic, but a continuous causal chain, from vaccine, to demyelination, to stunted development resulting from the demyelination. Id.

Petitioner cites to two previous cases heard by this Court where the Special Master found that the MMR vaccine had caused ADEM: Tufo v. Secretary of HHS, No. 98-0108V, 2001 WL 286911, 2001 US Claims LEXIS 46 (Fed. Cl. Spec. Mstr. Mar. 2, 2001) and Lodge v. Secretary of HHS, No. 92-0697V, 1994 WL 34609, 1994 US Claims LEXIS 19 (Fed. Cl. Spec. Mstr. Jan 25, 1994). Petitioner also cites to the 1994 report of the IOM, which found the theory that a vaccine can "induce...an autoimmune response...by nonspecific activation of the T cells directed against myelin proteins" to be "biologically plausible." See Pet. Ex. 36 at 19; see also Id. at 25 (stating "measles virus is associated with demyelinating disorders"). However, Petitioner concedes that "there is a

paucity of medical literature on the issue of whether ADEM can result in a diagnosis of PDD," but argues (without citation) that "there is medical literature that supports the association." Pet. Closing Brief at 18.

To bolster the Court's current gathered knowledge that "PDD is more descriptive than it is an actual diagnosis" (Tr. at 64), Petitioner references the Diagnostic and Statistical Manual of Mental Disorder, 4th ed., filed in part as Pet. Ex. 49:

> The clinician using [that manual] should therefore consider that individuals sharing a diagnosis are likely to be heterogeneous even in regard to the defining features of the diagnosis and that boundary cases will be difficult to diagnose in any but a probabilistic fashion....Nonclinical decision makers should also be cautioned that a diagnosis does not carry any necessary implications regarding the causes of the individual's mental disorder or associated impairments. Inclusion of a disorder in the Classification...does not require that there be knowledge about its etiology.

Pet. Ex. 49 at 10-12.

Finally, Petitioner cites the data in Table 4 of the Tenembaum study (filed as Pet. Ex. 46) which indicates that three children within the study group (4% of those studied) suffered mental handicap as a residual deficit or neurologic syndrome after suffering from ADEM. Pet. Closing Brief at 22, citing Pet. Ex. 46 at 1229, Table 4.

Moving now to Respondent's Post-Hearing Memorandum, the Court notes that Respondent's analysis hinges primarily upon legal arguments of burden of proof and credibility assessments. Respondent agrees with Petitioner that Bailey suffers currently from PDD and that ataxia is the most commonly manifesting feature of ADEM. However, Respondent contests that Bailey did not experience ataxia, that Bailey's PDD was not caused by ADEM, and that the PDD was not related to the MMR vaccination at issue.

Respondent relates the description of PDD from the same reference source as Petitioner used to describe PDD:

> Pervasive Developmental Disorders are characterized by severe and pervasive impairment in several areas of development: reciprocal social interaction skills, communication skills, or the presence of stereotyped behavior, interests and activities.

Pet. Ex. 49 at 18-19. Respondent argues, based upon this quote, that "PDD is the impairment of specific areas of development and does not refer to any cognitive abnormality," adding that "[w]hile there is no dispute that ADEM may leave survivors with 'permanent neurological sequelae' [(Pet. Ex. 37 at 1)], Respondent is not aware of any documented instances of ADEM being associated with PDD." Resp. Post-Hearing Memorandum at 16.

Respondent makes a similar point by reiterating Dr. MacDonald's opinion seeking to distinguish Petitioner's injury from the findings of the Tenembaum study:

> The Tennenbaum [sic] study does refer to a small group of children with ADEM that later developed what they call 'mental handicap'. Such a designation is very non-specific and not germane to our discussion of the well-defined neuro[-]behavioral disorder (PDD), which is diagnosed by psychologists utilizing standard DSM-IV criteria. The 'mental handicap' category is obviously vague and non-diagnostic of a specific neuro-behavioral disorder such as PDD, then they would have designated it as such in their conclusions.

Resp. Ex. I.

Respondent next argues that the type of injury associated with ADEM is not the type observed in PDD, such that Respondent's expert "does not see even a theoretical basis for an association between ADEM and PDD." Resp. Post-Hearing Memorandum at 17. Respondent concludes, therefore, that "[w]ithout any observed overlap in the presentation of these conditions, it is highly illogical to posit a causal association." Id.

Finally, Respondent's Post-Hearing Memorandum argues throughout that the law places a burden on Petitioner to disqualify by logical elimination all potential alternative *causata* in order to prove their theory of actual causation, and that, since alternative theories have been proffered by Respondent and were not wholly discredited by Petitioner, Petitioner has failed to carry such a burden.

In his surresponsive post-hearing memorandum, Petitioner frames the issue of dispute thusly: "Respondent acknowledges that Bailey experienced many symptoms that are recognized clinical features of ADEM, but argues that the symptoms did not present in a typical fashion....The possibility that Bailey's symptoms may not have manifest in a typical fashion certainly does not rule out ADEM." Id. at 4.

B. The Court's Conclusions

In sorting out the disputed issues presented above, the Court first notes certain matters that appear not to be in dispute. Both parties agree that ADEM is a monophasic illness or condition that reaches its apex quickly. Tr. at 38 and 73; Pet. Ex. 18 at 1. Both agree that ADEM should be diagnosed based upon a combination of radiographic scanning results and clinical examination findings. Tr. at 45 and 74; Pet. Ex. 16. The parties even agree that the IOM has cited demonstrative evidence of a biologically plausible relation between the measles vaccine and demyelinating diseases such as ADEM. Tr. at 101-02; Pet. Ex. 26 at 1310.

Both experts are personally and professionally credible; that premise is beyond a cavil of doubt in the Court's mind. However, the Court must analyze the differences between the opinions offered to determine whether Petitioner has established a logical sequence of cause and effect that is biologically plausible to tie together the factual sequence and explain Petitioner's injury. See Walther v. Secretary of HHS, __ F.3d. __, 2007 WL 1247047, 2007 U.S. App. LEXIS 10006, (Fed. Cir. May 1, 2007); Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

On its face, Petitioner has proffered a credible theory that, if the Court accepts its component parts, evidences a chain of logical and biological connection. It seems that Respondent's challenge in disputing and denying Petitioner's case in chief is a question of degree not kind: whether Bailey's lack of balance amounts to ataxia, whether Bailey's PDD constitutes a mental handicap, etc. Respondent acknowledges that Bailey currently suffers from PDD,[12] and that the MMR vaccine can cause ADEM. The only link on the logical "chain" of Petitioner's theory that Respondent really disputes, as it relates to the question of "can it?" (i.e., biologic plausibility), is whether ADEM can lead to PDD. Most of Respondent's contentions focus more narrowly on the issue of "did it?": i.e., was the mechanism proffered by Petitioner's expert really at work in this individual in this set of facts?

The Court first refers to the original treating records rendered by those individuals who were present to experience in a first-hand, sensory fashion the indicia of the injury which Bailey suffered. The first point worth noting is that Bailey was seen by a handful of neurologists, but not one of them actually diagnosed Bailey with ADEM. One, Dr. Philbrook, even cast aspersions on the conclusion of ADEM rendered by the treating radiologist. The plain truth, though, is that no diagnosis was given after Bailey's acute post-vaccinal incident because no etiology could be determined. Only later on was a diagnosis given, and that diagnosis was merely descriptive, not etiological: that of PDD, which is the condition both parties acknowledge that Bailey currently experiences. Even Dr. Lopez's treating diagnosis focuses on PDD as the continuing diagnosis, even while ascribing its development as "probably secondary to an episode of acute demyelinating encephalomyelitis that [Bailey] had at 18 months of age after this vaccine." Pet. Ex. 44 at 2.

Since most of the clinical symptoms of ADEM are nonspecific to ADEM, it is apparent from the medical literature filed that the primary diagnostic mechanism for ADEM is neural imaging scans, such as the MRI scan. These scans are administered by doctors with special skill and training in doing so: radiologists. As all have agreed, a full diagnosis of ADEM is best arrived at as a joint conclusion made between such a radiologist and a neurologist, the latter of whom can observe clinical indicia of the (admittedly nonspecific) symptoms associated therewith, in reaching that conclusion. However, it is clear that the MRI scan, administered by the radiologist, provides the most effective means of diagnosing ADEM. It is therefore very instructive to the Court that both radiologists opined that the results of the neural imaging were most consistent with a diagnosis of ADEM. Dr. Lopez, Bailey's treating neurologist and Petitioner's expert witness, has himself reviewed the MRI scans, and, for the reasons he explained, agrees with a diagnosis of ADEM. Tr. at 37.

Also apparent from the medical literature filed is that ataxia is the most consistent clinical sign associated with ADEM. It is statistically logical to presume that if Bailey suffered from ADEM in the period following his vaccination, symptoms would include ataxia, and that a treating clinician would look for such a sign as pertinent to diagnosis. Although Bailey visited several neurologists

[12] Respondent seems to have abandoned the earlier argument that Bailey suffered from autism, instead of PDD. The Court notes the various similarities between Bailey's condition and autism as defined above, but nonetheless rules that PDD better and more precisely describes Bailey's condition and symptoms than does autism. Respondent's acknowledgment serves to reaffirm the Court's conclusion on this point.

since March 2000, only one viewed Bailey during the time closest to the seizure, when acute signs of ADEM would be most apparent. Dr. Philbrook examined Bailey 11 days after his seizure and noted that Bailey's "gait and coordination [was] extremely immature in that his gait was wide based. There was also some hyperextension of both knees noted with poor balance and frequent falling." Pet. Ex. 5 at 40 *et seq*. Respondent attempts to distance these observations from ataxia, which is defined in Dorland's Medical Dictionary as a "failure of muscular coordination [and/or an] irregularity of muscular action." Id. at 170. Respondent maintains that, Dr. Philbrook knew what ataxia is, and could have used that term in his records if he thought it was pertinent, but he did not use that term. Dr. MacDonald also points to the physical examination record following the seizure that stated, upon discharge, that Bailey was "totally normal." Tr. at 76.

As noted above, Respondent's distinction seems one of degree, not of type, and strikes as a trifle semantic. As the rule cited in Murphy, supra, states, the Court looks more centrally at what a medical record *does* say, *vis-a-vis* what a record *does not* say. Respondent's expert quibbled that Bailey's "toddling" gait was not far outside normal ranges, as he was of the toddler age grouping, when children are beginning to learn to walk. This interpretation ignores the notation that Bailey's coordination was "extremely immature". Indeed, *this* was the notation made by the neurologist, the doctor most attuned to Bailey's precise condition, and *this* doctor did not pronounce Bailey "totally normal." Presumably, Dr. Philbrook was basing his judgment on maturity–not by comparing Bailey to a mobile, fully-developed adult, but through comparison to a child of the same age range. Bailey's coordination was immature for his age in comparison to standardized norms of development, and, according to Dr. Philbrook, "extremely" so. The fact that Bailey's extremely immature coordination caused "poor balance and frequent falling" no doubt qualifies Bailey's condition as a "failure of muscular coordination [and/or] an irregularity of muscular action". The Court therefore finds that Bailey experienced ataxia in the days or weeks following his post-vaccinal seizure, and that this atactic condition (or its residual effects) was described by Dr. Philbrook in the notes referring to Bailey's 10 April 2000 visit.

There is likewise some dispute regarding whether Bailey's poor health was an acute, monophasic condition, or whether it was merely one increment in a generally retarded biologic process: whether Bailey suffered from demyelination or from hypomyelination. Were his symptoms more consistent with the destruction of existing myelin structures, or were they the result of a failure to build or develop those structures? No one disputes that ADEM would fit correspondingly with the former of the two alternatives, but that it is not consistent with the latter.

It appears from the Record that Bailey's condition significantly worsened after the seizure and ataxia. Dr. MacDonald argued that his condition did not present with "the multiplicity of signs and symptoms [associated] with the typical ADEM case, but the literature filed indicates that while symptoms may vary, ataxia is by far the most common symptom. By all accounts, Bailey was a healthy child with no reported health problems or developmental delays of medical significance before his MMR vaccination. Then, beginning with his seizure sixteen days later, he began steadily to retrogress, before eventually improving gradually to his current condition. What was only "mild gross motor developmental delay" at the time of Dr. Philbrook's examination eleven days after the seizure had then retrogressed into global developmental delays, which included features associated with pervasive developmental delay, by the next neurological visit on 22 January 2001. By the time

of that visit, Bailey was already showing gradual improvement and development (despite still showing significant residua from the developmental delay), which, altogether, was more consistent with a monophasic condition of limited duration, less so than a permanent, fixed disease of congenital origins.

This series of circumstances, corroborated by the medical records prepared by treating doctors, fits much more closely with the monophasic illness of ADEM than it does with any other etiology proffered by either party. Combined with the radiologists' analysis of the MRI scans, and the Court's finding of ataxia, the Court accepts that Petitioner has met the burden of proof in showing the fact that Bailey more likely than not suffered from ADEM.

A finding of ADEM is not inconsistent with the medical records from the treating physicians in this case. The notations from both radiologists support this finding. At first glance, Dr. Philbrook seems to contradict this finding, but within his notes he gives only an impression, but no conflicting diagnosis; even though he doubted the diagnosis of ADEM, he was unable to rule it out.

Dr. MacDonald argued that Bailey did not have ADEM because Bailey's prognosis remained unimproved for a longer period, whereas ADEM cases almost always "improve dramatically" to benign effect, but that, in any event, "they change over time." Tr. at 78. This argument is repudiated by the medical records and medical literature filed in this case. First, as noted above, Bailey did slowly improve in some areas, after significant time had passed since his post-vaccinal seizure. Secondly, the medical literature noted that the monophasic nature of ADEM simply means that, after a precipitous period of acute symptoms, the patient either improves gradually, or retains residual effects. See Pet. Ex. 27 at 530 and Pet. Ex. 46 at 1229, Table 4. From the facts presented to the Court in medical records, this fits most closely with Bailey's clinical history. In contrast, even Dr. MacDonald realizes that his hypothesis of glucose transporter deficiency would have required that Bailey experience early-onset epilepsy within the first months of life and *progressive* neurological deterioration. Tr. at 80. This description does not jibe with Bailey's medical records.

That being said, the Court turns just for a moment to Respondent's proffered hypothesis of glucose transporter deficiency. This hypothesis, which Respondent's expert declined to incorporate as a plausible, probable theory of explanation, was used by Respondent to blunt Petitioner's theory of ADEM. However, this hypothesis was not given to a reasonable degree of medical probability or certainty, and Respondent's expert admitted that it was merely "a possible, not necessarily a probable diagnosis, but that he is not holding this out by a preponderance of the evidence more likely than not." Tr. at 101. Moreover, this hypothetical explanation does not square with the facts in the Record. Dr. MacDonald himself noted that, as a general rule, "all the initial cases presented with epilepsy in the first months of life, and a progressive neurological deterioration unless they were treated." Bailey's epilepsy was composed of one seizure event, when Bailey was a year-and-a-half old, and Bailey has since improved despite a notable delay in that progress. As such, the Court does *not* accept that Respondent has proffered, much less proved to a preponderance, a theory that a glucose transporter deficiency caused Bailey's condition and Petitioner's injury.

The next issue facing the Court is to determine whether the vaccine caused the ADEM from which Bailey suffered. The Court notes the Vaccine Program cases, the IOM report, and the several

articles of medical literature referenced by Petitioner's brief that have found that the MMR can directly cause ADEM.

In Lodge v. Secretary of HHS, No. 92-0697V, 1994 WL 34609, 1994 US Claims LEXIS 19, 31 (Fed. Cl. Spec. Mstr. Jan. 25, 1994), Special Master French found that ADEM had been tied to natural measles, mumps, and rubella infections, as well as to measles, mumps, and rubella vaccines. As such, she ruled that the Petitioner's injury was "vaccine-related and compensable under the Vaccine Program." Id. at 54. In Tufo v. Secretary of HHS, No. 98-0108V, 2001 WL 286911, 2001 US Claims LEXIS 46, 33-34 (Fed. Cl. Spec. Mstr. Mar. 2, 2001), Special Master Millman found that the MMR vaccine had caused ADEM because a theory that "measles vaccine [can cause] ADEM is biologically plausible," there was a medically appropriate temporal association (2.5 weeks after vaccination), and the injured party's symptoms corresponded with the accepted symptomatology for ADEM. In Saunders v. Secretary of HHS, No. 97-0808V, 2001 WL 1135035, 2001 U.S. Claims LEXIS 225, 9 (Fed. Cl. Spec. Mstr. Sep. 4, 2001), Special Master Hastings denied an ADEM claim, reasoning that if the injured party had suffered from ADEM, such injury "would have been obvious upon examination of the MRI," specifically through analyzing the brain's white matter.

In reviewing these cases, the Undersigned is benefitted from the transcribed wisdom of these, my august colleagues. The first two add credence to a finding of ADEM, and establish that the time period involved in this case fits within a time frame that those cases established to support a medically plausible temporal association. It is also significant that, in the Saunders case, the Court decided on whether the injured party had suffered from ADEM based upon MRI findings, *vis-a-vis* nonspecific clinical indicia. All of these findings are corroborated by medical literature supplied by the Petitioner in this case (see Section II-A, supra), and the Court accepts all of these materials as persuasive in making a factual finding here. Therefore, the Court finds that the MMR vaccine can cause ADEM, and that the MMR vaccine received by Bailey did in fact cause Bailey to develop ADEM.

Having suffered from ADEM, it remains to be discussed if and how the ADEM led directly to PDD as a sequela.

As a preliminary matter, even though Respondent conceded during briefing that Bailey suffers from PDD, Respondent's expert, Dr. MacDonald characterized Bailey's condition as autism; however, he at one point conflated the two as of one or of like kind. Tr. at 84-86. Despite his comments to that effect, the Court is inclined to view Bailey's condition as accurately as the medical records will allow; that is, to find that Bailey more likely than not suffers from PDD, and not from autism.

When asked, Petitioner's expert, in explaining the connection between ADEM and PDD, stated that almost half of the people who suffer from ADEM experience sequelae such as PDD. Tr. at 108. He acknowledged that "the majority of patients with ADEM improve significantly," but added that "the exception to this rule is when patients have been exposed to measles, just like in the case of MMR vaccine," in which case "sequela may occur in up to 50 percent of patients." Tr. at 107-08. Such sequelae potentially include "mental syndromes such as PDD." Tr. at 108.

In response, Respondent's expert stated that, although ADEM may result in "permanent neurological sequelae," nevertheless "all the medical literature is negative in that regard;" however, soon thereafter, he corrected this statement by clarifying, "I can find no literature relating ADEM to autism or [PDD]." Tr. at 84-85. It may be that Respondent's research reveals a dearth of evidence linking ADEM to PDD, but that is not the same as positive proof that the two are unrelated, something Respondent was unable to produce. Therefore, the statement that "all the medical literature is negative" is incorrect. Also, as noted above, Respondent's expert "does not see even a theoretical basis for an association between ADEM and PDD." Resp. Post-Hearing Memorandum at 17.

The Court notes the difference in opinion between the experts in this case, and realizes that there may not have been a specific study linking a tumultuous episode of ADEM *specifically* to the polymorphous category of symptoms encompassed by the term "pervasive developmental delay." That being said, the literature filed in this case is instructive: "In children[,] recovery from the acute stage [of ADEM] is sometimes followed by a permanent disorder of behavior [or] mental retardation..." (Pet. Ex. 27 at 530), and 4% of the Tenembaum study group suffered "mental handicap" as a residual deficit or neurologic syndrome (Pet. Ex. 46 at 1229, Table 4).

Respondent disputes that these sequelae fit the "definition" of PDD, and calls into question the applicability of the Tenembaum study. Respondent's expert averred that PDD is a "well-defined neuro[-]behavioral disorder," diagnosed using "standard" categorical criteria, and should not be conflated with the more general term 'mental handicap' used by the Tenembaum study authors, to which Petitioner referred. Resp. Ex. I.

Both Petitioner and Respondent vouch for the credibility of the Diagnostic and Statistical Manual of Mental Disorder, referenced *supra*, and that source is very forthright in describing its own limitations in describing PDD with both accuracy and precision. The Court does not accept the quibble posited by Respondent, and follows the caveat stated by the authors, who acknowledge the heterogeneity found in the general classification PDD. The same authors are quick to note that PDD carries no assumed etiology, and that Petitioner's theory of causation makes equal and greater logical sense than any other etiology that is apparent from the medical records.

In sum, the Court's factual findings are fourfold:

1. Bailey did show evidence of ataxia in the period surrounding his seizure, following his vaccination;

2. Such ataxia, when considered in conjunction with the radiological results and some other "soft indicia", together support the Court's finding that Bailey did, in fact, suffer from ADEM.

3. Bailey's ADEM was caused-in-fact and proximately caused by his vaccination. It is well-understood that the vaccination at issue *can* cause ADEM, and the Court finds, on the record filed herein, that it *did* actually cause the ADEM.

4. Bailey's ADEM was severe enough to cause lasting, residual damage, and retarded his developmental progress, which fits under the generalized heading of Pervasive Developmental Delay, or PDD. Additionally, this chain of causation was not too remote, but was rather a proximate sequence of cause and effect leading inexorably from vaccination to Pervasive Developmental Delay.

III. CONCLUSIONS OF LAW

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

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

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

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

> [Petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

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

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

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination. Pafford v. Secretary of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006)(emphasis added), rehearing and rehearing *en banc* denied, 2006 U.S. App. LEXIS 28907, cert. den., 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007)., citing Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir.1999). This threshhold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that petitioner would not have sustained the damages complained of, *but for* the effect of the vaccine. See generally Shyface, supra.

A. Determining Credibility

In their closing briefs, the parties discussed the respective weight to be afforded each medical expert. Respondent seized the initiative in his Post-Hearing Memorandum. After referencing general authority for undisputed rules, Respondent argues that Dr. Lopez's opinion "cannot be viewed as reliable or credible," and that, even though "Dr. Lopez is certainly qualified to testify in this case," nevertheless, his opinion "should be afforded little weight." Id. at 8. Respondent bases this strong assertion primarily on the fact that Dr. Lopez believes Bailey suffered from ADEM, in disagreement with Dr. Philbrook, another treating neurologist. Id. Respondent seeks to bolster Dr. Philbrook, and to give him alone the credibility of a treating doctor, exclusive of Dr. Sleight as a contemporaneously treating radiologist ("radiologists are not directly involved with the care of the patients whose scans they interpret") and Dr. Lopez as another treating neurologist at a later time ("the opinions of Dr. Lopez also do not merit consideration commensurate with that of a treating physician" as his treatment of Bailey "occurred more than three years after Bailey was treated for a seizure"). Id. at 13-14. In undercutting Dr. Lopez's opinion, Respondent states, "In order to draw his conclusion about the etiology of Bailey's PDD, Dr. Lopez would have been forced to rely upon the same reports and medical records available to any other physician." Id. at 14.

Petitioner attacked this position of Respondent in his surresponsive post-hearing brief. Petitioner first points out, "Respondent erroneously states that Dr. Lopez's diagnosis of ADEM contradicts the diagnosis of the neurologist that was treating Bailey at the time of his first seizure, Dr. Philbrook." Id. at 2. Petitioner rebuts Respondent's position by countering that Dr. Philbrook "never diagnosed Bailey," such that "[t]here are no inconsistencies between Dr. Lopez's and Dr. Philbrook's opinions." Id.

Secondly, Petitioner takes issue with Respondent's criticism that Dr. Lopez examined Bailey too late to adequately diagnose an etiology for the PDD: "The passage of time in this case, however, only strengthens Dr. Lopez's conclusions. Dr. Lopez's ability to view Bailey's three year clinical and radiological history, which both support a diagnosis of ADEM, adds *more* weight to his opinion." Id. at 2-3 (emphasis added).

Next, Petitioner turned the spotlight back towards Respondent, and Respondent's expert: "If little weight is to be afforded to a witness that testified in this matter, it should be the testimony of Respondent's witness, Dr. MacDonald," because he "never physically examined Bailey, but has

merely reviewed his medical records, ruled out a diagnosis of ADEM, which was never excluded by any other of Bailey's treating physicians." Id. at 3.

The Court briefly pauses to point out the similarities between this case, and the case of Walther v. Secretary of HHS, __ F.3d. __, 2007 WL 1247047, 2007 U.S. App. LEXIS 10006, (Fed. Cir. May 1, 2007) (slip opinion), another case where a petitioner alleged that the alleged injury was caused by a vaccine-related bout of ADEM. In that case, as here, there was no dispute that the vaccination at issue *could* cause ADEM, but Respondent disputed whether the petitioner *did* actually suffer from ADEM. The Special Master initially hearing the case ruled that the petitioner's expert "was not credible on the causation issue" and rejected the expert testimony (as Respondent advocates here) "because he harbored significant concerns regarding the quality and the substance" of such testimony. Id., Slip Opinion at 4. According to the Federal Circuit's interpretation, the Special Master excluded that testimony because of its probative weight, rather than its admissibility. Id. The Federal Circuit vacated that Decision, and remanded the case for further proceedings.

Respondent has argued, as it has in other cases, that this Court should apply *de facto* the standards set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), even if this Court is not technically bound to apply the analysis followed there *de jure*. This Court has indeed done so upon occasion, to the approval of the Federal Circuit. See Terran v. Secretary of HHS, 41 Fed. Cl. 330 (1998), aff'd, 195 F.3d 1302 (Fed Cir. 1999), rehearing and rehearing *en banc* denied, (2000). Specifically, Respondent states that "the Supreme Court crafted four proposed criteria" to determine the admissibility of expert opinion evidence: "testing; peer review and publication; known or potential error rate; and, general acceptance in the scientific community." Respondent's Post-Hearing Memorandum at 6.

The Daubert opinion addresses a trial court's "gatekeeper" function, to protect the fact-finder from unreliable testimony that will confuse, rather than inform, the fact-finding process. 509 U.S. at 595-597. The Supreme Court there connected the precondition that testimony comport as "scientific knowledge"[13] to "a standard of evidentiary reliability." Id. at 590. The Court then linked evidentiary reliability to a supportive foundation of scientific validity. Id., note 9. A proposition or theory is scientifically valid where it supports the conclusion that "it purports to show." Id.

The Court in Daubert readily distinguished, as a separate component, the issue of relevance. Id. at 591. Unsurprisingly, evidence is only admissible in the first place when it is relevant, but even potentially relevant testimony is excluded as inadmissible under the Daubert analysis of FRE 702 whenever it is not reliable. Id. at 592-93. Therefore, the two are distinct, and not to be conflated.

The Daubert opinion states that, prior to determining the relevance of expert opinion evidence, a trial judge must first assess "whether the reasoning or methodology underlying the testimony is scientifically valid and [] whether the reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93. The Court gives guidance for this determination by way of some factorial examples, but leaves the determinative process to the logic and reason of the trial judge:

[13] In Daubert, the Court was interpreting Federal Rule of Evidence 702, which allows expert opinion testimony regarding "scientific, technical, or other specialized knowledge." 509 U.S. at 589.

> We are confident that federal judges possess the capacity to undertake this review. Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate.

Id. at 593. The Court proceeds to list the four examples referenced by Respondent above (Id. at 593-94), but reiterates such an inquiry remains "a flexible one," focused not on a mechanistic weighing of predetermined factors, but on the scientific validity of the opinion offered. Id. at 594-95.

Later in the decision, the Daubert Court assuaged the fear that such a result would allow materials to be considered which might technically comport to the reliability standard, but which are only minimally relevant (i.e., of slight probative value). Id. at 595-96. The Court's assurance was that the assaying process of trial would sufficiently test, weigh, and prove the proper amount of weight to be afforded to such testimony. This reassuring concept makes clear that even if a proffered theory is not "generally accepted", it may still be admissible, and will be left to the winnowing analytical process of the fact-finder to assign an ultimate probative value.

Applying these rules, it appears that Respondent's argument conflates two very distinct concerns: admissibility and probative weight. Respondent seems to argue that, by Respondent's estimation, Petitioner's expert's theory is not convincing, and should therefore be excluded *in toto*. The cases discussed above militate against this result. So long as the testimony from Dr. Lopez is relevant, it is admissible, unless some concern of evidentiary reliability requires its exclusion. As Dr. Lopez gave the perspective of a physician who actually treated Bailey, who is commenting on Bailey's condition in light of the medical record extant, and who argues that such condition is vaccine-related, it is eminently relevant. If believed, such testimony covers much distance in carrying Petitioner's burden of proof. Moreover, his testimony follows the scientific method. If the Court as fact-finder accepts the premises proffered by Petitioner, the logical theory offered by Petitioner's expert supports a conclusion that Bailey's injury is vaccine-related, the conclusion such theory seeks to prove. There is nothing inherently unreliable or nonsensical in Petitioner's theory, and hence, nothing to require the Court to exclude from the appropriate body of evidence in this case. Therefore, the Court will not exclude the testimony of Dr. Lopez, and moves on to assign a degree of relative probative weight in determining the final conclusion of this case.

As Respondent references at page 6 of his prehearing memorandum, the Federal Circuit has ruled that "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Cappizano v. Secretary of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006), quoting Althen v, Secretary of HHS, 418 F.3d at 1280. Dr. Lopez was indeed a treating physician, and rendered an opinion supporting the Petition in his contemporaneous medical notations. He did so well before this Petition was filed, presumably with no knowledge that such a cause of action would be brought before this Court. Unlike the other treating neurologists that treated Bailey, he did render a diagnosis for Bailey's condition as well as a likely etiology to explain his diagnosis. His position on these matters has remained unchanged since that initial treating diagnosis, and the Court can see no reason to gainsay such medical opinion from a treating physician. The Court therefore takes quite seriously the opinion testimony given by Dr. Lopez.

B. Apportioning Procedural Burdens

Respondent argues at length that a burden should be borne by Petitioner to disprove all other potential *causata* as a component of proving the *causa* proffered by Petitioner: namely, the MMR vaccine. Respondent argues that, "in an actual causation case, the question of whether a factor other than the vaccinations was responsible for the condition is necessarily subsumed in petitioner's basic burden: proving that the vaccine was the most likely cause of the condition. Respondent's Post-Hearing Memorandum at 5. Respondent reads Pafford, supra, to collapse subsections (A) and (B) of 42 U.S.C. § 300aa–13(a)(1), the general rule for recovery in actual causation cases in the Vaccine Program, such that Petitioner's burden is, in essence, to prove that the vaccine actually caused the injury suffered by also proving that such injury was *not* caused by factors unrelated to the vaccine.

On 1 May 2007, in the case of Walther v. Secretary of HHS, supra, the Federal Circuit clarified the rule in Pafford so as to correspond squarely with the Vaccine Statute, which is the only authority conferring jurisdiction upon this Court.

The Vaccine Statue text reads as follows:

> (a) General rule
>
> (1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—
>
> (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11 (c)(1) of this title, and
>
> (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.
>
> The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

42 U.S.C. § 300aa–13(a)(1)(A)-(B). Vaccine cases follow the Restatement (2d) of Torts, which requires a petitioner to prove actual causation, which is bifurcated into causation in fact, also known as "but-for" causation; and proximate or non-remote causation, sometimes referenced as "substantial factor" causation. Walther, slip op. at 8-9; see also Shyface v. Secretary of HHS, 165 F.3d 1344 (Fed. Cir.1999). If a petitioner proves actual causation thus defined, Respondent is shouldered with task of proving a "factor unrelated" under subsection (B), above. Id.

The Federal Circuit in Walther states a general legal principle, and a common-sensical truth: that "our legal system rarely requires a party to prove a negative," and therefore, it is not a component of a petitioner's burden "to prove that 'there is not a preponderance of the evidence.'" Id., slip op. at 9. Applying traditional legal techniques of statutory interpretation the Federal Circuit also resolved that the reading urged by Respondent would render § 300aa–13(a)(1)(B) a legal

redundancy or superfluity, which is contradicted by the interpretive canon against reading statutory text as redundant or superfluous. Id. at 9-10.

In stating the general rule for the case, the Walther court explained that "[Respondent] bears the burden of establishing alternative causation by a preponderance of the evidence once the petitioner has established a prima facie case....[T]he text and structure of the Vaccine Act separates the inquiry for alternative etiologies from the inquiry for causation," and so "[t]hese are two separate inquiries under the statute." Id. at 11, quoting Grant v. Secretary of HHS, 956 F.2d 1144, 1149 (Fed. Cir. 1992) (internal marks omitted).

In a footnote, the court in Walther noted that, for the purpose of proving proximate causation (a.k.a. "substantial factor" causation), a petitioner may still bear a burden to *address* other potential *causata*, if significant, but that such a petitioner need not *disprove* that these other factors caused the injury suffered: "Where multiple causes act in concert to cause the injury, proof that the particular vaccine was a substantial cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine." Slip Op. at 11, note 4; see also Whitecotton v. Secretary of HHS, 81 F.3d 1099 (Fed. Cir. 1996).

The Federal Circuit concluded the Walther decision by holding "that the petitioner does not bear the burden of eliminating alternative independent causes." Id. at 12. That holding directly applies in this case.

In light of the clear explanation given by the Federal Circuit to aid in reading the operative portions of the controlling statutory provisions, this Court now holds that Petitioner bears no burden to disprove, as a component of his case in chief, the glucose transporter deficiency hypothesis raised by Respondent. Petitioner's burden under the Vaccine Act, as well as the controlling cases interpreting the Act, is to prove that, "but for" the consequential effect(s) of the vaccine, the alleged injury would not have been suffered, and that the vaccine's effect was a substantial, proximate (i.e., non-remote) cause of that injury.

C. Applying the Law to the Facts

As a matter of elucidation, the Undersigned takes note of the following two-part test, which has been viewed with approval by the Federal Circuit,[14] and which guides the Court's practical approach to analyzing the Althen elements:

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[14] See Pafford v. Secretary of HHS, No. 01-0165V, 2004 U.S. Claims LEXIS 179, *16, slip op. at 7 (Fed. Cl. Spec. Mstr. Jul. 16, 2004), aff'd, 64 Fed. Cl. 19, 2005 U.S. Claims LEXIS 31 (2005), aff'd 451 F.3d 1352, 1356 (2006) ("this court perceives no significant difference between the Special Master's test and that established by this court in Althen and Shyface"), rehearing and rehearing *en banc* denied, 2006 U.S. App. LEXIS 28907, cert. den., 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007).

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

Weeks v. Secretary of HHS, No. 05-0295V, 2007 U.S. Claims LEXIS 127, *64, slip op. at 25, n. 15 (Fed. Cl. Spec. Mstr. Apr. 13, 2007).

The Court found, supra, that Bailey's ADEM was both caused-in-fact and proximately caused by his vaccination. It is well-understood that the vaccination at issue *can* cause ADEM, and the Court found, based upon a full reading and hearing of the pertinent facts in this case, that it *did* actually cause the ADEM. Furthermore, Bailey's ADEM was severe enough to cause lasting, residual damage, and retarded his developmental progress, which fits under the generalized heading of Pervasive Developmental Delay, or PDD. The Court found that Bailey would not have suffered this delay but for the administration of the MMR vaccine, and that this chain of causation was not too remote, but was rather a proximate sequence of cause and effect leading inexorably from vaccination to Pervasive Developmental Delay.

Based upon that finding of fact, it follows as a natural conclusion that Petitioner has carried his burden of proving to a preponderance that the MMR vaccine at issue actually caused the condition(s) from which Bailey suffered and continues to suffer. Inasmuch as the other elements of § 300aa–11 (b) and (c) have already been satisfied, the Court holds that Petitioner has met his burden on his case in chief.

These facts likewise satisfy the Althen test set forth above. Petitioner's theory of PDD caused by vaccine-related ADEM causally connects the vaccination and the ultimate injury, and does so by explaining a logical sequence of cause and effect showing that the vaccination was the ultimate reason for the injury. Also, the timetable in this case for the onset of ADEM fits within the range found to be reasonable in the cases addressing the same question. See Lodge v. Secretary of HHS, No. 92-0697V, 1994 WL 34609, 1994 US Claims LEXIS 19, 31 (Fed. Cl. Spec. Mstr. Jan. 25, 1994), Tufo v. Secretary of HHS, No. 98-0108V, 2001 WL 286911, 2001 US Claims LEXIS 46, 33-34 (Fed. Cl. Spec. Mstr. Mar. 2, 2001), and Saunders v. Secretary of HHS, No. 97-0808V, 2001 WL 1135035, 2001 U.S. Claims LEXIS 225, 9 (Fed. Cl. Spec. Mstr. Sep. 4, 2001).

In contrast, the Court found, as a matter of fact, that Bailey did not suffer from glucose transporter deficiency, or any other factor unrelated to vaccination. Without such a finding, based upon preponderant proof, Respondent has not satisfied his burden under § 300aa–13(a)(1)(B). To paraphrase a citation provided in Respondent's own Prehearing Memorandum, the "possibility" of a causal relationship between a *factor unrelated* and a condition does not support a finding in Respondent's favor. Duncan v. Secretary of HHS, No 90-3809V, 1997 WL 75429 *4, 1997 U.S. Claims LEXIS 73 (Fed. Cl. Spec. Mstr. Feb. 6, 1997).

III. CONCLUSION

Therefore, in light of the foregoing, the Court rules in favor of entitlement in this matter. The parties are to contact the Court as soon as practicable to schedule a status conference on the issue of damages.

IT IS SO ORDERED.

Richard B. Abell
Special Master