

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-0120V

Filed: 30 July 2008

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ERIN ZELLER and BENJAMIN S. *
ZELLER, parents of BENJAMIN J *
ZELLER, a minor, *

Petitioners, *

v. *

PUBLISHED

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

* * * * *

Thao Da Ho, Esq., Conway, Homer & Chin-Caplan, Boston, Massachusetts, for Petitioner;
Rebecca Trinrud, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT RULING¹

ABELL, Special Master:

On 15 February 2006, the Petitioners 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 17 November 2004, their child, Benjamin, suffered persistent, intractable seizures, encephalopathy, and developmental delay. Petition at 1.

This petition was assigned to my chambers on 15 February 2006. Eventually, an evidentiary hearing on the ultimate issue of entitlement for compensation was held telephonically at the Court's

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

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

Chambers in Washington D.C. on 25 May 2007. Hearing Transcript (“Tr.”) at 1. Whereupon, the Court heard from medical expert witnesses for both parties: Dr. Marcel Kinsbourne for the Petitioner, and Dr. Max Wiznitzer 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 Petitioners have satisfied the pleading requisites found in § 300aa-11(b) and (c) of the statute, by showing that: (1) they are the valid legal representatives of the injured party, Benjamin J. Zeller; (2) the vaccine at issue is set forth in the Vaccine Injury Table (42 C.F.R. § 100.3); (3) the vaccine was administered in the United States or one of its territories; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 16 requirement that the petition be timely filed have been met. On these matters, Respondent tenders no dispute.

The Vaccine Act authorizes the Office of Special Masters to make rulings and decisions on petitions for compensation from the Vaccine Program, 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 Benjamin’s medical records, there is, unsurprisingly, a pronounced conflict between the parties on certain factual issues of interpreting Benjamin’s medical records and viewing understood scientific mechanisms of vaccine injury within the context of those medical records. Considering these disputes and the Court’s commission to resolve them, it behooves the Court to explain the legal standard by which factual findings are made.

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 or obtains. Put another way, it is required that a special master, “believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence.” *In re Winship*, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Moreover, mere conjecture or speculation does not meet the preponderance standard. *Snowbank Enterprises v. United States*, 6 Cl. Ct. 476, 486 (1984).

This Court may not rule in favor of a petitioner based on his asseverations alone. This Court is authorized by statute to render findings of fact and conclusions of law, and to grant compensation upon petitions that are substantiated by medical records and/or by medical opinion. §§ 12(d)(3)(A)(i) and 13(a)(1).

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

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

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

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

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

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

A. MEDICAL RECORDS *ET AL.*

The Court turns first to the recorded facts drawn from the medical records engendered and maintained by those responding to, and treating, Benjamin's condition:

The medical records indicate that Benjamin suffered from a static encephalopathy³ and microcephaly⁴ beginning around the time of birth, as recorded when he was seven months old, on 16 June 2004. Petitioners' Exhibit (Pet. Ex.) 5 at 255. At that time, according to the medical record, under the heading "Growth & Development," Benjamin was able to "reach[] and transfer[]," "roll[] back to front," "sit[] with support," bear weight, "react[] to strangers," and had "no head lag." *Id.* At that time, Benjamin underwent CT scanning to assess his static encephalopathy, microcephaly, and nystagmus.⁵ Pet. Ex. 5 at 180. The CT scan of the brain showed normally-sized and -configured

³ A "static encephalopathy" is a non-progressing "degenerative disease of the brain" in which the degeneration at issue has slowed or ceased. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 610.

⁴ "Microcephaly" is "abnormal smallness of the head, usually associated with mental retardation." DORLAND'S, *supra*, at 1151.

⁵ "Nystagmus" is "an involuntary, rapid, rhythmic movement of the eyeball, which may be horizontal, vertical, rotary, or mixed, i.e., of two varieties. Lateral nystagmus is that "which the movement of the eyes is from side to side. DORLAND'S, *supra*, at 1296.

ventricles,⁶ but evinced some unconfirmed “very tiny calcifications in the left putamen⁷...[which] may just be random mottle.”⁸ *Id.* As a general impression, the reporting doctor noted that Benjamin’s head was not obviously microcephalic, and that the “tiny densities ... in the region of the left putamen ... could represent very tiny calcifications.” *Id.*

By mid-September 2004, Benjamin was noted to be dragging his leg “side to side” when he crawled, and the treating doctor recommended follow-up with a neurologist and an “ortho”, which the Court interprets as orthopedic specialist. Pet. Ex. 5 at 243. Benjamin also suffered from nystagmus (*Id.*; Pet. Ex. 5 at 147) and a diaper rash (Pet. Ex. 5 at 146), although it remains unclear what relation those conditions may bear to the issues in dispute here.

By 20 September 2004, Benjamin was admitted to the hospital (West Boca Medical Center) due to a developing history of “eyes shaking”, for which he was given eye drops. Pet. Ex. 6 at 88. The Admission Assessment from that visit is useful because it notes several then-current facts about Benjamin’s developmental condition. It notes that both of Benjamin’s feet were “turned out” and “not straight”. The nine-month group of developmental markers (the closest to Benjamin’s age at that time) did not have a check mark in the field accompanying the phrase “Initially shy with strangers.” *Id.* at 89. It did have a check mark next to “Imitates speech sounds,” but a hand-written note of “NO” was scrawled immediately next to the check mark (*Id.*), which the Court takes to mean that Benjamin did not imitate speech sounds at that time. There is a check mark, without further notation, on the next entry, marked “Able to clap hands” (*Id.*), which the Court takes to mean that Benjamin was able to clap hands at that time. Lastly, on the final entry, marked “Pulls self to stand,” there is no check mark in the corresponding box, and another hand-written note immediately adjacent reads “NO” (*Id.*), which the Court interprets as indication that Benjamin was not pulling himself to stand. At the bottom of that field are two potential assessments with check-boxes next to each. For the entry of “Patient demonstrates age appropriate development,” there is a check mark that was scribbled out, and the entry “Patient’s development delayed” is checked off; immediately to the right there is a hand-written note indicating that Benjamin does not sit up or stand. *Id.*

Respondent’s expert has argued that the note of “NO” written next to the entry of “imitates speech sounds” is also a negation of the entry “able to clap hands.” Tr. at 110. The Court rejects this argument. It appears from the Court’s review that placing a check mark on “Imitates speech sounds” was an error, sought to be corrected by that hand-written notation. The document’s other entries (“Initially shy with strangers” and “Pulls self to stand”) demonstrate that the official completing the form knew that leaving the box unchecked indicated a negative response. In fact, regarding the last entry of “Pulls self to stand,” the box was left unchecked and a notation of “NO”

⁶ Ventricles of the brain are “cavities within the brain that are filled with cerebrospinal fluid, including two lateral ventricles ([the] *ventriculus lateralis cerebri*), the third ventricle ([the] *ventriculus tertius cerebri*), and the fourth ventricle ([the] *ventriculus quartus cerebri*). DORLAND’S, *supra*, at 2030.

⁷ The “putamen” is “the larger, darker and more lateral part of the lentiform nucleus, separated from the lateral globus pallidus by the lateral medullary lamina.” DORLAND’S, *supra*, at 1549.

⁸ “Mottling” is “spotting with patches of color.” DORLAND’S, *supra*, at 1176. The Court understands this as a reference to suspicion to interference spots on the film itself, as opposed to an actual physiologic finding.

was added as well, which militates against reading the former “NO” notation as negative for the whole series following. Were the initial “NO” sufficient for all of the following entries (even though written as a superscript abutting the apparently misplaced check mark), it would be redundant and superfluous to repeat the notation two entries later. Respondent’s expert’s argument does not require medical knowledge to refute, but is a simple issue of textual interpretation.

In the same Admission Assessment, the medical personnel performed a “Special Needs Screening” and a “Functional Screening,” concluding that Benjamin had “No Problems” with either Hearing or Speech, and that there was no “Decline in functional status.” Pet. Ex. 6 at 91. The Nurse’s notes from that visit noted “knowledge deficit” and “neurologic” problems in her multidisciplinary plan of care, but stated that the “neuro[logic]” issue noted was “stable” at that time. *Id.* at 96.

At a pediatric neurology consultation coincident to that same admission on 20 September 2004, referred thereto due to “nystagmus, developmental delay [and] microcephaly,” Dr. Susan Shulman noted the “history of developmental delay ... [with] microcephaly”. Pet. Ex. 6 at 34. Much of what Dr. Shulman transcribed is difficult to decipher, some of it prohibitively so. She appears to reference a “gross motor delay,” adding some potential etiologies that could provide causative explanations for the delay. *Id.* She notes that Benjamin suffered from “horizontal nystagmus [but [that he] has good fixation and tracing [*sic*],” such that he “smiles socially.” *Id.* She also adds that he has “no history of seizures.” *Id.* Later in the record, Dr. Shulman notes a “small gross motor delay,” in addition to the microcephaly and nystagmus, and speculates that the condition is linked to a “glucose transporter deficiency.”⁹ *Id.* Later, she observes that Benjamin showed “poor weight gain,” but that, “otherwise, his parents feel he has been developing well” with “no systemic manifestations.” Pet. Ex. 6 at 35. In her progress notes from that visit, she repeats the parental clinical history, that “when he crawls he drags his legs,” and once again mentions “horizontal nystagmus and microcephaly.” Pet. Ex. 6 at 41. There she also explained that Benjamin’s “feet turn out,” that he has “tight heel cords,” that he has neurological problems as previously noted, but that he showed “otherwise intact development” that was “appropriate for age.” *Id.*

Also on 20 September 2004, Benjamin underwent magnetic resonance imaging (MRI) to assess his nystagmus. Pet. Ex. 5 at 149. Part of the focus of that testing, based upon the report composed, seemed to be on the optical areas of the brain, due to concern with Benjamin’s nystagmus and its potential connection to a problem with his optic nerve(s). However, beyond some “minimal mucosal disease ... in the ethmoid¹⁰ air cells,” the testing evidenced “No significant MR abnormalities of the orbits, upper facial structures, or intracranial portions of the optic tracts.” *Id.* MRI testing further represented that Benjamin’s cerebral ventricles were “normal in size and

⁹ “Glucose Transporter Deficiency” is an condition in which “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.” *Banks v. Secretary of HHS*, Case No. 02-0738V, 2007 WL 2296047, *8 (Fed. Cl. Spec. Mstr. Jul. 20, 2007).

¹⁰ “Ethmoid” cells are those which are “cribriform” or “sievelike.” DORLAND’S, *supra*, at 646.

configuration,” without demonstrating “parenchymal abnormalities.”¹¹ Pet. Ex. 5 at 163. The overall impression was that there were “no MR abnormalities of the brain or adjacent structures,” and that the “myelination pattern is age appropriate,” without “focal lesions.” *Id.* Another, possibly separate, round of MRI testing was performed, also dated 20 September 2004, ostensibly to follow-up on the CT scans discussed *supra*. Pet. Ex. 5 at 95. That testing showed “no intra-axial or extra-axial hemorrhage,” “no areas of abnormal CT density,” “no mass effect or shift of the midline,” and ventricles and cortical sulci¹² that were “within normal limits.” *Id.* The impression was concluded as “normal”, stating, “The previous examination of 6-17-04 had raised the question of possible tiny calcifications in the basal ganglia,”¹³ but that “these [were] not identified [in that] examination.” *Id.*

On 4 October 2004, Benjamin was seen for another pediatric neurological consultation, this time with Dr. Adel Helmy, who, it seems, did not have the advantage of viewing Benjamin’s previous medical records. Pet. Ex. 5 at 77. She states:

The great aunt stated that the patient is here today, because she had a concern that the eyes were going from one side to the other and when she told the pediatrician about this episode, the baby was taken to West Boca Medical Center. The baby was hospitalized for 3 days[;] according to the aunt[,] he had further work up that included CT, MRI and other testing. ... I believe that the patient has nystagmus that is well apparent in both eyes, especially the right eye[;] it is horizontal nystagmus. I believe he cannot see and this is why he has the nystagmus, because he is trying to fixate. I am wondering if the patient can hear or not...

Id. Under “developmental history,” Dr. Helmy states that, “There is a history of delay[;] the patient is not sitting up on his own, [and] he is not crawling.” *Id.* Her impression was that of “Developmental delay and with [*sic*] possible perinatal infection with horizontal eye nystagmus, possible torch infection.” *Id.* at 75.

The Court reads Dr. Helmy’s report *cum grano salis* due to its facial inconsistency with the weight of the other filed medical records from over Benjamin’s course of treatment. Dr. Helmy’s beliefs, that Benjamin could not see, sit or crawl, along with the suspicion of deafness, are simply incredible when taken in conjunction with the medical records before and after that visit. As noted, only two weeks before, at the West Boca Medical Center, the records reflect Benjamin’s parents’ concern that *when he did crawl*, he dragged his leg. Pet. Ex. 6 at 41. Likewise, Benjamin was perceived to have adequate vision in previous and subsequent medical records. *See infra*. To be fair to Dr. Helmy’s report, it is apparent throughout that Benjamin’s foregoing medical records, test results, and diagnoses were not available at the time of that evaluation. Pet. Ex. 5 at 77.

¹¹ The “Parenchyma” is “the [functional] elements of an organ,” “as distinguished from its framework, the stroma.” DORLAND’S, *supra*, at 1371.

¹² A cortical sulcus is “a groove, trench, or furrow” in the cerebral cortex. DORLAND’S, *supra*, at 1785-86.

¹³ The basal ganglia, or “nuclei basales” are “specific interconnected groups of masses of gray substance deep in the cerebral hemispheres and in the upper brain stem.” DORLAND’S, *supra*, at 1284.

At Benjamin's twelve-month visit on 17 November 2004, Benjamin's nystagmus was assessed in the "Interval History" section to be "much better... once in a while." Pet. Ex. 5 at 236. Later on, in the "General Appearance" section, in the field space corresponding to the category/phrase "Eyes", the doctor noted that there was no nystagmus at that point ("θ nystagmus now"). *Id.* The Court reads these two entries in conjunction to mean that Benjamin's nystagmus had improved, such that on the pediatrician's observation, it was absent, and Benjamin's parents reported observing evidence of such condition only "once in a while." Also in the General Appearance section, the pediatrician made note under "Extremities" of a "poor [turned] toe [and] tight heel cords," and noted under the "Neuro / Dev[elopment]" category that Benjamin was at the "lower ext[remities]." *Id.* Nevertheless, Benjamin was assessed as well and awaiting a visit with a Doctor Jefferson about one month later. *Id.* It was on that date, 17 November 2004, that Benjamin received the vaccination at issue. Tr. at 36.

From the same 12-month visit, under the heading of "Growth and Development," in the field spaces corresponding to the phrases "walks with support or alone" and "Plays Peek-A-Boo," the examining pediatrician wrote "No". Pet. Ex. 5 at 236. However, the field is checked that corresponds to the phrase "Gives hugs," the word "Dada" is circled from the phrase "Uses Mama & Dada correctly," and the word "clap" is added after the phrase "Plays Peek-A-Boo." *Id.* The rest of the phrases and their corresponding field spaces were left unmarked. *Id.* From these notations, it appears that, although Benjamin was not walking with support or alone, was not throwing objects or giving them upon request, was not using a mature pincer grasp, was not making 1-3 words or meaningful words, was not playing peek-a-boo, and was not using the word "Mama" correctly; even still, he was giving hugs, clapping, and using the word "Dada" correctly. *See also* Pet. Ex. 5 at 11 ("Benjamin was babbling as an infant and had the "da-da" sound at 12 months of age ... and then had this sudden regression in developmental milestones shortly after receiving [his] vaccinations"). Regarding Pet. Ex. 5 at 236, at the hearing, Petitioner proffered an interpretation that the notation of "NO" next to the phrase "walks with support or alone" (admittedly quite sloppily-written) was actually an affirmative check and circling of that entry; however, a close reading leads to the conclusion that it is indeed the word "no". Respondent's expert believed at the hearing that the note of "NO" written next to the entry of "Plays Peek-A-Boo" is also a negation of the hand-written entry "Clap". Tr. at 64, 110. However, the Court's reading, after analyzing the document, is that, even though Benjamin was not playing peek-a-boo, he was able to clap, rather than that he was unable to do either.

The next pertinent medical records in this case are emergency records from the City of Deerfield Beach, dated 27 November 2004. Pet. Ex. 15. According to those records, the Zellers contacted emergency service personnel at 6:49 PM on 27 November, who arrived approximately six minutes later, at 6:55 PM, before departing with Benjamin ten minutes later, at 7:05 PM. *Id.* at 1. Benjamin then arrived at the hospital at 7:10 PM, approximately twenty minutes after the emergency call was initiated. *Id.*

The emergency responders found his skin temperature to be "hot", but noted otherwise that he appeared "within normal limits." *Id.* Although the dispatch was for "cardiac arrest," the emergency responders designated its emergent nature as "seizure". *Id.* The narrative portion of that report notes the clinical history, as received by Benjamin's father, that he "suddenly stiffened up and

turned blue for approx[imately] 45 sec[onds] just prior to calling 911.” *Id.* at 4. That statement also notes that, upon arrival, although Benjamin’s vital signs were good, he “initially appeared to have a [left-]sided gaze[,] but [] was able to respond to noise and touch” within minutes of the emergency crew’s arrival. *Id.* Within the same narrative summary section, in the section regarding transport, there appears the following notations: “During transport – [Patient] sta[r]ted to clear / Op A (L) sided ??? Gain. Temp. EKG Temp 98.8 / 102.9 Neck / at ER [Benjamin] was exposed for cooling upon [] arrival”. *Id.* From these notations, the Court gathers that Benjamin continued somewhat his left-sided gaze noted by the paramedics when they arrived.

Upon arrival at the hospital, the chief complaint listed was that after receiving one-year immunizations seven [*sic*] days previous, that day Benjamin “tensed up and ‘turned blue’ around [the] lips,” and that, at the time the first responders arrived, there was no seizure activity, he was of “pink color” and “crying well,” and was taken to the emergency room for evaluation. Pet. Ex. 16 at 4. As a “current and associated symptom” the same document, engendered at 7:30 PM, records Benjamin’s temperature at 99.7 degrees “at home.” *Id.* The Emergency Department record from 7:39 PM lists fever and seizure as the primary and secondary complaints, respectively, and records Benjamin’s temperature at 102.9 degrees Fahrenheit by rectal measurement. Pet. Ex. 16 at 5. That document reiterates the clinical history that: “Per EMS, Father stated, [Benjamin] [stiffened] up and became blue for about 45 seconds.” *Id.*

There is some question regarding the antecedent(s) modified by that prepositional phrase, “for about 45 seconds.” Respondent urges the construction that the duration of Benjamin’s stiffening *and* his cyanosis both together lasted only 45 seconds, whereas Petitioner advocated that the phrase modifies the latter symptom only, and that the record is silent on the duration of the stiffening. Tr. at 42-43.

On the Physical Exam/Constitutional Report composed some hours later, under the phrase “vital signs”, was recorded “102.7 / USS,” and the interpretation of Benjamin’s condition was abnormal, with fever. Pet. Ex. 16 at 3. Although much of the form bears non-descript check marks, there are no irregular marks of note. The clinical impression stated is “(1) fever from MMR vaccine[:]; (2) febrile seizure.” *Id.*

The next day, on 28 November 2004, Benjamin was seen by his pediatrician again, this time for urgent care, with recorded chief complaints of “seizure, stuffy nose, and fever.” Pet. Ex. 5 at 231. The history of the illness taken (presumably) from Benjamin’s parents, was that the fever lasted for four days, and rose up to 98.9 degrees, with a maximum temperature of 99.2 degrees, taken rectally. *Id.* It is likewise noted that the 102.7 degree temperature was recorded in the hospital. *Id.* He is also noted to have suffered a lowered appetite for a few days. *Id.* It then states that he suffered a “sudden onset of L[oss] O[f] C[onsciousness], turned blue,” and then was administered “CPR by [the] nurse [who lived] next door,” after which, he “revived.” *Id.* The records states that there was no “shaking”, that it “lasted [less than] [four] minute[s], and that during the postictal stage, Benjamin was “out of it.” *Id.* The diagnosis was Benjamin’s first “febrile seizure.” *Id.* Under the “plan of action” heading, the pediatrician stated there were “muscle tone problems [and a] developmental delay,” and that Benjamin was not yet crawling. *Id.*

Benjamin visited a rehabilitation clinic for an evaluation on 6 December 2004, due to the fact that he was “not crawling or sitting.” Pet. Ex. 5 at 87. The summarized findings were that Benjamin functioned “at the gross motor level of a 5-6 month old,” and that his reflexes were “delayed”. *Id.*

On 13 December 2004, Benjamin was admitted to Miami Children’s Hospital, and was not discharged until 22 December, with diagnoses of “seizure disorder,” “encephalopathy”, “developmental delay,” and “respiratory syncytial virus positive bronchiolitis.”¹⁴ Pet. Ex. 7 at 108. Per the parents’ clinical history, Benjamin acted noticeably differently three to four days after the MMR vaccination, by “sleeping more” and by being “less active than before.” *Id.*

There seems to be a factual issue between the medical records, as the timing recounted by the Miami Children’s Hospital records does not seem to jibe with those preceding them. First, the account from Miami Children’s states that “seizure activity occurred approximately a month after the MMR [vaccination].” *Id.* The parties agree that the MMR vaccination from that period was administered on 17 November 2004. A month from that date would have fallen about halfway through Benjamin’s stay at Miami Children’s Hospital, which is certainly not the case. Second, that account also states that, “The first seizure occurred 8 to 10 days prior to the admission to Miami Children’s lasting 1 to 2 minutes.” *Id.* If, by the notation at the top of the same page, Benjamin was admitted to Miami Children’s Hospital on 13 December 2004, that would place the first seizure between 3 and 5 December 2004. Suffice it to say that the Miami Children’s Hospital’s official records are valuable for what they say concerning the time that Benjamin was actually at that facility, and are of lesser use—or potentially no use at all—for what they purport to recount from before that stay. The Court therefore takes the following statements of that recounting *cum grano salis*:

The seizures were referred [to] as being tonic followed by some apnea, eyes diverted towards the left and eyes tilted in the same direction [*sic*]. This was not associated with any fever. It seems that shortly after the MMR, the child did have some fever but [at] that time no seizure activity had been documented.”

Id.

As stated, that medical record is useful for its description of Benjamin’s course of treatment at that specific hospital; the section titled “hospital course” indicates that Benjamin

was evaluated by the Department of Neurology as well as Genetics and Metabolic Diseases. Significant workup has been initiated which includes an MRI of the brain. The conclusion of that MRI showed “findings of white matter signal abnormality and delayed myelin deposition.” [Among several other disorders,] Hypoxic ischemic disease¹⁵ cannot be totally excluded, and *follow up is recommended to differentiate neurodegenerative disease from a static encephalopathy.*

¹⁴ “Bronchiolitis” is “inflammation of the bronchioles,” which are “the finer subdivisions of the branched bronchial tree, 1 mm or less in diameter, differing from the bronchi in having no cartilage plates and having cuboidal epithelial cells.” DORLAND’S, *supra*, at 252-53.

¹⁵ Hypoxic ischemia is the insufficiency of oxygen and blood in body tissues, “occurring in tissues when the blood supply is cut off, particularly in a fetus or infant with asphyxia.” DORLAND’S, *supra*, at 900, 954.

Pet. Ex. 7 at 108-09 (emphasis added). From a radiology consultation during the same hospital stay at Miami Children's Hospital, there were findings of "signal abnormality of the white matter which is symmetrical and diffuse," thinning of the corpus callosum,"¹⁶ prominence of the lateral ventricles, and "delayed myelin deposition." Pet. Ex. 7 at 120.

A physical examination at Miami Children's Hospital on 13 December 2004 assessed Benjamin as a thirteen-month-old with "new onset" seizures and developmental delay, recording that, at that time, Benjamin could not "sit up" but was able to say "Da-Da." Pet. Ex. 7 at 111-112. In the history section, Benjamin's November seizure was described as an "apneic episode,"¹⁷ after which he was stable until 12 December 2004, when suddenly his "eyes diverted to [the left], [his] head tilted," he was nonresponsive to stimuli, and he became stiff, which lasted about one minute, and recurred five or six times. Pet. Ex. 7 at 111. However, there was no fever associated with those episodes. *Id.*

In progress notes taken 17 December 2004, the reason Benjamin went to Miami Children's Hospital was described as "episodes of head drop and [hypotonia of the upper extremities], unresponsiveness, and eye staring lasting [approximately thirty seconds]," and the incidence noted included both the initial seizure in November and the series of seizures requiring hospitalization in December. Pet. Ex. 7 at 306. The same document also references his history of nystagmus. *Id.* Elsewhere, in progress notes from the same day, Benjamin's condition was said to include "developmental regression and seizures," in addition to the preexistent "encephalopathy → microcephaly." Pet. Ex. 7 at 317.

Certainly of note are the results of "nuclear SPECT¹⁸ brain imaging" that left Richard Neubauer, M.D. with the impression of "Acute encephalopathy due to adverse vaccine reaction" on 12 January 2005. Pet. Ex. 14 at 1.

By the beginning of January 2005, it appears that Benjamin's family began to suspect that the uptick in neurological problems was vaccine-related. Benjamin's pediatrician was contacted to compose a letter averring that the seizures *et al.* initiated following the MMR vaccination. Pet. Ex. 5 at 224. The same notations relate that, according to his family, Benjamin's "seizures were [worsening, such that] he had 8 in an 45 minute time frame." *Id.* The pediatrician then prepared the VAERS form (*Id.* at 225), which summarizes that "MMR [and] varivax given on [17 November 2004]," that Benjamin's adverse event "began with a seizure [on 27 November 2004], that "he had done well," but that "on [12 December 2004] he was admitted for intractable seizures," for which he spent eleven days at Miami Children's Hospital. *Id.* at 226. Dr. Shulman, in completing the

¹⁶ The "corpus callosum" is "an arched mass of white matter, found in the depths of the longitudinal fissure, composed of three layers of fibers, the central layer consisting primarily of transverse fibers connecting the cerebral hemispheres; its subsections, from anterior to posterior, are called the rostrum, genu, trunk (truncus), and splenium." DORLAND'S, *supra*, at 421.

¹⁷ "Apnea" is "cessation of breathing." DORLAND'S, *supra*, at 115.

¹⁸ "SPECT" stands for "single-photon emission computed tomography." DORLAND'S, *supra*, at 1730.

form, notes that Benjamin's temperature was "102 degrees after the first seizure," but that there were "no other fevers [with] subsequent seizures." *Id.*

The rest of the relevant medical records are all from Miami Children's Hospital in the early part of 2005. At a visit on 26 January 2005, Benjamin's parents reiterated their recollection in the clinical history that, in the period three or four days following the MMR administration, "he seemed less active and he was sleeping more than usual." Pet. Ex. 7 at 79. The same history also repeats the previous understanding of the Miami Children's Hospital staff, that "three weeks after his immunization, he had his first seizure described as tonic activity with eyes diverted toward the left and lasting for about one-to-two minutes," as well as the fact that "he had further seizures" while admitted to Miami Children's Hospital. *Id.* At that time in January of 2005, apparently, Benjamin was suffering "almost every[] day or every other day...[or] three to four episodes in a day" a "tonic stiffening of the body," wherein his eyes would "roll up." Pet. Ex. 7 at 80. Of especial note, the record goes on to state that Benjamin "has some developmental regression as he started to sit with minimal support by thirteen months of age [] and today they mentioned the he is not sitting up anymore," and that he was, at that time, "unable to take steps and no speech is noted." *Id.* Likewise, Benjamin "was unable to fixate and no proper tracking of objects was noted," although there was no indication of the previous nystagmus either. *Id.* Benjamin did "pay[] attention to voices," however. *Id.* By that time, Benjamin's head circumference of 42.5 cm was "below the 2nd percentile." *Id.*

The basic impression from the visit calls into question Benjamin's parents' attribution of Benjamin's seizure disorder and developmental delay to the MMR vaccination, noting that his previous history of "developmental delay, microcephaly and history of nystagmus" undercuts that diagnosis in the doctor's mind. Pet. Ex. 7 at 81. As to a definitive answer on the essential question of etiology however, the doctor was silent, beyond referencing a "white matter disease," because the testing and evaluations performed "remain[ed] inconclusive," such that "the etiology of his symptoms [was] still unknown." *Id.* That doctor sent Benjamin to a genetics evaluation, also on 26 January 2005, which proved to be of little utility, and provided no guidance on etiology. Pet. Ex. 7 at 82; *see also* Pet. Ex. 5 at 12.

At a neurologic evaluation on 13 April 2005, the consulting doctors stated, perhaps based upon history received from Benjamin's parents, that Benjamin reached "normal developmental milestones in that he smiled at 2 months, but by 6 months it was noted that he was unable to sit independently and he was not crawling," and that he "was standing and walking alone at 12 months of age prior to receiving the immunization ... and then had this sudden regression in developmental milestones shortly after receiving [his] vaccinations." Pet. Ex. 5 at 10-11. By that point, it was discerned that Benjamin's frequency of seizures was related to his incidence of febrile illness, which were frequent (at least in the weeks preceding that visit). *Id.* at 9.

The examining doctors relate that by that point, Benjamin had undergone "an extensive neurological workup" over the course of Benjamin's life, producing several medical records, some of which Mr. Zeller raised concern over due to what he noted as contradictions and/or inconsistencies in some of the records, uncorroborated by Benjamin's actual condition at the time to which they relate. Pet. Ex. 5 at 11. That record repeats consistently throughout that Benjamin's

appearance was similar to children suffering from “failure-to-thrive”, in his medical course and even in his physical countenance, adding that Benjamin “will briefly fixate, but does not track well at all,” although he was observed to respond to the voice of his father. *Id.* at 11-12.

The doctors also noted that Benjamin had “poor head and truncal control with increased tonicity¹⁹ in the lower extremities compared to the upper extremities.” *Id.* at 12. While in the examining room, the doctors observed “four episodes back-to-back in which he had sudden tonic jerks involving the upper extremities with a head drop lasting for 1-2 seconds at a time.” *Id.* They concluded that, “Clearly this is a child that is having clinical events that appear to be seizures” concurrent with “a febrile illness at [that] time.” *Id.*

On 16 April 2005 at Miami Children’s Hospital, Benjamin was assessed as suffering from “acute encephalitis²⁰ and white matter disorder” that was attributed as a “likely encephalopathy [after] vaccin[ation]” or that was “otherwise likely [caused by a] viral syndrome.” Pet. Ex. 7 at 559.

By 19 May 2005, perhaps in response to the father’s account that “everything started after [Benjamin] got the MMR and Varivax [vaccines] at 1 year of age,” the infectious disease staff checked Benjamin’s immunoglobulin levels via serum titer testing. His measles and mumps serum titers tested positive for IgG, but not for IgM; moreover, they were surprised to find that both the IgG and the IgM for rubella were both negative in the serum, indicating that Benjamin “did not respond to the rubella vaccine.” Pet. Ex. 5 at 14. Within Benjamin’s cerebrospinal fluid, “the rubella and mumps titers were negative, but the titers for measles for IgG were slightly positive but quite below the serum level and the IgM was negative.” *Id.* This testing was said to have been performed because the consulting infectious disease doctors wondered whether “he could be suffering from encephalopathy after vaccine as a chronic problem, and then, having a viral infection [at the time of his hospital visit] on top of everything else,” and so “they decided to obtain the IgG and IgM studies ... in order to evaluate the immune status of the patient with relation to these particular immunostudies.” Pet. Ex. 7 at 444.

Upon physical examination, Benjamin appeared “a significantly delayed child with significant hypertonicity that is worse in the lower extremities than in the upper extremities[, who] does not walk, [] does not sit up, [] does not roll over.” Pet. Ex. 5 at 14. Their diagnosis was “mental retardation, developmental delay and hypertonicity.” *Id.* at 15. They were unable to affirm the potential diagnosis of “subacute sclerosing encephalitis,”²¹ a condition which, in the treating doctors’ minds, appeared to be linked to the MMR vaccine in particular. *Id.*; Tr. at 23-24. Another MRI performed at that time, when compared to the MRI conducted in December 2004, “demonstrated progressive cerebral atrophy,” and led to “findings likely representative of neurodegenerative disorder.” Pet. Ex. 7 at 443-44. Benjamin’s discharge summary from that stay

¹⁹ “Tonicity” is “the state of tissue tone or tension.” DORLAND’S, *supra*, at 1920.

²⁰ “Encephalitis” is any “inflammation of the brain.” DORLAND’S, *supra*, at 608.

²¹ “Subacute sclerosing encephalitis” is brain inflammation that involves “an induration or hardening, such as hardening ... from inflammation.” DORLAND’S, *supra*, at 608, 1668.

at Miami Children's Hospital states that he "regressed to [a developmental stage coordinate to a child of] 3 months of age 10 days after receiving his MMR shots," and "now currently has significant global delay." *Id.* at 443.

Lastly (for the purposes of determining entitlement), Benjamin was examined to evaluate his vision on 21 July 2005, upon concerns that Benjamin's optic nerves were not developing well or correctly. Pet. Ex. 7 at 84. Contrary to what specialists of other fields had said, the examination found that Benjamin did "fixate and follow with each eye ... with no obvious nystagmus or fixation preference." *Id.* In fact, Benjamin was found "to have reasonably good visual function given his global delay." *Id.* Regarding the concern for his optic nerves, they were observed to be "borderline small although there is healthy, pink, neural rim tissue present," although, taken together with other observations, "does give the illusion of a 'double-ring sign.'" *Id.* Even though Benjamin's optic nerves were "not overwhelmingly impressively small," but were "at least 80% of normal size," the overall impression given was "borderline optic nerve hypoplasia."²² *Id.*

B. TESTIMONY AT THE ENTITLEMENT HEARING

1. Marcel Kinsbourne, MD

At the hearing, Dr. Kinsbourne was welcomed by the Court as undeniably qualified in expertise to testify as a pediatric neurologist, and Respondent stipulated by accepting him as a pediatric neurologist without cavil or question on voir dire. Tr. at 5.

Dr. Kinsbourne stated on the issue of whether the vaccine in question could cause neurologic damage, that "there is reliable medical scientific evidence that the MMR vaccine can cause seizures, particularly in the second week after it has been administered," and agreed that Benjamin's first seizure occurred "ten days after vaccination." Tr. at 6-7.

Dr. Kinsbourne described the overall course of Benjamin's development by summarizing, "although he presents a general picture of an early static encephalopathy and developmental impairment, [he] did have some development of an age-appropriate nature." Tr. at 8. And, even though "his brain was not within the normal range," his abilities did increase over time in the first year of life" before heading "downhill after the vaccination." Tr. at 25. In the earlier stage, by Dr. Kinsbourne's scenario, Benjamin's "head would continue to grow, but more slowly, so that [the head growth curve] would take its own upward trajectory at a more gradual slope[;] rather than [tracking the] slope of the mainstream," instead "it is flatter than the rate of normal progress." Tr. at 33-34.

On direct examination, Dr. Kinsbourne briefly summarized the course of the medical records, most of which are discussed *supra*. Regarding the leg dragging noticed by Dr. Shulman, Dr. Kinsbourne categorized it as evidence of a "static neurological injury." Tr. at 10. Dr. Kinsbourne

²² "Hypoplasia" is "incomplete development or underdevelopment of an organ or tissue," and is differentiated from "aplasia" by being less severe. DORLAND'S, *supra*, at 897.

synthesized these indicia in his mind to conclude that, up until his vaccination, Benjamin was “still in a way holding his own,” i.e., he was maintaining a progressive developmental growth rate, despite his early setback of microcephaly and static encephalopathy. Tr. at 11.

Regarding the first seizure reported in the medical records, which followed vaccination by ten days, Dr. Kinsbourne gave his interpretation as follows:

When the EMS arrived, the baby was breathing again. However, when the EMS arrived, the baby still was not immediately responsive and his eyes were turned to the left, and it took several more minutes before the baby in fact responded to sounds and other stimulation.

I'm relating this because it tells me that the total seizure event, although in the record said to have lasted something between 45 seconds and 2 minutes, must have lasted considerably longer than that for the child to be [cyanotic],²³ for the neighbor to be procured, for the CPR to be administered actually several times, and then for there still to be signs of the seizure when the EMS came.

Tr. at 12. Dr. Kinsbourne concludes that “the seizure was still going on when the EMTs arrived ... because [they arrived in time to observe Benjamin’s] eyes were turned to the left.” Tr. at 41. This is significant, first because Benjamin’s history of seizures include “looking to one side [a]s a feature” (Tr. at 41-42), and because “it is a focal feature” (Tr. at 48). He was adamant that the left-sided gaze observed by the paramedics was not attributable to the post-ictal state, but was a tell-tale manifestation of continued seizure activity. Tr. at 44. Neither was it attributable to the nystagmus that had affected Benjamin: “It’s a totally different phenomenon, comes from a totally different part of the brain.... They didn’t see nystagmus, or they would have said so.” Tr. at 45-46.

Dr. Kinsbourne noted the change in differential diagnosis from “static encephalopathy” to “neurodegenerative disease” in December of 2004, after Benjamin started to have significant seizures, and explained that, whereas “up to the time of the vaccination, [Benjamin’s diagnosis was] static encephalopathy from damage at or before birth,” subsequently “the situation is changed” in that Benjamin was “losing ground” such that neurodegeneration was suspected. Tr. at 16. However, even when “a full neurological workup” had been performed, the results “had not validated the diagnosis of a neurodegeneration.” Tr. at 17. Hence, even in 2005, “the etiology of his symptoms [remained] unknown.” Tr. at 18. Dr. Kinsbourne views the turning point at or soon after the date of vaccination: “Well, there is no question that he had developmental delay probably from the start, which was interpreted as static encephalopathy. And then after the immunization, his development actually fell off...”. Tr. at 20. Dr. Kinsbourne placed the first diagnosis of acute encephalopathy in the medical records at 13 April 2005, in Pet. Ex. 7 at 442. Tr. at 21. Regarding the impression of “encephalopathy after vaccination, with secondary seizure disorder” given in the medical records (Pet. Ex. 7 at 444), Dr. Kinsbourne explained:

They take it to be the case that although he had some static neurological damage long before, that the event at the time of the seizure caused by the MMR did allow, lead

²³ “Cyanosis” is “a bluish discoloration, especially of the skin and mucous membranes due to excessive concentration of deoxyhemoglobin in the blood.” DORLAND’S, *supra*, at 455.

to encephalopathy. And the fact that the encephalopathy had occurred was taken to his explanation for his losing ground quite dramatically developmentally thereafter.

Tr. at 23.

Dr. Kinsbourne explained his theory of causation thusly: that, (1) based upon the medical literature extant, the MMR vaccine can cause seizures “during the timeframe that Benjamin had his seizure;” (2) that Benjamin presented a special case because he was already weakened or compromised due to his underlying conditions (static encephalopathy and microcephaly), which may also have included a “predisposition to a seizure disorder;” (3) it was, however, a fact that Benjamin had suffered from no seizure activity (febrile or afebrile), despite experiencing his share of occasional fevers, prior to the MMR vaccination; and (4) that “when the MMR was given and did cause a seizure, that was the start of a refractory intense seizure disorder which continues to the present day. Tr. at 24. Consequently, Dr. Kinsbourne concludes that “the MMR vaccine triggered the seizure disorder in Benjamin Zeller.” *Id.*

On cross-examination, Dr. Kinsbourne explained in some detail the different ways—acting independently or in concert—that the MMR vaccination could have been a substantial factor in causing Benjamin’s seizure disorder and neurological degeneration:

I am not predicating my opinion on a specific mechanism of injury. The damage could have been done by the shortage of oxygen, which maybe was longer than the father said. Or it could have been done by the MMR vaccine in parallel with the oxygen deprivation, in terms of the mechanism of encephalopathy that I referred to in my report and gave reference to.... [T]here were several circumstances which were potential causes of some brain damage at the time.... He had an encephalopathy caused by the MMR, but I can't tell you whether it was a direct viral one, whether it was immune-mediated, or whether it was secondary to the seizure, or whether it was combination of both.... It manifested itself by the abrupt change in this child's condition from a very slow ascent to a rather more steep descent in his mental development, and with his neurological signs becoming more obvious after the event.

Tr. at 49-52.

One way of understanding Dr. Kinsbourne’s explanation is that the MMR vaccine significantly aggravated an underlying predisposition towards seizures, by initiating the first in a series of increasingly severe seizures as part of “a refractory seizure disorder.” Tr. at 25-26. He cited to filed literature to explain that “in less usual cases where the seizure disorder is intense, where it's refractory to medication, and where multiple medications have to be used, that there is a progressive decline in mental function parallel with progressive damage to the brain.” Tr. at 26.

Dr. Kinsbourne also testified that the MMR vaccine could have caused an acute encephalopathy that could explain the decline of Benjamin’s condition into neurodegeneration and seizures: “We also know that the MMR vaccine on rare occasions can cause an encephalopathy,” of which severity may vary; here, “the encephalopathy came nowhere close to meeting the [Table definition], but nonetheless was enough to tip this vulnerable child into a downward course of [retrogression].” Tr. at 24-25.

Regarding the dispute over the duration of the seizure, Dr. Kinsbourne advocated for a longer duration than 45 seconds, because “seizures that are as brief as 45 seconds to a minute don’t typically have postictal states,” and noted further that “the postictal state is still the reflection of the severity of the seizure.” Tr. at 42. Regarding the duration of that initial seizure, the damage caused thereby, and its propensity to incur permanent sequela, Dr. Kinsbourne reminded the Court that Benjamin “was a neurologically fragile child with a preexisting [condition] and it could well be that the degree of anoxia was enough to cause some impairment of brain function in this particular case.” Tr. at 48. However, he added that any lasting damage might not be immediately apparent, especially against the backdrop of his preexisting condition(s). Tr. at 49.

Dr. Kinsbourne’s testimony also raised the legal question of logic that appears at the crucial legal issue of this case: how, for purposes of analyzing causation, does one perceive a vaccine-related seizure that triggers the onset of a seizure disorder, in a child with a genetic predisposition (or destiny, as Respondent’s expert termed it, Tr. at 117) towards a seizure disorder that had not manifested itself prior to the vaccination?²⁴ He stated:

Sometimes a child who has an underlying seizure tendency or lowered seizure threshold will[,] during an episode of fever[,] have the first of his or her many seizures. In that sense one can say that that first seizure triggered the onset of the seizure disorder.... A child may have a preexisting low seizure threshold, which isn’t actually described as a preexisting neurological condition. It’s sort of a variant, probably genetic in most cases. And if there is for any reason a large seizure threshold, and for example preexisting brain damage may itself not cause a seizure disorder, but may make the child more vulnerable to events that could provoke seizures. And once the seizure is provoked, then others may follow, [once] the seizure disorder has been triggered.

Tr. at 55-56.

2. Max Wiznitzer, MD

Dr. Wiznitzer has testified before the Court on numerous occasions, and is a very knowledgeable and erudite expert in the area of Pediatric Neurology. The Court accepts his testimony into evidence (having heard no *voir dire* objection from Petitioner) as a welcome guide in understanding the facts, circumstances, and events in this case from his expert medical perspective.

Dr. Wiznitzer agrees that Benjamin evidenced signs of neurologic delay before the date of vaccination at issue. Tr. at 60. He also agreed with Dr. Kinsbourne that after some early period of a retarded, though slowly improving development, there was a diminution of development, such that Benjamin’s slow progression early-on was followed by actual retrogression at a later stage. *See, e.g.*, Tr. at 83. The bone of contention arises in that Dr. Wiznitzer perceives the retrogressive,

²⁴ Dr. Wiznitzer’s statement that “this is a child with an abnormal brain and he’s destined to have seizures” obviously raises metaphysical, theological, and doctrinal issues as well. However, that is not the province (or competence) of this Court; therefore, only the legal implications of that assertion are addressed by this Decision.

degenerative process to have begun some time before the vaccination, and to have been an independent process, rendering the vaccination as insignificant and unrelated; whereas Dr. Kinsbourne views the vaccination as the trigger and turning point that initialized the degeneration. According to Dr. Wiznitzer's testimony on direct examination, "[T]here was a neurodegenerative process in place prior to Benjamin being vaccinated" which "also persisted after that time and continued in its course." Tr. at 83.

Dr. Wiznitzer attempted to convince the Court that it should rely solely on the medical records (or his extrapolation from data in the medical records) that support his position, and to ignore the medical records that are not in concordance. Tr. at 64-73. However, the Court's task under the mandate of the Vaccine Act is to glean its conclusion from the medical records (and other filed evidence) as a whole, not through contortion or imagining content therein that is not manifest. See Section 13(b) of the Vaccine Act. Ultimately, the interpretive approach urged by Dr. Wiznitzer amounts to *eisegesis*, reading content and meaning into a document or text, instead of its appropriate judicial task of *exegesis*, reading a text to derive the meaning invested by its author or authors, so as to apply that contextual meaning to the case at bar. See Craig Allen Nard, "A Theory of Claim Interpretation," 14 HARV. J.L. & TECH. 2, 60-61 (Fall 2000); Jeffrey Brauch and Robert Woods, "Faith, Learning and Justice in Alan Dershowitz's the Genesis of Justice: Toward a Proper Understanding of the Relationship between the Bible and Modern Justice," 36 VAL. U.L. REV. 1, 15-16 (Fall 2001); Laura Kalman, "From Slavery to Freedom," 90 GEO. L.J. 161, 163-64 (Nov. 2001). The Court declines to do so here.

Dr. Wiznitzer's analysis of the seizure on 27 November 2004 involves several vectors of approach, including further critical textual analysis of the medical records, reference to his own experience treating and counseling patients, and testing the medical theoretical plausibility of Dr. Kinsbourne's theory against his conclusions in both. The Court reproduces it in part as follows:

He had a brief tonic seizure, which means he had a brief seizure with stiffening. That was it. And it was provoked by fever. Technically speaking, just looking at that seizure by itself, it was a simple febrile seizure. And the medical literature tells us that a simple febrile -- or actually a short febrile seizure is even probably a better way of saying it -- a short febrile seizure after MMR immunization is not associated with the develop of a later epilepsy.

...[W]hen the paramedics showed up, they noticed that there was left gaze. There was no longer any body stiffening. [They] did not document on their examination that he was cyanotic all over at that point in time. They basically said left gaze, but the child easily could be postictal. Which means after the seizure...you're a little bit out of it. Your eyes don't work right, your body doesn't work right. And it takes you a little while to recover. It is not true that the postictal state reflects the severity of the seizure. ... The postictal state is actually idiosyncratic, relatively speaking, for the child, in that regard.

But I don't think that you state because the paramedics came in, saw the eyes deviated to the left with no other ongoing seizure activity, that you can state that

number one, a seizure was still ongoing, or number two, that that clearly is a localizing sign. There's not enough information to come to that conclusion.

...Dr. Kinsbourne has literally stated that this cyanosis is clearly a sign of anoxia. But that is medically impossible. And let me explain why it's medically impossible. It's medically impossible because this seizure only lasted 45 seconds, according to the father's representation, and in my clinical experience when parents state that a seizure lasts for a period of time, many of us actually will divide by two[,] because it seems to last longer than it really does.

...[W]e know that the cyanosis that's there can't be the cause of poor oxygen delivery in the entire body, and the real question we have to ask ourselves is: What does it represent? And the anoxia actually represents the body's typical response to the stress. When the body is stressed, it basically says, I need to protect the vital organs in the body. ... So what all this really is is an autonomic change, which really means it's a blood control in the skin change and not a sign or reflection or more global anoxia, or poor oxygen delivery in the body.

...Therefore, the argument that he had anoxia that caused brain damage from the seizure of November 27, 2004, is not biologically possible in any way. There's not even a probability. It's biologically impossible. You can't come to that kind of a conclusion, because the records don't support it.

Tr. at 84-89. Later, on cross-examination, Dr. Wiznitzer clarified that, "It was a benign febrile seizure simply because it was a generalized seizure provoked by fever that was short in duration," that it was a generalized seizure because Benjamin "just stiffened all over," and that it was a short, non-complex seizure because it lasted less than 20 minutes and did not possess strong lateralizing features." Tr. at 134-35.

On cross-examination, Dr. Wiznitzer conceded that, "The MMR vaccination caused the fever," and that, "but for the MMR vaccination he would not have had that febrile seizure on [27 November 2004]." Tr. at 113. He also stated that Benjamin "could have a tendency towards simple febrile seizures." Tr. at 115. However, he maintained his essential position that Benjamin "still would have developed epilepsy later on," and that, to his mind, that seizure on 27 November 2004 was "not associated with later epilepsy." Tr. at 113. In essence, Dr. Wiznitzer saw that seizure, and the intractable seizures that followed thereafter, as "separate incidents...not related" inasmuch as Benjamin "had an underlying encephalopathy," and "was going to have seizures no matter what." Tr. at 114-115. As a consequence, Dr. Wiznitzer postulated that one "cannot state with certainty that the two seizures, the febrile seizure in November and the seizure in December are definitely related to the same underlying reason." Tr. at 115. Petitioner's Counsel questioned Dr. Wiznitzer whether the two *could be* related, even if they were not predicated by logical necessity, to which Dr. Wiznitzer replied: "You're talking about a causal relationship, where the first seizure then causes you to have later seizures. The answer is definitely 'No.'" Tr. at 116-17. He did address what he saw as the central, if not sole, causative factor: "If you're saying that this is a child with an abnormal brain and he's destined to have seizures and therefore seizures show themselves, the answer is yes." Tr. at 117.

The Court attempted to summarize Dr. Wiznitzer's opinion, to which he agreed, that "the first seizure and the subsequent seizures could be related, or they might not be related," and that, if they are somehow related, all of Benjamin's seizures are "interrelated as a manifestation of an underlying disorder." Tr. at 117-18. It was this latter explanation, that they were all manifestations of an underlying encephalopathic process, that Dr. Wiznitzer extended as the explanation which he found to be more plausible than not. Tr. at 119.

C. POST-HEARING SUBMISSIONS

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

Petitioners argue that the similarity of symptoms between the seizure following vaccination and the intractable seizures that followed (most notably the leftward eye fixation), as well as the temporal association of the first seizure within the medically appropriate time frame militate for Petitioners' case. Petitioners' Posthearing Brief at 3, 12; Petitioners' Reply Brief at 7, 8. Petitioners reiterated Dr. Kinsbourne's opinion that "Benjamin's first febrile seizure, caused by the MMR [vaccination], is responsible for Benjamin's current condition," because it "either triggered a refractory seizure disorder in Benjamin or it caused an encephalopathy that caused Benjamin to lose skills." Petitioners' Posthearing Brief at 9-10. Petitioners' argument also incorporated two premises from the medical literature filed in this case: "(1) one seizure can trigger multiple additional seizures; and (2) refractory seizure disorders can cause "progressive brain damage." Petitioners' Posthearing Brief at 10, citing Pet. Ex. 22 at Tab B, C, G, and E.

Moreover, Petitioners' argue that, inasmuch as Dr. Wiznitzer "concedes that the [27 November 2004] seizure was caused by the MMR vaccination," and "concedes that the subsequent seizures could be related to [that initial] seizure," then it is inconsistent for him to maintain that "if all the seizures are actually related, then none of them were caused by the vaccine, including the first one." Petitioners' Posthearing Brief at 10-11. Petitioners employ Dr. Wiznitzer's statements to argue that, "Once he has conceded that the MMR [vaccination] caused the initial seizure and that all of the seizures may be related, he has unwittingly provided additional support to [Petitioners' theory of causation supporting entitlement]."

Petitioners also pointed out that "none of [the] treating physicians ever attempted to disconnect the [initial seizure] from the other seizures," but that "[o]nly Dr. Wiznitzer attempts to do so." *Id.* at 11. This is error, argues Petitioners, as Dr. Wiznitzer does not draw the connection between the seizures based on the similarity in observable indicia common to the seizures. *Id.* at 12. Similarly, Petitioners contrast Dr. Wiznitzer's denial of encephalopathy associated with the first seizure with the treating physician opinion(s) contained within the medical records. *Id.*

Petitioners reiterated their argument in the alternative, that the MMR vaccine significantly aggravated the static encephalopathy or even neurodegeneration that may have preexisted the vaccination, in that, by triggering the seizures as an ongoing symptom, it added a new component to Benjamin's degenerating condition. Petitioners' Reply Brief at 8. They point out that neither Dr. Wiznitzer nor the treating doctors are or were able to describe with detail the retrogression or the etiology of any neurodegeneration preceding the vaccination. *Id.* at 9. Also, they point to Dr. Wiznitzer's admission that seizures do not accompany every all neurodegenerative disorders to argue

that seizures may not have necessarily become an aspect of Benjamin's condition, but for the triggering of seizures by Benjamin's receipt of the MMR vaccine. *Id.*

As a legal argument for the sufficiency of the evidence proffered on causation, Petitioner's state that, "While the vaccine must be a 'substantial cause' of the injury, the Federal Circuit has said, 'it need not be the sole cause of the injury or even the predominant factor.'" Petitioner's Posthearing Brief at 8, citing *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1357 (Fed. Cir. 2006).

In contradistinction, Respondent argues that "Dr. Kinsbourne's theory [] that the seizure could only be responsible for the significant aggravation of Benjamin's condition as a result of anoxia" is "problematic" because such explanation fails to "explain how such a short seizure could lead to such a damaging level of oxygen deprivation," notwithstanding his stated assumption that the seizure lasted "considerably longer" than reflected in the medical records filed. Respondent's Posthearing Brief at 13. On this count, Respondent points out that, "Had Benjamin actually suffered from anoxia, Dr. Wiznitzer indicated that the inevitable result would have been an acute encephalopathy—an event neither documented in the records nor claimed by Petitioners." *Id.* at 15. Respondent also references Dr. Wiznitzer's statements that anoxia sufficient to cause encephalopathy and eventually intractable seizures, is "not biologically possible in any way ... not even a probability ... biologically impossible." *Id.*

Of the three possible mechanisms by which the measles virus may cause cerebral damage, Respondent cites Dr. Wiznitzer's testimony to conclude that "none of the three were applicable to this case." *Id.* at 16. Regarding the connection between the vaccination and the first seizure, and the connection between the first seizure and the subsequent seizures, Respondent explains Dr. Wiznitzer's testimony as "not suggest[ing] in any way that the seizures share any sort of causal link with each other." *Id.*

In summation, Respondent's basic argument is a legal one against the sufficiency of Petitioner's proffer of evidence: "that [Petitioners'] expert was simply never able to articulate a logical sequence of cause and effect explaining how Benjamin's MMR vaccination either caused him to develop a seizure disorder or significantly aggravated his pre-existing condition. By his own admission, Dr. Kinsbourne could not point to a specific mechanism causing injury, but rather appeared to be relying merely on the fact that Benjamin's condition deteriorated following vaccination as evidence of causation." *Id.* at 19.

II. ULTIMATE FINDINGS OF FACT

A. THE PARTIES' ARGUMENTS

Regarding the *terminus a quo* and *terminus ad quem* of Benjamin's vector of developmental progression, the parties are not in dispute. The medical records seem unequivocal that Benjamin began life with a certain quantum of damage already affecting him, as evidenced by his static encephalopathy and microcephaly. His nystagmus could have also been a manifestation of the same fact. Likewise, there seems to be little question that Benjamin's development retrogressed from a steady, albeit delayed, progress to a downward spiral of intractable seizures and neurologic

degeneration. The open and contentious issues appear to be when and why: When did the retrogression initiate? Why did he retrogress when he did? Why were seizures a part of that?

Petitioners certainly believe that the trigger, the keystone, the snowball that began the descent was the seizure on 27 November 2004 that followed on the heels of the MMR vaccination. They thus view the vaccine as a substantial factor in his decline, even if there was a genetic susceptibility or physiologic weakness that also played roles that might have been absent from the average child. Respondent does not assign such *gravitas* to that November seizure, because, by his estimation, the decline had begun before that moment, was not significantly accelerated thereby, and led inexorably, like a runaway train down a steep (previously-constructed) track, to Benjamin's developmentally delayed condition of intractable seizures. Rather than the circumstantially-dependent sequence that Petitioners envision, Respondent contemplates a predetermined sequence born of factual necessity. Taken in that light, the Court does not read Respondent's determined view of the facts as positing a particular "factor unrelated" other than this genetic/physiologic backdrop; Respondent did not seem to assume the viral explanations raised by some of the treating doctors.

B. THE COURT'S CONCLUSIONS

Both experts were personally and professionally credible; that premise is beyond a cavil of doubt in the Court's mind. However, the Court must analyze the differences between the opinions offered to determine whether Petitioner has established a logical sequence of cause and effect that is biologically plausible to tie together the factual sequence and explain Petitioner's injury. *See Walther v. Secretary of HHS*, 485 F.3d 1146 (Fed. Cir. 2007); *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

A preliminary issue to dispose of is Benjamin's nystagmus. Although not explicit, Respondent seemed to propose a reading of the medical records that would conflate the leftward eye fixation or staring with Benjamin's nystagmus, which seemed to ebb and flow over his developmental trajectory. Tr. at 45. Dr. Kinsbourne noted in response to this insinuation that "a left-sided gaze is nothing like nystagmus," the former being "a totally different phenomenon, com[ing] from a totally different part of the brain." *Id.* Dr. Kinsbourne did not believe the paramedics witnessed or described nystagmus, "or they would have said so." Tr. at 46.

To determine whether emergency responders would have known to distinguish nystagmus from other only slightly different conditions is not necessary here. The medical record from that initial seizure, both in the contemporaneous emergency records and in subsequent references thereto, are quite clear in describing the indicium as "gazing", "fixation", or "staring", all of which denote a constancy of direction and even focus, the categorical opposite of nystagmus as it is defined *supra*. Nystagmus is by definition erratic movement of the eyeball(s), and, even as described in Benjamin's diagnoses, the inability to "track" or "focus". In contrast, even Benjamin's later seizures were described as including "eye staring lasting 30 seconds." Pet. Ex. 7 at 306. The two phenomena are altogether too mutually inconsistent to conflate, and the Court does not accept the invitation to do so here.

The next point of consideration for the Court regards the seizure of 27 November 2004, in both its qualitative and quantitative aspects. There is ample evidence that the seizure persisted longer than the cyanosis that prompted the parents' call to emergency services. As Dr. Kinsbourne pointed out, even though Benjamin was breathing by the time the emergency personnel arrived, he "still was not immediately responsive and his eyes were turned to the left, and it took several more minutes before the baby in fact responded to sounds and other stimulation." Tr. at 12. Even if the lack of response to stimulation could be counted as attributable to the post-ictal state, the leftward glance is not. From the emergency records, as well as from later reiteration, the well-established fact of a leftward gaze at the time of the paramedics' arrival militates for a finding that Benjamin was yet in the throes of his seizure at that time. As this was Benjamin's first seizure, and given Mr. Zeller's lack of familiarity with what would become a pattern of seizure behavior, Mr. Zeller's characterizations of its duration may be inaccurate. Given his lack of medical expertise as a layman, the fact that apnea and/or cyanosis persisted for less than a few minutes may have led him to conclude that the seizure had ceased. He very well may not have been attuned to the subtleties of leftward gaze, which the more knowledgeable paramedics noticed immediately upon their arrival, the emergent circumstances notwithstanding.

In light of this analysis, it seems appropriate to resolve the interpretive question surrounding Pet. Ex. 16 at 5, regarding the paramedics' restatement of Mr. Zeller, that Benjamin "[stiffened] up and became blue for about 45 seconds," in Petitioner's favor, by applying the limiting prepositional phrase to the latter feature only. Even assuming that the severe tonic, stiffening features of the seizure lasted less than a minute as well, that does not mean that the seizure itself ceased at the same time. *A fortiori*, if only the cyanosis ceased after forty-five seconds, it is more likely than not that the tonic stiffening lasted longer. However, even this timetable seems truncated. Forty-five seconds of cyanosis does not result from an equivalent duration of apnea. As Dr. Wiznitzer himself noted for Respondent, one does not turn blue merely from holding one's breath for forty-five seconds. Tr. at 86. It would seem that forty-five seconds of cyanosis can only result from a significantly longer period of apnea. Such longer period makes even more sense when the Court considers that during the duration of Benjamin's severe symptoms, the Zellers had time to retrieve the nurse from the residence next door, for her to initiate CPR, and for them to contact the emergency responders. Then, several minutes after that, the paramedics arrived to find signs that indicate that some seizure activity was yet ongoing.

At the hearing, Dr. Wiznitzer argued, without support from the medical records, that Benjamin did not actually suffer from true cyanosis due to oxygen deprivation, but that what Benjamin really experienced was a bluish-gray pallor, linked solely to an "autonomic change." Tr. at 86-87. This reasoning is tautological at best. It assumes the absence of true apnea-based cyanosis to rebut the mention of apnea in the medical records. As such, it must fail. The medical records reference apnea and cyanosis, and there are no sources of contemporaneous facts that begin to contradict this reference, only the subsequent postulate of Dr. Wiznitzer. There are not even noted facts in the record to support a different interpretation. Accepting Dr. Wiznitzer's argument requires disregarding the contents of the medical records based solely on the Dr. Wiznitzer's conclusion. As Respondent's brief astutely noted, the Court should not "[s]econd-guess[.], during litigation, medical judgments made contemporaneously to treatment[, as doing so] sets a dangerous precedent[.] in the absence of convincing evidence of the incorrectness of the concurrent diagnosis or treatment," but

should instead “grant considerable weight to treating physicians opinions rather than engage in or permit the ‘re-diagnosis’ of a vaccinee’s illness years later.” Respondent’s Posthearing Brief at 19, quoting *DeRoche v. Secretary of HHS*, No. 97-0643V, 2002 WL 603087, *38 (Fed. Cl. Spec. Mstr. Mar. 28, 2002). The Court therefore finds as a factual determination that the seizure on 27 November 2004 lasted for several minutes, and that, due to the leftward gaze, it was focal.

The Court next turns to the dispute concerning the deterioration of Benjamin’s developmental curve, which, for some period, had tracked below, but alongside, a statistically normal developmental curve before devolving through a process of neurodegeneration. By mid-June 2004, Benjamin was able to reach, transfer, roll, bear weight, react to strangers, and sit with support, and he evidenced no head lag. Pet. Ex. 5 at 255. By at least mid-September he was crawling, although when he did, he did so with some trouble with leg-dragging. Pet. Ex. 5 at 243. Later in September, it was noted that he did not pull himself up to stand, did not stand, did not sit by himself, did not imitate speech sounds, and was not initially shy with strangers; however, he was able to clap hands, and, interestingly enough, the doctor noted no decline in Benjamin’s functional status, that he had stabilized neurologically, that his development was good and intact, with no sign of systemic problems. Pet. Ex. 6 at 89, 91, 96. Against Dr. Wiznitzer’s argument that milestones could be lost without notice in the medical records due to communication gaps between the doctor and the parents, these later notations indicate to the Court that the doctor followed a thorough protocol of questioning Benjamin’s parents and consciously considered Benjamin’s development, with a watchful eye for any sign of retrogression, and did not note any. By the beginning of October, Benjamin still did not appear to be sitting by his own strength or volition.²⁵ Pet. Ex. 5 at 77. By the date of the vaccination, mid-November, Benjamin was able to give hugs, able to say “Da-Da”, and able to clap his hands; however, he was unable to play Peek-A-Boo, unable to walk (either with support or alone), unable to use a mature pincer grip, unable to throw objects or give them, and not making compound or complex use of language. Pet. Ex. 5 at 236; 11.

Though there does not appear to be anything close to “normal” developmental progress reflected in Benjamin’s medical records, there does not appear to be any retrogression of skills or loss of developmental milestones over that period reflected in the reliable medical records extant. The first note of regression noted in the medical records appears to be from December of 2004, following the vaccination, the initial seizure ten days subsequent, and the bout of successive seizures in early December. The medical progress notes from 17 December 2004 include a description of Benjamin’s “developmental regression and seizures.” Pet. Ex. 7 at 317. Similarly, by the end of January 2005, Benjamin had lost the ability to sit up, even with support, had lost whatever speech he had previously, and was no longer visually tracking or fixating properly, which the medical records refer to as “developmental regression.” Pet. Ex. 7 at 80. This latter condition persisted, and only slightly improved by April of that year, when it was noted that he would “briefly fixate, but [did] not track well at all.” Pet. Ex. 5 at 11. At the neurologic evaluation on 13 April 2005, the doctor summarized that Benjamin “had this sudden regression in developmental milestones shortly after receiving [his] vaccinations.” Pet. Ex. 5 at 11.

²⁵ As noted above, other aspects reflected in the report of Dr. Helmy are not assigned significant weight by the Court, due to facial inconsistencies.

Given this history, the Court finds Petitioner's position preponderantly persuasive, that Benjamin was developing in a progressive, albeit non-linear sequence, and that the *denouement* of his retrogression followed a point of climax that is roughly commensurate with the date of his initial seizure on 27 November 2004, following his 17 November MMR vaccination. This reading of the medical records is not overborne by any consistent reading of the medical records taken together as a whole.

The last factual issue to be resolved short of resolution of the fundamental issues in dispute is how to view the imaging testing performed on Benjamin, and its use as a measure of Benjamin's neurodegeneration. The CT scan that Benjamin underwent in June of 2004 found "tiny densities" that may have been "very tiny calcifications," but those results were uncertain enough to warrant referral for a MRI evaluation in September. Pet. Ex. 5 at 180. Both tests were focused on Benjamin's nystagmus, as it constituted the most emergent of Benjamin's health conditions (Pet. Ex. 5 at 149), further indication that neurodegeneration was not a substantial concern at that point prior to vaccination and seizures. Evidence of the calcifications suspected in the CT testing from June was absent. Pet. Ex. 5 at 95. By that time in September 2004, there were "no MR abnormalities of the brain or adjacent structures." Pet. Ex. 5 at 163. Of substantial significance is the fact that, at that stage, the MRI testing gave indication of "no intra-axial or extra-axial hemorrhage" and concluded that Benjamin's "myelination pattern [was] age appropriate," lacking any "focal lesions." Pet. Ex. 5 at 95; 163. This certainly stands in contrast with later MRI results from a December 2004 evaluation following the onset of seizures, which found "white matter signal abnormality and delayed myelin deposition" and recommended further evaluation "to differentiate neurodegenerative disease from a static encephalopathy." Pet. Ex. 7 at 108-09. Likewise, from testing at the same visit, there was radiological evidence of "thinning of the corpus callosum" and "delayed myelin deposition," as well as a widening of the spaces in the brain. Pet. Ex. 7 at 120. Finally, by January 2005, results from nuclear SPECT brain imaging left the treating doctor with a conclusion of "Acute encephalopathy due to adverse vaccine reaction." Pet. Ex. 14 at 1.

It is not overstatement to find these results of radiological testing strongly corroborative of Petitioner's position in this case. Prior to the administration of the vaccine and the seizures that followed, neurodegeneration was not even a consideration faced by the doctors reviewing the testing results; after that point, such concern became their focus. Certainly, these results provide no support for Respondent's contention that neurodegeneration was steadily ongoing prior to the vaccination and seizures as a *fait accompli*.

The resolution of these several factual issues lead toward certain findings regarding the general issues of fact upon which the Court is charged to rule. The first is that whatever caused the decline in Benjamin's neurologic developmental progress can be temporally localized to the period between mid-November and mid-December 2004, and seems more likely than not to have hinged on the seizure that followed vaccination. That seizure, says Dr. Kinsbourne, fits neatly within the time frame understood by the medical community as appropriate to relate it to the vaccination received ten days before, and Dr. Wiznitzer agreed that that seizure of 27 November 2004 is more likely than not related to the MMR vaccination received 17 November 2004, ten days previous. Dr. Wiznitzer also agreed that the 27 November seizure could be related to the same pathologic process

as the sequence of seizures that followed in December 2004, and became intractable, with greater and lesser success in treatment, up to the present day.

The clinical and radiological observations in the medical records, the opinions of the treating doctors taken together, and the opinions of the expert witnesses heard by the Court at the evidentiary hearing, all lead the Court to believe that the MMR vaccine was related to Benjamin's seizures which followed, and to the encephalopathy that resulted in his retrogressive neurodegeneration. Whether *via* measles vaccine encephalopathy as a more likely explanation, or *via* anoxia experienced at the time of the first seizure as one less likely, the vaccine worked to damage Benjamin's already compromised and weakened condition. At least to some substantial extent, it is more likely than not that the seizures and the ensuing neurodegenerative injury would not have occurred as they did, but for the administration of the MMR vaccine on 17 November 2004. That is not to say that the vaccine has caused every malady which Benjamin faces. Certainly, as has been repeatedly mentioned, there were preexisting impediments which retarded Benjamin's development, most notably his static encephalopathy and microcephaly. Understood from a different perspective, it can also be said that the administration of the MMR vaccine on 17 November 2004 significantly aggravated the preexisting static encephalopathy and delayed development by causing additional damage to Benjamin's brain through seizures and acute encephalopathy, and represented serious deterioration of his already weakened, albeit stable, condition prior to vaccination.²⁶

III. CONCLUSIONS OF LAW

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

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

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

²⁶ "The term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4).

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

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

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

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

Of importance in this case, it is part of Petitioners' burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007), citing *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir.1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that petitioner would not have sustained the damages complained of, *but for* the effect of the vaccine. See generally *Shyface, supra*.

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,²⁷ and which guides the Court's practical approach to analyzing the *Althen* elements:

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

Weeks v. Secretary of HHS, No. 05-0295V, 2007 WL 1263957, 2007 U.S. Claims LEXIS 127, slip op. at 25, n. 15 (Fed. Cl. Spec. Mstr. Apr. 13, 2007).

The Court found, as a matter of fact, that Benjamin would not have experienced the seizure disorder and acute encephalopathy or the marked deterioration in neurologic development evidenced by the medical record in this case, but for the administration of the MMR vaccine on 17 November

²⁷ See *Pafford v. Secretary of HHS*, No. 01-0165V, 2004 WL 1717359, 2004 U.S. Claims LEXIS 179, *16, slip op. at 7 (Fed. Cl. Spec. Mstr. Jul. 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd* 451 F.3d 1352, 1356 (2006) ("this court perceives no significant difference between the Special Master's test and that established by this court in *Althen* and *Shyface*"), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007).

2004 and the ensuing seizure on 27 November 2004. As such, the law applicable in the Vaccine Program leads the Court to conclude that the vaccination at issue was the cause-in-fact of the injury discussed in the Court's findings. *Shyface, supra*.

It also seems evident that the vaccine was a substantial factor in causing the injury found by the Court, which, *prima facie*, would appear to satisfy the element of proximate cause in this case. Applying the traditional legal rule from Tort law, that Respondent takes Petitioner as he finds him (a.k.a. the "Eggshell Skull Rule"), the fact that Benjamin may have had a genetic predisposition or a physiologic susceptibility does not defeat Petitioner's case as a superseding factor. So long as the vaccine was a substantial factor, and its influence was not overborne by a superseding cause, the Court is justified in ruling that the proximate causation requirement is satisfied.

Applying the so-called *Althen* elements to Petitioner's theory of causation, the Court rules that Petitioner, through Dr. Kinsbourne, has proffered a medically plausible theory of causation that links the injury found by the Court to the vaccination at issue *via* a logical explanation of cause and effect, all within a medically appropriate time frame between vaccination and the onset of the initial seizure, and the overarching timeline of Benjamin's medical course. Dr. Kinsbourne's theory, corroborated by the medical literature filed in this case, posits preponderant evidence that the MMR vaccine can cause encephalopathy and seizures. Likewise, a review of the medical records filed in this case serve to support the contention that such pathologic process was indeed at work in the instant case. Accordingly, the evidence proffered and the findings of the Court stated above combine to satisfy the "can it–did it" test as well.

The logical sequela of these findings of fact is that Petitioners have carried their burden of proof on the issue of vaccine-related causation. Inasmuch as the other elements of § 300aa–11 (b) and (c) have already been satisfied, the Court holds that Petitioners have met their burden on their case in chief, on the ultimate issue of entitlement to compensation.

The burden now shifts to Respondent to proffer a factor unrelated to the vaccine as either a more likely cause of the injury found by the Court, or as a superseding cause of the injury that obviated any effect of the vaccine. This Respondent has not done. The only medical explanation proffered by Respondent was the predestination of intractable seizures, encephalopathy, and developmental delay based on an undetermined genetic predisposition toward neurodegeneration. As discussed by the Court above when addressing proximate causation on Petitioner's case in chief, the Court's findings in this case are inconsistent with a ruling that Benjamin's genetic susceptibilities overbore the effect of the vaccine as a superseding cause. Likewise, there is not a preponderance of evidence from within the medical records that any specific alternative diagnosis—not a single named etiology confirmed by testing—could be identified. Unconfirmed speculation by a few treating doctors, as with Dr. Wiznitzer's hypothesization, were unconfirmed by testing in the first instance, and unsupported by the medical records in the second. Consequently, the Court concludes that there is not a factor unrelated to overcome Petitioner's evidence on causation.

III. CONCLUSION

Therefore, in light of the foregoing, the Court rules in favor of entitlement in this matter. The parties are instructed to contact the Court for further proceedings, regarding the issue of damages.

IT IS SO ORDERED.

Richard B. Abell
Special Master