In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 04-1500V

Filed: January 19, 2007

TO BE PUBLISHED

MATTIE CARTER, Parent of GERALD MORRIS, a minor,	*	
Petitioner,	*	Entitlement; DTaP, Table Encephalopathy, Failure to Establish Causation-in-Fact; Re-diagnosis of contemporaneous diagnosis.
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Homer, with whom was Sylvia Chin-Caplan, Conway, Homer, and Chin-Caplan, Boston, MD, for Petitioner.

Glenn Macleod, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

GOLKIEWICZ, Chief Special Master

I. PROCEDURAL BACKGROUND

On September 27, 2004, petitioner, Mattie Carter, filed a petition on behalf of her son,

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days 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 will be available to the public. Id.

Gerald Morris, pursuant to the National Vaccine Injury Compensation Program[2] ("the Act" or "the Program") alleging that Gerald's injuries, including encephalopathy and seizures, are the result of the diphtheria-tetanus-pertussis (hereinafter "DTP") vaccine he received on October 1, 2001. Petition ("Pet.") at 1. On January 10, 2005, petitioner filed an amended petition alleging that Gerald suffered a Table encephalopathy, seizures, and neurological sequella as a result of his diphtheria-tetanus-acellular pertussis (hereinafter "DTaP") vaccine he received on October 1, 2001. Amended Petition ("Am. Pet.") at 1. On May 16, 2005, respondent filed a Rule 4 Report contesting the sufficiency of the evidence and concluding that compensation is not appropriate in this case. Respondent's Report ("R. Report"), filed May 16, 2005.

To elicit expert testimony, a Hearing was held on February 16, 2006. Petitioner presented David A. Griesemer, M.D., as an expert witness. Respondent presented John MacDonald, M.D., as an expert witness.

Following the Hearing, the undersigned issued an order on April 6, 2006 instructing the parties to brief the significance of the treating doctors' diagnosis and treatment for viral myeloencephalitis and the treating doctors not diagnosing and treating for acute disseminated encephalomyelitis (hereinafter "ADEM"). See Order, filed Apr. 6, 2006. On April 13, 2006, petitioner filed several medical articles in support of his position. See P. Ex. 30-38, filed Apr. 13, 2006. On May 18, 2006, petitioner filed a response to the April 6, 2006 Order. See Petitioner's Posthearing Memorandum ("P. Post. Mem."), filed May 18, 2006. On May 19, 2006, respondent filed a response to the April 6, 2006 Order. See Respondent's Post-Hearing Brief ("R. Post. Mem."), filed May 19, 2006. On May 31, 2006, the parties filed their reply briefs. See Petitioner's Reply to Respondent's Posthearing Memorandum ("P. Post. Rep."); Respondent's Post-Hearing Reply Brief ("R. Post. Rep."), filed May 31, 2006.

The record is now closed and the case is ripe for decision. After reviewing the entire record, and for the reasons set forth below, the court finds petitioner has failed to carry the burden of proof required under the Act, and thus is not entitled to compensation. A full discussion follows.

II. FACTUAL BACKGROUND

The following is a condensed version of the facts as they appear in the Mattie Carter's affidavit and in the medical records. Mattie Carter's affidavit contains facts that do not appear in

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

the medical records. Both experts relied upon the medical records for their testimonial opinions.[3] Thus, the relevant facts of this case are generally undisputed.

Gerald Morris was born on March 1, 2001. On October 1, 2001, Gerald received his immunizations for DTaP, Comvax[4], and Prevnar[5]. Petitioner's Exhibit ("P. Ex.") 16 at 29. Gerald's mother alleged, in her affidavit, that over the next few days Gerald slept more after receiving his vaccinations, he had a slight twitch in his eye, his arms and legs were jerking, but that he woke up long enough to be fed and have his diaper changed. P. Ex. 20. She alleged that she called Trinity Hospital's triage unit on October 5, 2001 and was told not to worry. Id. at 4. On October 9, 2001, Gerald was taken to the emergency department at Roseland Community Hospital where his mother complained that he was sleeping too much and he had persistent eye twitching. P. Ex. 9 at 4. A head CT scan of Gerald was normal; he was given Benadryl and discharged. Id. at 8, 3. His physician diagnosed him with an acute seizure disorder. Id. at 3.

Gerald was then brought to his pediatrician's office at Advocate Health Centers later that same day. P. Ex. 20 at 5. There, Dr. Williams noted that Gerald's mother complained that Gerald had not been the same since he was vaccinated on October 1. P. Ex. 16 at 30. Dr. Williams also noted that upon his examination, Gerald had no eye contact, his head was turning to the right, and he had mild jerking of the upper extremities. Id. Dr. Williams assessed that Gerald had infantile seizures and arranged for his transfer to Trinity Hospital. Id.

At the Trinity Hospital Emergency Department, Gerald was diagnosed with seizures and treated with Valium. P. Ex. 13 at 7. A spinal tap showed clear fluid and a high number of white blood cells. Id. at 2. Gerald was then transferred to Advocate Christ Hospital and Medical Center. Id. at 7. The attending physician at Advocate Hospital noted that the transport team reported three episodes of generalized tonic-clonic seizures that day. P. Ex. 15 at 11. He also noted that Gerald had increased tone in all four extremities, and he would spontaneously move

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[3] Ms. Carter was not presented as a witness, thus the undersigned makes no ruling regarding the reliability of facts presented in her affidavit. Since neither expert relied upon her affidavit for their testimonial opinions, and the undersigned cannot make a ruling "based on the claims of petitioner alone, unsubstantiated by medical records or by medical opinion," §13(a), Ms. Carter's credibility is a moot point.

[4] COMVAX is indicated for vaccination against invasive disease caused by *Haemophilus influenzae* type b and against infection caused by all known subtypes of hepatitis B virus in infants 6 weeks to 15 months of age born to HBsAg-negative mothers. MerckVaccines.com, http://www.merckvaccines.com/vaccines/heph/ (last visited Oct. 31, 2006).

[5] Prevnar is indicated for vaccination against certain pneumococcal bacteria that can cause serious diseases such as meningitis (an infection of the covering of the brain and spinal cord) and bacteremia (an infection of the blood). Prevnar.com, http://www.prevnar.com/home.asp (last visited Oct. 31, 2006).

his arms and legs. Id. at 10. Gerald was administered Versed, Dilantin, Rocephin, and Acyclovir. Id. at 10.

On October 10, 2001, Gerald was examined by a pediatric neurologist who thought that he had possible encephalitis or meningitis. P. Ex. 15 at 6. Gerald was then examined by an infectious disease specialist and thought to have encephalitis, likely viral in nature. Id. at 8. The physician recommended an MRI to rule out encephalitis. Id. at 8, 108. The MRI showed there was signal abnormality in the cerebellum, with the left cerebellar hemisphere more involved than the right. P. Ex. 15 at 108. The MRI findings were nonspecific, "but may be seen in postinfectious/inflammatory processes such as ADEM," according to the radiologist. Id. An EEG was also performed and was within normal limits. Id. at 109.

Gerald's condition improved over the next several days. On October 14, 2001, it was noted that Gerald was afebrile and had no seizure activity. He was assessed as having encephalitis. P. Ex. 3 at 71. On October 18, 2001, Gerald was discharged from Advocate Hospital with a discharge diagnosis of "meningoencephalitis, most likely viral etiology," and was continued on his medications to treat his seizures. Id. at 3.[6]

On November 5, 2001, Gerald had a follow-up examination with a pediatric neurologist who recommended that he continue on Dilantin and begin therapies to help with his tone and development. P. Ex. 7 at 5-6. On February 9, 2002, Gerald was taken to Roseland Hospital because he was having seizures. P. Ex. 10 at 3. He was treated there and then transferred to Little Company of Mary Hospital where he was found to have increased tone throughout all of his extremities. Id. Gerald was discharged on February 13 with no further seizure activity. Id. at 4. His discharge diagnosis was seizure, respiratory syncytial virus bronchiolitis, pneumonia, hypocalcemia, and hypomagnesemia. Id.

According to the mother's affidavit dated January 7, 2005, Gerald no longer has seizures and is no longer taking any seizure medication. P. Ex. 20 at 6. However, he is developmentally delayed and at three and a half years of age is unable to walk. Id. Gerald is currently receiving speech, physical, and occupational therapies. Id.

[6] Several related medical terms were used in diagnosing Gerald's condition: meningitis; encephalitis; meningoencephalits; and, myeloencephalitis. When asked about the differences, Dr. Griesemer responded, "It is all in the terminology, but encephalitis implies an inflamation of the substance of the brain. Meningitis implies an inflammation of the covering of the brain; and myeloencephalitis lumps them both together . . . ." Tr. at 44. The exact diagnosis is not critical to the resolution to this case; what is critical is that the treating doctors diagnosed a viral cause.

III. DISCUSSION

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.[7]

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). Gerald is alleged. to have suffered a Table encephalopathy caused by the administration of DTaP. For reasons discussed below, Gerald's alleged injury does not fit the description of a Table injury. Thus, petitioner must prove that the vaccine in-fact caused his injury, a so-called "off-Table" case.

To demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, "[petitioners must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Secretary of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960.[8] See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

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[7] A preponderance of the evidence standard requires a trier of fact to "believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

[8] The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (continued...)

While petitioners need not show that the vaccine was the sole or even predominant cause of the injury, petitioners bear the burden of establishing "that the vaccine was not only a but-for

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[8](...continued)
(1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that "Daubert is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert's opinion. Id. In other words, the "testimony must be supported by appropriate validation – i.e., 'good grounds,' based on what is known." Id. Factors relevant to that determination may include, but are not limited to:

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

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

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert, 509 U.S. at 594. However, the Supreme Court's only guidance to lower courts in determining the reliability of a novel proposition is that

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

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

cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation")); Hodges, 9 F.3d at 960. Finally, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

In Althen v. Secretary of HHS, 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioner's burden is to produce "preponderant evidence" demonstrating: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury." The Federal Circuit stated further that "requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court's well established precedent." Id. at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act's preponderant evidence standard that petitioners submit "objective confirmation," such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants." Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Secretary of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter "Capizzano III"]. Moreover, the Federal Circuit stated, "The purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id.

The Federal Circuit affirmed Althen's three-part test in Capizzano III and most recently in Pafford v. Secretary of HHS, 451 F.3d 1352 (Fed. Cir. 2006). The panel in Pafford, however, explained that the three prongs in Althen "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." Pafford, 451 F.3d at 1355. Fairly interpreted, the Pafford court held that it is petitioner's burden to rule out other competing possible causes of the injury in establishing that the vaccine was the "but-for cause of the harm." Id. at 1355, 1357; see also Althen at 1281. ("[T]he elimination of other causes [] is merely a recitation of this court's well-established precedent.")

However, the legal requirement that a petitioner support her proposed causation theory with a "sound and reliable medical or scientific explanation" is undisturbed. Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994); see also Grant, 956 F.2d at 1148 ("A reputable or scientific explanation must support this logical sequence of cause and effect."). Thus, when considering the evidence in a case, the special master is to "consider all relevant and reliable evidence, governed by the principles of fundamental fairness to both parties." Vaccine Rule 8(c); see also DeBazan at n12 ("A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness's testimony regarding causation." citing Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998)); Campbell v. Secretary of HHS, 69 Fed. Cl. 775, 781. (Althen's requirement of a "reputable medical or scientific explanation" "[l]ogically [ ] requires a special master to rely on reliable medical or scientific evidence . . . .")

The undersigned weighs the evidence presented in this case against the above legal standards. The issue in this case is whether the DTaP vaccination caused or significantly aggravated Gerald's injury or in the alternative, as petitioner argues, whether the DTaP, Prevnar, and Comvax vaccines received on October 1, 2001, either alone or in combination, significantly aggravated a pre-existing condition. **The undersigned finds that it did not.** A complete discussion follows.

A. The Experts' Opinions

1. The Experts' Reports

Dr. Griesemer[9]

In petitioner's expert report, in summary, Dr. Griesemer opines that "Gerald developed somnolence after receiving 7-month immunizations. The precise time when abnormally increased somnolence evolved as a sign of encephalopathy is not clearly documented, but 48 hours after immunization Gerald manifest [sic] decreased responsiveness and onset of seizures . . . ." P. Ex. 23 at 5, filed Jul. 18, 2005. Dr. Griesemer states that an MRI of the brain "confirmed multi-focal areas of demyelination consistent with post-immunization ADEM." Id. Additionally, he states that "there were no later indications of an infection which could be an alternative cause of ADEM." Id. Gerald's cortical visual impairment, nystagmus, developmental regression, and spastic diplegia are other consequences of his ADEM. Id. Dr. Griesemer did not give an opinion in his report, but stated under Diagnoses that Gerald had an "Encephalopathy secondary to immunization at age 7 months" and "MRI changes consistent with acute disseminated encephalomyelitis (ADEM)." Id. at 5.

[9] Dr. Griesemer's curriculum vitae is found at P. Ex. 23.

Dr. MacDonald[10]

In respondent's expert report, in summary, Dr. MacDonald opines that there is no direct evidence of a relationship of Gerald's encephalopathy to the October 1 immunizations other than temporal. R. Ex. B at 3, filed Sep. 26, 2005. He states that the onset of the acute encephalopathy began "between 4-8 days after the immunizations" of October 1. Id. Dr. MacDonald also notes that Gerald was eating and his weight increased from October 1 to October 9 (the date of his hospital admission). Thus, he states "[t]his would be consistent with a child who is adequately hydrated and eating well, and would strongly argue against an acute encephalopathy." Id. Dr. MacDonald also notes that "the onset of the abnormal movements was not within the first three days after the immunization . . . ." Id. He notes that from the mother's report the child is exhibiting tiredness. Id. After an extensive analysis of the record, Dr. MacDonald concluded that "the most likely possibility here is what the treating doctors originally thought and that this child had an episode of viral encephalitis, with onset of the acute encephalopathy between 4-8 days after the immunizations of October 01, 2001. I do no see any direct evidence of a relationship to the immunizations other than the time course." Id. at 3.

2. The Hearing Testimony

Dr. Griesemer

At the February 16, 2006 hearing, Dr. Griesemer opined that the cause of Gerald's injuries is the immunizations he received on October 1, which substantially contributed to Gerald's ADEM.[11] Tr. at 9. Dr. Griesemer testified, after reviewing Gerald's medical records, that he disagreed with Gerald's treating doctors' diagnosis of a viral encephalitis because the MRI was not supportive of such a diagnosis. Id. at 13. Instead, Dr. Griesemer testified that the radiologist who reviewed the MRI thought Gerald **may** have ADEM, and he agreed with the radiologist's report. Id. at 12. Further, Dr. Griesemer testified as to whether he thought the fever Gerald had three weeks earlier or the vaccine was the cause of Gerald developing ADEM; he stated that "the timing is more suggestive that it is post-vaccine." Id. at 21. Dr. Griesemer testified that most standard textbooks recognize that ADEM can be associated with post-infection or post-vaccination. Id. at 19.

Dr. Griesemer testified that the medical records document a "significant change in [Gerald's] neurological functions, which occurs approximately a week after his immunizations."

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[10] Dr. MacDonald's curriculum vitae is found at R. Ex. B.

[11] At the February 16 Hearing, Dr. Griesemer defined ADEM, which stands for acute disseminated encephalomyelitis. He stated, "Acute simply means rapid onset; disseminated means that we are seeing involvement of multiple parts of the nervous system; encephalomyelitis means that this can involve either the brain, the brain stem, or spinal cord." Tr. at 19.

Tr. at 23. He testified that the results of Gerald's MRI are consistent with a post-immunization process. Id. Additionally, Dr. Griesemer testified that he believed there was "no evidence of a predisposing illness or other developmental problem that offers a more attractive alternative explanation for [Gerald's] neurologic impairment that began at the time of his seizures and has continued in some form to the present day." Id. Thus, Dr. Griesemer testified that, but for the administration of immunizations on October 1, Gerald would not have developed ADEM. Id. at 22. The undersigned then questioned Dr. Griesemer on the importance of the timing of the onset. Dr. Griesemer testified that ADEM is not a process that occurs immediately after immunization. Id. at 23. Unfortunately, there is a lack of medical records during the first week following the October 1 immunizations. Id. Thus, Dr. Griesemer testified that he relied on what Gerald's mother reported in her affidavit. Id. However, Dr. Griesemer noted that her observations were limited because she does not have a medical background and thus, he is "not sure what weight to give that perspective." Id. at 23-24. Nonetheless, Dr. Griesemer testified that the medical records document "a clearly defined process that is consistent with ADEM. Retrospectively, there are citations in the records that indicate that it began one day before the child was seen, or two days, or five days, and there is a great deal of inconsistency about the precise onset. But I think the timing is a relevant issue here." Id. at 24.

On cross-examination, respondent's counsel questioned Dr. Griesemer about Gerald's possible pre-existing developmental delay. Respondent's counsel first questioned Dr. Griesemer about Gerald's head circumference measurement which Dr. Griesemer referred to in his expert report. Tr. at 25. Respondent's counsel noted that the second measurement had not significantly changed in the two months since the last measurement. Id. at 26. Dr. Griesemer testified that it is possible that his brain growth had stabilized - as respondent's counsel stated - but the more likely conclusion is that the one or both of the measurements was not fully accurate. Id. at 27. Next, respondent's counsel questioned Dr. Griesemer about a notation in Gerald's records which states that Gerald is "sitting with support." Id. at 27, see also P. Ex. 16 at 29. He notes that there are no other developmental milestones noted in this record. Thus, respondent's counsel asked if this notation meant that Gerald is not sitting without support at the age of seven months. Tr. at 27-28. Dr. Griesemer testified that the notations likely meant that Gerald is not sitting without support. Id. at 28. However, although sitting with support is more typical of a six-month old, Gerald's development is within a normal range of development and would probably not trigger any concern. Id. Dr. Griesemer noted that Gerald's pediatrician noted that the child was well and "okay to immunize." Id. He stated that this may be a first warning sign of something, but at the time it was not something that caused concern.

Respondent's counsel continued to question Dr. Griesemer about notations in Gerald's medical records which may indicate some pre-existing developmental delay such as occasional eye crossing, possible spasticity, and not rolling or reaching for objects. Tr. at 30-33. Respondent's counsel asked if these notations could indicate abnormal development before Gerald's immunizations. Id. at 33. Dr. Griesemer testified that one could conclude there were problems prior to immunization, but he questioned the correctness of the medical history. He testified that these were notations taken from the mother and were not observed. Id. at 34. The

undersigned questioned Dr. Griesemer what, if any, impact a pre-existing developmental condition may have on his opinion as to the cause of Gerald's injury. Dr. Griesemer testified that if in fact these developmental milestones were substantiated, it would suggest there was some developmental delay. Id. at 36. He stated that if this were the case "we would be looking at a slightly different issue, which would be the impact of ADEM on a child who had previous developmental delay, as opposed to the impact of ADEM on a child who was presumably normal." Id. Dr. Griesemer testified that a possible pre-existing condition did not impact his opinion that Gerald had ADEM. Id. At most, Dr. Griesemer stated, "[o]ne could argue to what degree his present condition is related to the ADEM, and to what degree his present condition is related to this speculative pre-existing developmental problem." Id. at 36-37.

Respondent's counsel then questioned Dr. Griesemer as to whether he would have diagnosed Gerald with ADEM if he were his treating physician. Tr. at 40. Dr. Griesemer testified that based on the records and tests at the time of the hospitalization in October 2001, he would have diagnosed ADEM. Id. at 40. Respondent's counsel asked Dr. Griesemer what was Gerald's discharge diagnosis; Dr. Griesemer could not recall. Id. at 41. Respondent's counsel pointed Dr. Griesemer to Petitioner's Exhibit 15 at 113, the discharge orders. Dr. Griesemer responded, "Hmm, interesting, viral myeloencephalitis." Id. [12] He noted that the physicians did not "sign this out as viral encephalitis. They just sort of left it as a very non-specific diagnosis." Id. at 42. Dr. Griesemer conceded that there are many viruses that can cause myeloencephalitis and that the current technology is incapable of identifying all of them. Id. He testified that perhaps one-third of the viruses which cause myeloencephalitis can be identified. Id. at 42-43.

Dr. Griesemer testified that he disagreed that Gerald had a viral myeloencephalitis because the CSF[13] findings and MRI findings are inconsistent with such a diagnosis. Tr. at 43. Gerald had a spinal tap done at the time of his admission and the results showed fifteen white blood cells. Dr. Griesemer testified that while this is slightly above normal, it is not impressive for an active infection. Id. However, he conceded that the normal range for a white blood cell count is zero to five. Id. at 44. Additionally, he testified that Gerald's white blood cell count is not inconsistent with a diagnosis of viral myeloencephalitis, but that one would expect to see a much higher white blood cell count. Id. Dr. Griesemer did not indicate what the exact number or range of white blood cell count one would expect to see with this type of infection. Next, he testified that the MRI showed an inflammatory process, but did not necessarily show an infection. Id. at 46. While the radiologist noted that the MRI findings was consistent with a post-infectious process, Dr. Griesemer testified that nothing about the MRI implicates a direct

[12] Actually, the medical record states "viral meningoencephalitis." P. Ex. 15 at 113. But as stated at page 4, note 6 supra, the exact diagnosis is not critical; the viral cause is the critical factor.

[13] CSF stands for cerebral spinal fluid.

infection in the brain.[14] Further, Dr. Griesemer stated that he believed the MRI was done with gadolinium, a contrast agent which shows the breakdown of the blood-brain barrier and areas of inflammation. Id. at 47. He testified that the MRI did not show any part of the brain enhanced with gadolinium that would indicate an "active infectious process at the time of the MRI." Id. Thus, Dr. Griesemer testified that there was "from an infectious perspective, a normal MRI [and] from a CSF perspective, a very minimal increase in the number of white blood cells, and that leaves you with very weak evidence for active infection." Id.

Respondent's counsel then questioned Dr. Griesemer about the onset of Gerald's acute encephalopathy. Dr. Griesemer testified that Gerald was observed by physicians and had seizures on October 9th "as a manifestation of his encephalopathy." Tr. at 51. However, it is unclear whether Gerald's staring or jerking represented seizure activity or another movement disorder. Id. at 52. He also testified that it is unclear when the jerking began because the records document different dates. Id. Thus, Dr. Griesemer testified that when he wrote his expert report, he "relied more heavily on the affidavit of Gerald's mother in the absence of any other medical evidence, my thought process being any other date is going to also be from Gerald's mother but through the interpreting eyes of some other physician." Id. Respondent's counsel pointed out that the medical records were written more contemporaneous to the event than the mother's affidavit. Id. Dr. Griesemer agreed that the contemporaneous records have the advantage over the mother's affidavit. However, he noted that there was disagreement among the contemporaneous recorders about when the jerking started. Id.

Finally, Dr. Griesemer was questioned by respondent's counsel about the treatment for ADEM. Dr. Griesemer testified that sometimes the child is treated with steroids or if the child is doing better they "just let it go . . . ." Tr. at 55. In Gerald's case, respondent's counsel noted that his treating physicians did not consider ADEM in the differential diagnosis and Dr. Griesemer agreed that **ADEM was not noted in any of the progress notes except for the radiologist's report**. Id. at 55-56. Respondent's counsel also pointed out that Gerald was not treated with steroids and was instead treated with Acyclovir. Id. at 57. Dr. Griesemer testified that Acyclovir is prescribed for treating Herpes encephalitis. Id. at 55. He agreed that Gerald improved after receiving Acyclovir, but he testified that it was not clear that Acyclovir was the reason that Gerald improved. Id. at 57.

On re-direct examination, Dr. Griesemer testified that he believed the treating physicians continued to prescribe Acyclovir because it is a risk-free solution even though the infectious disease specialist doubted that Gerald had Herpes encephalitis. Tr. at 62. Additionally, the results of the herpes PCR obtained from Gerald were negative which, Dr. Griesemer testified, meant it was less likely that Gerald had Herpes encephalitis. Id. at 63.

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[14] Dr. Griesemer testified that a "post-infectious process is where the body has developed an immunological response to the infection, and that the changes seen in the brain are a consequence of this immunological response rather than a direct infection." Tr. at 46.

In response to the undersigned's question, Dr. Griesemer explained how a child who was immunized would develop ADEM. Dr. Griesemer testified that when a child is immunized the child is exposed to a foreign agent and normally mounts an immune response to the foreign agent. Tr. at 74. However, "if there is sufficient cross-reactivity between neuro-structures and the antigen presented to the child, then the body's response is not only to develop the desired antibodies . . . which is a good thing, but it also develops an immunological response against cross-reacting brain tissue." Id.

Dr. MacDonald

Dr. MacDonald opined at the February 16, 2006 hearing that, after reviewing Gerald's medical records, "looking at the preponderance of the evidence here . . . I think there was evidence to suggest at least some mild developmental delay, particularly in the motor areas." Tr. at 79. Dr. MacDonald pointed to several notations in the medical records on which he bases his opinion. He notes the ability of Gerald to use his upper extremities, evidence that his lower extremities were not working as they should, and his not sitting with support. Id. Thus, Dr. MacDonald testified that this evidence suggests that Gerald was developing a spastic diplegia form of cerebral palsy. He further testified that the fact that Gerald's head circumference did not change indicated that his brain growth was slowing for a couple of months even though the measurements are within the lower normal range. Id. at 81-82. Dr. MacDonald also testified that the occasional eye crossing noted in Gerald's records is something that is commonly found in children with cerebral palsy. Thus, this is "just another indicator that there might be something affecting the brain here." Id. at 82.

Next, Dr. MacDonald was questioned about Gerald's hospitalization beginning on October 9. He testified that, based on the cumulative evidence gathered after several specialists had examined Gerald, the treating doctors diagnosed him with a viral myeloencephalitis and the doctors treated him with Acyclovir. Tr. at 85. He testified that even though the PCR tests came back negative for Herpes, a note from the infectious disease specialist said that there was a concern that the amount of spinal fluid tested "may have been insufficient to actually document that genetic abnormality, and that is something that comes up occasionally." Id. Thus, they continued treatment for a viral myeloencephalitis because the treatment is "fairly benign." Id. Dr. MacDonald also testified about the fifteen white blood cells that were found in Gerald's CSF. He stated that "if one finds increased white cells in the spinal fluid, the immediate issue is infection, acute infection." Id. at 86. Further, most doctors "are afraid of underestimating the significance of a few extra cells in the spinal fluid. So I think [Gerald's doctors] had no choice but to treat for Herpes encephalitis." Id. at 87. Additionally, Dr. MacDonald testified that the fact that Gerald's cultures came back negative does not rule out a viral infection. Id. at 88. Dr. MacDonald also testified that he agreed with Dr. Griesemer in that the current technology only allows identification of a specific virus in about one-third of cases. Id.

Dr. MacDonald then testified about the possible viral etiology for Gerald's condition.

He noted that his parents reported a fever on September 19, 2001 and that this was possibly some type of viral illness. Tr. at 89-90. Dr. MacDonald then noted that according to the medical records, Gerald lost five ounces between September 19 and October 1, the date of his vaccination. Id. at 90. Although Dr. MacDonald conceded getting the exact weight of a young child may be difficult, if one was to view the recordations as correct in addition to the fever, he testified that this may indicate "a more significant viral-type illness." Id. Then he stated, "I think the weight loss, plus the fever, the overwhelming preponderance of the evidence would be there was a significant viral illness." Id. at 91. Thus, Dr. MacDonald testified that the timing of the viral illness on September 19 is consistent with the post-infectious finding in the MRI from October 11, and hypothetically, if one was to diagnose that Gerald had ADEM, "the most common cause in 90 percent of the time or more is a viral illness." Id. Dr. MacDonald also referred to a study in the Journal of Pediatric Infectious Diseases which showed that the vast majority of ADEM cases were caused by viral illnesses, and that "a two or three week time course would not be unusual." Id.; see also R. Ex. C. However, to be clear, Dr. MacDonald does not believe that Gerald has ADEM. He disagreed with Dr. Griesemer's diagnosis of ADEM and testified that he agreed with the treating doctors diagnosis of a viral illness. Tr. at 97.

Finally, Dr. MacDonald testified that Gerald did not suffer a Table injury. Based on the mother's affidavit, Dr. MacDonald notes that the child's behavior during the period immediately following vaccination is not consistent with an encephalopathy. Dr. MacDonald testified that Gerald is "waking up, feeding well, [and] gaining weight," and, according to the mother's affidavit, wanting his diaper changed. Tr. at 93. When Gerald is brought to the hospital on October 9, Dr. MacDonald testified that he was described as awake and having seizures, but "this is not an entirely comatose child." Id. at 94. Dr. MacDonald testified that he reviewed the legal table definition for encephalopathy the morning of the hearing and that based on the evidence in the record, Gerald did not suffer a table encephalopathy seventy-two hours after his immunizations. Id. at 97.

On cross-examination, Dr. MacDonald conceded that the record is inconsistent and conflicting regarding Gerald's developmental milestones. Tr. at 109-110. Additionally, he testified that the there is nothing in the medical records that indicated that Gerald's pediatricians were concerned about a possible developmental delay. Id. at 112. Dr. MacDonald then testified as to what he believed were three possibilities for Gerald's condition. First, Gerald could have suffered a brain injury in an intrauterine accident, second, Gerald could have suffered a brain injury caused by a viral myeloencephalitis, or third, Gerald had a preexisting injury which caused cerebral palsy. Id. at 114-115. While Dr. MacDonald disagreed with the ADEM diagnosis, he agreed that the time course for developing ADEM after immunization was appropriate. Id. at 125.

Dr. MacDonald further testified that he agreed that the diagnosis for ADEM is often made retrospectively. Tr. at 126. However, the criticism of this diagnosis is that "looking for the offending agent is sometimes tenuous at best. Viral infections are number one on the list . . . ." Id. at 127. The undersigned then questioned Dr. MacDonald about his expert report. While he

stated in his report that he disagreed that Gerald suffered an acute encephalopathy within the first three days after immunization, he agreed that Gerald did suffer from an acute encephalopathy by day seven, eight, or nine. Id. at 134. Additionally, Dr. MacDonald testified that ADEM is usually diagnosed in older children - four, five, six or seven year olds. Id. at 135. He testified that ADEM occurs in children younger than one year of age less than one percent of the time. Id. at 137. Dr. MacDonald testified that one cannot remove ADEM from the differential diagnosis, but in his experience most children with ADEM do very well once the disease has passed and "[a] very small group end up like Gerald. Whereas, [a] viral encephalitis can be devastating." Id. at 142, 145.

B. Petitioner's Arguments

Petitioner, in his Posthearing Memo, presented three alternative arguments alleging that the October 1, 2001 administration of DTaP, Comvax, and/or Prevnar caused Gerald's injury or significantly aggravated Gerald's injury. Petitioner's Posthearing Memorandum ("P. Post. Mem.") at 1, filed May 18, 2006. Each argument will be discussed in turn.

1. Gerald Suffered an On-Table Encephalopathy

Petitioner's amended petition alleges that Gerald suffered a Table injury as a result of the administration of DTaP vaccine. See Am. Pet. Petitioner argues that Gerald's injury, encephalopathy and its sequella, meets the definition of a Table injury under the "Qualifications and Aids to Interpretation" ("QAI"). See 42 U.S.C. §300aa-14(b). In support of his argument, petitioner submits as evidence the affidavit of his mother, medical records, and an expert opinion. This evidence, petitioner argues, indicates that he suffered a "significantly decreased level of consciousness"[15] for more than twenty-four hours within seventy-two hours after his vaccination. P. Post. Mem. at 19.

According to the mother's affidavit, Gerald slept more than usual, he jerked his arms and legs, he awoke to be fed and have his diaper changed, and he was not interactive when he was awake. See P. Ex. 20. None of these events are clinical signs which meet the definition of "significantly decreased level of consciousness." The QAI excludes sleepiness as a clinical feature which would demonstrate an acute encephalopathy or change in mental status. QAI 2(i)(E). Thus, the fact that Gerald was sleeping more is not an indication of an acute

[15] According to the QAI, a "significantly decreased level of consciousness" is indicted by the presence of at least one of the following clinical signs for at least 24 hours or greater (in children less than 18 months of age): (1) decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

encephalopathy. Additionally, Gerald woke up to be fed and have his diaper changed. Thus, Gerald was able to respond to the environment by feeding and indicating he needed his diaper changed. The QAI states that under the clinical sign of a decreased or absent response, a child responds, if at all, "only to loud voice or painful stimuli." QAI (2)(i)(D)(1). The mother's affidavit does not indicate that this was the case with Gerald.

Next, petitioner argues that the contemporaneous medical records are evidence of a Table encephalopathy. P. Post. Mem. at 20. Petitioner argues that all the immediate records note that Gerald is sleeping more or sleeping too much. Id. However, there are no medical records from the time period between October 1, 2006 (when Gerald was vaccinated) to October 8, 2006. The first medical record submitted is dated October 9, 2006 when petitioner's mother first took him to the hospital. Thus, there are no contemporaneous nor corroborating medical records which make note of the clinical symptoms in the mother's affidavit. The symptoms of increased sleepiness or of sleeping more noted in the medical records are merely statements taken from the mother of her observations during the time period from October 1 to October 9. There is no objective evidence that indicates that Gerald had a significantly decreased level of consciousness.

Finally, petitioner states that he has an expert opinion which supports his argument that this is a Table injury. P. Post. Mem. at 19. Petitioner submitted the expert report of Dr. Griesemer. Dr. Griesemer, in his report, does not state that this is a Table injury. See P. Ex. 22. Further, Dr. Griesemer did not testify at the entitlement Hearing that he thought this was a Table injury. In fact, Dr. Griesemer agreed that the record is unclear from the time period between October 1 to October 9. Tr. at 10. He relies instead on the objectively documented information in the medical records in order to form and present his medical theory. Id. at 11. Additionally, Dr. Griesemer testified at the Hearing that he did not believe Gerald was slipping into a coma during the first seventy-two hours after immunization. Id. at 53. He testified that Gerald's clinical condition was "relatively stable from day one [of the immunizations] until the child was admitted on the 9th, I think there were mild encephalitic changes there. However, I am not sure that I would use that term in the way that necessarily meets with table requirements for encephalopathy . . . ." Id. Thus, it is Dr. Griesemer's opinion that Gerald suffered from acute disseminated encephalomyelitis ("ADEM") which was caused by his vaccinations. P. Ex. 22 at 5; Tr. at 19-20. ADEM is not an injury associated with any vaccine on the Table.

Petitioner submits that Dr. Griesemer's written report states that Gerald experienced "manifest decreased responsiveness" forty-eight hours after immunization. P. Ex. 22 at 5. Dr. Griesemer testified that he made the conclusions in his report "based exclusively on what Gerald's mom has reported." Tr. at 23-24. However, Dr. Griesemer also testified that the mom's observations are limited since she is not making observations from a medical background, but "from a mother's perspective." Id. at 24. Thus, he is "not sure what weight to give that perspective." Id. Further, Dr. Griesemer does not elaborate in his report what other evidence, if any, he relies on in making the statement. Additionally, as noted previously, Dr. Griesemer did not state in his report that he thought Gerald suffered a Table injury. Respondent's expert, Dr. MacDonald, stated in his expert report that "[i]t appears from the contemporaneous records that

the onset of the abnormal movements was not within the first three days after the immunization and that by the mother's report, mainly we have tiredness at that point . . . ." R. Ex. A at 3. Dr. MacDonald also testified, as noted previously, that he reviewed the definition of a Table injury and that he did not see any evidence that Gerald suffered a Table encephalopathy. Tr. at 92. Thus, Dr. MacDonald concluded that it does not appear that petitioner suffered an encephalopathy within the seventy-two hour time frame as defined by the Table.

Petitioner correctly states that the determination of whether petitioners have met their burden for a Table case requires a finding of fact by the special masters. A special master can make this determination if it is clear from the medical records and requires no interpretation of the facts and statements therein. However, petitioner is incorrect in stating that expert testimony is not needed in order to aid the special master in making this determination. In the instant case, the medical records are unclear as to whether Gerald suffered a Table injury because there are no contemporaneous medical records of the time period in question. Thus, an expert is needed to interpret the information in the medical records and the statements in the mother's affidavit.[16] As noted above, petitioner's expert, Dr. Griesemer, testified that he was not "sure" that Gerald suffered a Table injury; Dr. MacDonald testified that he did not suffer a Table injury. Accordingly, the undersigned finds that petitioner failed to prove by a preponderance of the evidence that Gerald suffered a Table injury.

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[16] See Capizzano v. Secretary of HHS, No. 00-759, 2006 WL 3419789 (Fed. Cl. Spec. Mstr. Nov. 8, 2006)(discussing how the vast majority of treating doctors do not provide causation evidence through their records, but are instead providing a medical "snapshot" through their contemporaneous notes that allow medical experts and the decision-maker to tie the medical theory to the clinical course). Id. at *14. See also Raley v. Secretary of HHS, No. 91-0732, 1998 WL 681467 (Fed. Cl. Spec. Mstr. Aug. 31, 1998)(stating "[t]he requirement that petitioners' claims must be supported either by medical records or medical expert opinion simply addresses the fact that the special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone." Id. at *9; and Bernard v. Secretary of HHS, No. 91-1301, 1992 WL 101097 (Fed. Cl. Spec. Mstr. Apr. 24, 1992)(stating "The medical significance of the facts testified to by the lay witnesses must be interpreted by a medical doctor, who, in turn, expresses the opinion either that a compensable Table injury has occurred or that the vaccine in question actually caused the injury complained of. If such an opinion appears in the medical records, then it is unnecessary to call a retained expert witness in order to establish a prima facie case; if, on the other hand, the medical records do not provide such substantiation, then a petitioner must retain a medical doctor who, upon review of the entire record, concludes that it is more likely than not that a compensable injury has occurred." Id. at *1; Wolfe v. Secretary of HHS, No. 05-878, 2006 WL 3419835 (Fed. Cl. Spec. Mstr. Nov. 9, 2006)(stating "Congress prohibited the special masters from awarding compensation 'based upon the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.' § 300aa-13(a)"). Id. at *2.

2. Gerald Suffered a Significant Aggravation of a Preexisting Injury

Petitioner's first alternative argument, if the undersigned finds that Gerald had a preexisting condition, is that his October 1 vaccination significantly aggravated his underlying condition. P. Post. Mem. at 31. Respondent's expert testified at the February 16, 2006 Hearing that there was evidence of a preexisting condition, perhaps caused by a pre-natal injury, and that there were signs of developmental delay even prior to Gerald's October 1 vaccinations. Tr. at 79-81. For instance, Dr. MacDonald testified that there is a notation in Gerald's records that Gerald was not sitting without support. Id. at 79; P. Ex. 16 at 29. He testified that there is other evidence in the record that the lower extremities were not working; he testified that the mother reported that "the child had this jiggling of the legs, this clonus, that was long-standing, that would stiffen when she changed the diapers." Tr. at 79; P. Ex. 8 at 14-15. There are other notations in the records which may indicate pre-existing developmental delay: a plateau in growth of Gerald's head circumference (P. Ex.16 at 24, 29) and occasional eye crossing (Id. at 29). Dr. MacDonald testified that these notations suggest that Gerald's "lack of ability to sit could be secondary to spasticity in the legs that is chronic and long-standing, and that would be more and more obvious with time, and present, as he does now, with the lower-extremity predominant cerebral palsy." Tr. at 81.

Dr. Griesemer conceded that a stabilization in head growth indicates it is possible that Gerald's head stopped growing which could have neurologic implications or that it is possible that the measurements were not fully accurate. Tr. at 27. He also testified as to the notation about not sitting with support. Dr. Griesemer testified that not being able to sit without support is more typical for a six-month old and not a seven-month old, as Gerald was when the physician made the note, but that it is within the normal range of development. He also testified that the physician's note was based on a report rather than her actual observation because it is listed in the history rather than the physical examination portion of the record. Id. at 28. However, Dr. Griesemer testified that "it is a possibility that this was the first warning sign of something to come, but it clearly did not cross [the pediatrician's] threshold of concern at that time." Id. Further, Dr. Griesemer testified that if the history is correct regarding the notations in the records that Gerald was not rolling or reaching for objects, has stiffness, and stiffens legs when changing diapers, "one could conclude there were problems before the immunization." Id. at 33. However, he testified that there is no prior recording of clonus. Id. Additionally, Dr. Griesemer testified that the notations are observations made by mother retrospectively. He testified that "[t]hese are not observations that have been made and validated. This is presumably a history taken from mom after all of these experiences.[17] Id. at 34. Further, he testified that when taking a history "we describe what we are told, we don't give a diagnosis." Id.

Respondent's expert conceded that there are conflicts in the record regarding Gerald's

[17] This is an interesting observation by Dr. Griesemer considering that he relied upon the mother's retrospective reporting for his affidavit diagnoses. To his credit, Dr. Griesemer backed off of this reliance during his testimony. See p.16 supra, citing Tr. at 23-24.

development. Tr. at 109. Further, Dr. MacDonald testified that there is nothing in the pediatric records which specifically indicate that Gerald was not rolling over. Id. at 110. He stated that he assumed the notation regarding rolling over was taken from the mom's history. Id. Finally, Dr. MacDonald testified there is nothing in the medical records that indicated Gerald's doctors were concerned about Gerald's development or that Gerald suffered from spasticity. Id. at 112, 114. However, he did note that the record from Gerald's October 1 immunization notes that Gerald was not sitting unsupported. Id. at 112.

The undersigned agrees with petitioner that, after thoroughly reviewing all of the medical records in this case and the testimony of both experts, respondent has not established that Gerald suffered from a preexisting condition or prior developmental delay. None of Gerald's pediatricians diagnosed a developmental delay nor is there any notation in the medical records either for Gerald or Gerald's mother which indicates a pre-natal injury. Although there are some notations in the record of possible developmental indicators, not one of Gerald's treating physicians makes the observation that these indicators are in fact a sign of a possible developmental delay. Both experts agree that several of the notations were taken from the mother's observations and not the observations of the treaters themselves. As respondent quoted in his posthearing brief, an attempt at "[s]econd-guessing, during litigation, medical judgments made contemporaneously to treatment sets a dangerous precedent in the absence of convincing evidence of the incorrectness of the concurrent diagnosis or treatment." DeRoche v. Secretary of HHS, No. 97-643, 2002 WL 603087, *38 (Fed. Cl. Sp. Mstr. Mar. 28, 2002); see R. Post. Mem. at 12. In the instant case, there is no convincing evidence of the incorrectness of Gerald's doctors' diagnosis or treatment. Thus, the undersigned relies upon the contemporaneous findings of the treating doctors. Therefore, because the undersigned finds that Gerald did not suffer from a preexisting injury, it follows that there can be no significant aggravation of a preexisting injury.

3. Gerald's Injury Was Caused By a Vaccine

Because Gerald does not benefit from presumptive causation provided by the vaccine Injury Table, he must prove that his injury was caused-in-fact by the October 1 vaccination. The undersigned weighs the evidence presented in this case against the legal standards set forth above. At issue are two competing diagnoses, a viral encephalitis as diagnosed by Gerald's doctors and ADEM as advocated by petitioner's expert, Dr. Griesemer. The proper diagnoses is critical to resolving this case because a viral encephalitis, as the name logically suggests, has a viral cause; while ADEM can be caused by an immunization. See Tr. at 125 (Dr. MacDonald agreed that immunizations have been "implicated" in ADEM).

The critical issue devolves to whether Gerald suffered from ADEM or, as diagnosed by the treating physicians, a viral encephalitis**.** See Pafford, 451 F.3d at 1355. The undersigned finds that Gerald was correctly diagnosed and treated for a viral disorder and not ADEM. Therefore, the undersigned finds that the October 1 immunization was not the cause of Gerald's

injury. A complete discussion follows.[18]

Dr. Griesemer's medical theory of this case is that Gerald suffered post-immunization ADEM following his October 1, 2001 vaccination, and the ADEM is responsible for his current developmental delay and present condition. Dr. MacDonald, on the other hand, would not diagnose Gerald with ADEM, but agreed with the diagnosis of viral encephalitis and subsequent treatment chosen by Gerald's treating physicians. Entitlement to compensation in this case rests on the key issue of whether Gerald suffered post-immunization ADEM because Dr. Griesemer's opinion is premised on Gerald having ADEM – that is, Dr. Griesemer's medical theory of how the vaccine logically caused petitioner's injury in this case rests on the fact that petitioner suffered from ADEM. See Althen at 1278 ("Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury . . ."). Thus, if Gerald did not suffer from ADEM, then petitioner is not entitled to compensation. After considering the entire record, including the experts' testimony, the undersigned finds that Dr. MacDonald's testimony was far more persuasive than Dr. Griesemer's, and finds accordingly that petitioner failed to prove by preponderant evidence that the vaccine caused Gerald's injury.

Dr. MacDonald recognized that Gerald's diagnosis involves "debatable" issues, Tr. at 116, and that ADEM is "in the differential." Id. at 141. Dr. MacDonald testified that, while Gerald's "clinical course is sort of classic for viral encephalitis," there is "a lot of overlap with the ADEM features too." Id. at 140. However, in the final analysis, Dr. MacDonald testified that "the preponderance of the evidence supports the treating doctors" who diagnosed a viral cause of Gerald's injuries. See id. at 141. As can be seen in the transcript of the Hearing, Dr. MacDonald's views and opinions were explored and tested in depth by both counsel and the undersigned. A representative explanation of why he believes the treating doctors should be relied upon can be seen at pages 84-87 of the transcript. The relevant portions of Dr. MacDonald's testimony at those pages are as follows:

[18] The court notes that it benefitted from the testimony of two experts who are both exceptionally well-qualified. However, the undersigned found Dr. MacDonald far more persuasive as he testified consistently with the findings and conclusions in the medical records. Dr. Griesemer's testimony on the other hand, while not necessarily inconsistent with the medical records, requires accepting several interpretive leaps that struck the undersigned as educated conjecture. Ultimately, Dr. Griesemer's willingness to re-diagnose Gerald in the face of the treating doctors contemporaneous diagnoses and treatment and based heavily upon the strength of a radiologist's "nonspecific" findings, not diagnosis, undermined his credibility in the eyes of the undersigned.

> THE COURT: What was the approach . . . of the treating physicians to Gerald's case?
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> . . .
>
> THE WITNESS: Well, I think they did a differential diagnosis, which included a variety of possible causes of his neurological symptoms at that time. I think their approach was standard. There were looking for particularly treatable conditions. . . . I think they thought he was having seizures, or at least abnormal movements. That was the clinical course here. It led to the spinal tap, looking for infection or something in the nervous system, inflammatory. They did that. They did various scans; they did some chemical tests. They had multiple specialists see him. I think they took a fairly detailed history and then they made a decision, based on the cumulative evidence, that this is consistent with what they called a viral myeloencephalitis, that this brought up the possibility of a treatment. If it's Herpes, you start the Acyclovir. And they persisted, and I think there is [a] note from the infectious disease doctor later, that even though the PCR tests came back negative, they were concerned that the amount of spinal fluid they sent might have been insufficient to actually document that genetic abnormality, and that is something that comes up occasionally. So they persisted in the treatment knowing that . . . is fairly benign, as we have already heard, and at least would offer the child a specific treatment. They did not use steroids or immunological intervention I assume because they considered, if they [were] considering taking ADEM, they didn't think that was high on their diagnostic list. So they treated the child as a viral encephalitis. He seemed to improve. They gave him anticonvulsants for the seizure-like activity; and I think that I can only agree with the treating doctors that this is the standard of care.

Tr. at 84-87.

In Capizzano III, the Federal Circuit counseled that "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" 440 F.3d 1317, 1326 (Fed Cir. 2006)(quoting Althen v. Secretary of HHS, 418. F.3d at 1280). In this case, the treating doctors, as Dr. MacDonald

cogently explained, diagnosed and treated Gerald for a viral illness[19], not ADEM. Dr. Griesemer agreed. See Tr. at 55-56. Considering the entire record, the undersigned agrees with the treating doctors and Dr. MacDonald in finding that Gerald did not suffer from ADEM.

In accepting Dr. MacDonald's testimony, Dr. Griesemer's testimony and opinion is necessarily rejected. Dr. Griesemer believes that Gerald suffers from ADEM which was caused by his immunizations. A summary of his reasoning follows.

Dr. Griesemer opined that Gerald had ADEM based the following. Dr. Griesemer testified that the time period between Gerald's vaccination and the onset of ADEM was appropriate i.e. a week or two after the initial insult. Tr. at 20. Dr. MacDonald agreed that if one were to assume ADEM, then the time frame is appropriate. Id. at 125. In the instant case, Dr. Griesemer testified that the medical records document "a significant change in his neurological functions, which occurs approximately a week after his immunizations . . . ." Id. at 23. He testified that Gerald's MRI was "consistent with a post-immunization process," and that there is "no evidence of a predisposing illness or developmental problem that offers a more attractive alternative explanation for [Gerald's] neurologic impairment that began at the time of his seizures . . . ." Id. Dr. Griesemer further testified that the results of Gerald's MRI showed abnormalities, "but not in the way that is suggested in Herpes encephalitis. It suggested instead to the radiologist a **diagnosis**[20] of acute disseminated encephalomyelitis." Id. at 12 (emphasis added). Additionally, Dr. Griesemer testified that Gerald's white blood cell count of fifteen "is not very impressive for an active infection." Id. at 43. Thus, he testified that the number of white blood cells and red blood cells obtained from Gerald was not supportive of a diagnosis of Herpes encephalitis. Id. at 14.

Putting this clinical information together, Dr. Griesemer testified "that the EEG was not supportive, the MRI was not supportive, the CSF was not supportive, the PCR was not supportive, and the clinical case was, or the clinical presentation was not as dramatic as we sometimes see [in cases of Herpes encephalitis]." Tr. at 15. However, Dr. Griesemer agreed that the clinical presentation for Herpes encephalitis is similar to the clinical course for ADEM in that there were seizures, decreased responsiveness, and injury to the brain. Id. at 17. Thus, he testified that "[i]t is not that the clinical course was inconsistent in its initial presentation as much as the clinical course was not as dramatic or as severe as we sometimes see." Id. However, after

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[19] There is no allegation or testimony from Dr. Griesemer that the vaccine is related in anyway to the viral illness. Thus, a finding that the treating physicians are correct that a virus is the cause of Gerald's illness rules out the vaccine as a contributing factor. See Pafford 451 F.3d at 1355 (holding that petitioner must show "that the vaccination was 'a but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm").

[20] As will be discussed more fully below, the radiologist did not diagnose ADEM. See P. Ex. 15 at 108.

reviewing the clinical course and the lab data, Dr. Griesemer testified that "[a]lthough there remains some questions in my mind about when the symptoms actually began, I think what we are seeing evolving eight days out is clearly consistent with a post-immunization ADEM . . . ." Id. at 19. Accordingly, Dr. Griesemer opined that Gerald's immunizations substantially contributed to his ADEM. Id. at 21, 22-23.

In analyzing Dr. Griesemer's testimony in support of the vaccine causing ADEM, the testimony can be broken into two parts: the reasons the clinical data do not support the treating doctors' diagnosis of a viral encephalitis (which in Dr. Griesemer's view would by exclusion leave ADEM as the likely diagnosis) and a discussion of what medical proof supports the diagnosis of ADEM, in this case the radiologist's report. As will be shown below, Dr. Griesemer's testimony is strong on conclusions but very weak on specific evidence buttressing those conclusions.

Regarding the clinical evidence that does not support a viral condition, Dr. Griesemer devoted much time discounting the evidence of Herpes Encephalitis. See Tr. at 12-17. However, Dr. MacDonald agreed that Gerald did not have Herpes Encephalitis. Id. at 99. What Dr. Griesemer fails to point out is that Gerald was not specifically diagnosed with Herpes encephalitis. Gerald's discharge diagnosis was a viral encephalitis, but no specific virus was identified. Dr. Griesemer attempts to show that because the MRI did not show a pattern for Herpes encephalitis, then this must mean that Gerald did not suffer from any viral encephalitis. That simply is not the case. Even if Gerald did not have Herpes encephalitis, this does not mean that he did not have a viral encephalitis. A Herpes encephalitis is simply one type of viral encephalitis. Dr. Griesemer conceded that there are many viruses that can cause myeloencephalitis. Id. at 42. He also recognized that medical technology can only identify the "most common ones." Id. In fact, the specific causative virus is known in only about one-third of the cases. Id. Dr. MacDonald concurred. Id. at 88. It should be noted that despite the negative lab reports for Herpes virus, the treating doctors treated Gerald with Acyclovir. Id. at 15, 57. Both experts testified that this was appropriate treatment. See id. at 55, 85. Dr. MacDonald testified that the physicians would not forego "treat[ing] a child they strongly suspected of encephalitis, even with a normal MRI scan." Id. at 106. Thus, the fact that the MRI did not show a pattern for **Herpes** encephalitis does not indicate that Gerald did not have a viral encephalitis. And, Gerald's condition improved following the treatment with Acyclovir.[21] See id. at 57. As Dr. MacDonald succinctly stated, "I think their diagnosis was viral myeloencephalitis. They treated the baby. Gerald seemed to respond in their mind and he looked better, so they considered that their diagnosis. I don't disagree with that." Id. at 122. There is no persuasive evidence to the contrary.

[21] Dr. Griesemer stated that "it not clear that the Acyclovir is the reason that the child improved." Tr. at 57. Dr. Griesemer did not expand on this statement nor provided any basis for it. Quite frankly, the undersigned viewed it as a somewhat desperate attempt to salvage a position in the face of strong contrary evidence.

The course of treatment of Gerald is a critical factor in this case. The doctors treated Gerald with Acyclovir, which is the treatment for Herpes encephalitis. They continued this treatment despite the negative lab reports for Herpes. See P. Ex. 16 at 28. Both Drs. Griesemer and MacDonald recognized that continued treatment as reasonable, since the treatment is "relatively benign." Tr. at 15; see also id. at 85. Importantly, the treating doctors did **not** treat for ADEM. The accepted treatment for ADEM is steroids. Id. at 55, 85, and 142. One would not prescribe Acyclovir for ADEM. Id. at 55. Steroid treatment could be harmful to a child with encephalitis - they could make the child worse. Id. at 141. As Dr. MacDonald summarized, "the treatments are different and not potentially compatible." Id. Thus, not only did the treating doctors not consider ADEM in their differential diagnosis, they did not treat Gerald with the accepted treatment, steroids, for ADEM. The doctors treated Gerald for encephalitis with Acyclovir, and he improved after that treatment. This is very strong evidence supporting the treating doctors' diagnosis of a viral cause.

Dr. Griesemer further attempted to bolster his opinion with his testimony that the results of the CSF indicating a fifteen white blood cell count was not high enough for viral infection. However, he conceded that a fifteen white blood cell count is higher than normal and that even a lower number of white blood cells could be consistent with viral infection. Tr. at 43. He agreed that the normal range for a white blood cell count is zero to five and that what was obtained from Gerald was three times the upper limit of normal. Id. at 44. Further, Dr. Griesemer testified that the results were not inconsistent with a viral myeloencephalitis, but that the white blood cells are typically much higher with myeloencephalitis. Id. However, Dr. Griesemer did not say what the typical number of white blood cells would be for a myeloencephalitis. He also testified that it could be lower than what was found in Gerald if the spinal tap is done very early in the clinical course and there has not been much of an inflammatory response. Id. at 45. Dr. MacDonald conceded that fifteen white blood cells is not inconsistent with ADEM, but stated that it is more consistent with a viral encephalitis. Id. at 142. Dr. MacDonald testified that the fifteen white blood cells is evidence of an inflammatory process and "the most common reason this occurs is an active viral infection." Id. at 139.[22] He testified that the treating doctors had the lab report and had to make a treatment decision. The elevated white blood cells is more consistent with a viral encephalitis and there is a treatment for it, thus, the doctors treated Gerald for the viral encephalitis. Id. at 143. While agreeing that there is "a lot of overlap with the ADEM features too," id. at 140, Dr. MacDonald testified that Gerald's overall clinical course is "classic for a viral encephalitis." Id. It is clear from the experts' discussion of the medical significance of the white blood cell count that the issue is not determinative. Both doctors recognized that white blood cells in the cerebral spinal fluid are indicative of inflammation. Dr. MacDonald conceded that the number of cells was not inconsistent with ADEM. The treating doctors interpreted the clinical information as supporting a viral cause, and treated Gerald accordingly. Gerald responded positively to that treatment. In light of the totality of the evidence, it is reasonable to

[22] Dr. Griesemer agreed. When asked whether it is concerning to have white blood cells in the cerebral spinal fluid in "an abnormal amount, however you want to define it;" Dr. Griesemer responded "Absolutely, that is the reason for the concern." Tr. at 45-46.

conclude that the treating doctors and Dr. MacDonald are correct that the white cell count was evidence of a viral infection.

In teasing out Dr. Griesemer's opinion, the primary piece of clinical evidence he relies upon to distinguish ADEM from a viral encephalitis is the radiologist's report. Dr. Griesemer recognized that the radiologist is the only treater that considered ADEM in the differential diagnosis. See Tr. at 55-56. The relevant portion of that report states as follows:

> The findings are nonspecific but may be seen in postinfectious/inflammatory processes such as ADEM.

P. Ex. 15 at 108 (duplicated at P. Ex. 5 at 286).

Dr. Griesemer relied upon this report to both discount the probabilities of a viral cause and to buttress his diagnosis of ADEM. Discussing the possible viral cause, Dr. Griesemer testified they if a child had Herpes encephalitis, an MRI would often show a characteristic pattern of abnormality. Gerald's MRI was abnormal, but not in the way that would suggest Herpes encephalitis. Tr. at 12. Dr. Griesemer went on to state that the MRI showed a post-infectious process, not an infectious process. Id. at 46. The difference being that in an infectious process, the MRI changes are "due to the changing agent," whereas in a post-infectious process "the changes seen in the brain are a consequence of this immunological response rather than a direct infection." Id. In addition, Dr. Griesemer stated that since the MRI was done with gadolinium, a contrasting agent, the MRI "clearly indicated that there was no active infectious process at the time of the MRI." Id. at 47. He later stated that this is evidence against a myeloencephalitis. Id. at 64.

Dr. MacDonald ascribed far less certainty to the findings of the MRI. First, he noted that the while the MRI was abnormal, the findings were "non-specific." Tr. at 106. He stated that, contrary to Dr. Griesemer's testimony, the finding of a possible post-infectious process would be indicative of a prior viral illness. In fact, there was some evidence of a viral illness on September 19, 2001, which is consistent with a finding of a post-infectious process on MRI done on October 11. Id. at 91. Dr. MacDonald stated that "if you want to, there are many explanations for the MRI scan changes, not just ADEM." Id. Regarding whether the MRI rules out an myeloencephalitis, Dr. MacDonald stated emphatically, " Not necessarily. There may be signs of inflammation with enhancement as we mentioned. But I don't think that anyone would not treat a child they strongly suspected of encephalitis, even with a normal MRI scan. And I think it depends on when the MRI is done during the illness. So I think there are several possibilities to explain this MRI scan." Id. When asked why the radiologist did not mention encephalitis, Dr. MacDonald responded that it "depend[s] on the report of the MRI." Id. at 106. Unfortunately, there is no radiologist report in the record. See Tr. at 56. Dr. MacDonald went on to say that "I believe that they were probably looking for encephalitis, but I don't remember a specific comment by them." Id. When pressed as to whether that means that they did not find encephalitis, Dr. MacDonald responded, "Well, I wouldn't say that. I think the radiologist's

interpretation is very brief, and he or she does say it is non-specific and they commented on the ADEM issue. I definitely agree with non-specific. I think the differential diagnosis is much wider than they postulated." Id. at 106-07.

Dr. Griesemer also relied upon the MRI to support a diagnosis of ADEM. The MRI is even less convincing on this point. Dr. Griesemer simply stated that the MRI "suggested to the radiologist a **diagnosis** of acute disseminated encephalomyelitis." Tr. at 12 (emphasis added). Of course, there is no diagnosis in the radiologist's findings, it says that the findings "are nonspecific but may be seen in postinfectious/inflammatory processes such as ADEM." P. Ex. 5 at 108. Later, Dr. Griesemer states that "[t]he radiologist interpreting the films felt that it was consistent with a post-infectious or inflammatory process such as ADEM." Tr. at 18. And finally, when challenged on cross-examination to concede that no treating physician diagnosed ADEM, Dr. Griesemer responded "[o]ther than the radiologist, that's correct." Id. at 56. However, when asked to show where that diagnosis appears in the radiologist's report, Dr. Griesemer replied:

> We don't have documentation of that. They didn't note ADEM in any of the progress notes. So it could be that they never checked the final, or transcribed the report of the MRI. I don't know.

Id. What is clear from Dr. Griesemer's testimony regarding the MRI scan and the radiologist's report is that the MRI raises questions but provides no persuasive answers. The radiologist read the scan and found it to be "nonspecific." While the findings may be seen in an inflammatory process such as ADEM, it may also be seen in an inflammatory process such as a post-infectious process. The one thing we know for certain is that contrary to Dr. Griesemer's statement, id. at 12, the radiologist's findings were **not** diagnostic. When you consider the cumulative evidence surrounding the MRI - the nonspecific findings, Dr. MacDonald's testimony of alternative explanations for the MRI, and finally, the treatment of Gerald for a viral condition, not ADEM, it is difficult to reach any conclusion except that the MRI is nonspecific and does not represent the medical smoking gun that Dr. Griesemer propounds.

While both experts agreed that most cases of ADEM are diagnosed retrospectively, there is nothing in the medical records to show that the treating physicians mis-diagnosed Gerald or that the treatment was inappropriate for his condition at the time. Gerald's treating physicians had all of the lab data and the medical information before them, and they diagnosed and treated for a viral encephalitis. In the absence of such evidence, an effort to re-diagnose Gerald several years after the fact must be accorded less weight than the contemporaneous medical records of the treating doctors. See DeRoche v. Secretary of HHS, 2002 WL 603087 (Fed. Cl. Spec. Mstr. Jun. 6, 2002). More recently, in Capizzano v. Secretary of HHS, 2006 WL 3419789 at *15 (Fed. Cl. Spec. Mstr. Nov. 8, 2006) [hereinafter "Capizzano IV"], the undersigned found that "[i]f as in this case, the treating doctors provide a consistent clinical picture that comports with the experts' medical theory, the treating doctors' opinions are as the Federal Circuit determined, 'quite probative'"(quoting Capizzano III, 440 F.3d 1317,1326 (Fed. Cir. 2006). Here, the undersigned

is presented with the testimony of two qualified experts both of whom agree that Gerald's clinical presentation is similar to that of both a viral encephalitis and ADEM, but who disagree on the eventual diagnosis. However, petitioner has not alleged or presented any evidence that Gerald was not accorded proper treatment at the time of his illness. The treating doctors, after considering the clinical data, diagnosed Gerald with a viral encephalitis. Gerald was treated accordingly and his condition improved. Notably, ADEM was not ever considered in the differential diagnosis. In the face of this "quite probative" evidence, the undersigned finds that petitioner failed to prove by preponderant evidence that Gerald had ADEM and not a viral encephalitis.

Finally, petitioner makes two arguments in her post-hearing memoranda that require discussion. In discussing the presented evidence and arguing that the cumulative evidence meets petitioner's burden of proof as delineated in Althen, petitioner states that Gerald's "treating physicians all associated Gerald's injury, by whatever name, with his vaccines." P. Post. Rep. at 15.; see also id. (treating physicians "attributed his injury, by any name, to his vaccines"); P. Post. Mem. at 24 ("These records indicate that several of his treating physicians associated his injury with his vaccines.") There are two threads of argument running through petitioner's contention: first, petitioner contests whether the decision in this case hinges on whether the diagnosis in this case is ADEM; and, second, after discounting the importance of the diagnosis, petitioner elevates the probative value of the treating doctors' "associating" the vaccine to Gerald's injury, whatever that injury is named. See P. Post. Rep. at 12-15. The undersigned strongly disagrees.

The undersigned focused the resolution of this case on the following:

> Entitlement to compensation in this case rests on the key issue of whether Gerald suffered post-immunization ADEM because Dr. Griesemer's opinion is premised on Gerald having ADEM – that is, Dr. Griesemer's medical theory of how the vaccine logically caused petitioner's injury in this case rests on the fact that petitioner suffered from ADEM.

Page 20 infra.

Relying upon Kelley v Secretary of HHS, 68 Fed. Cl. 84 (Fed. Cl. 2005), petitioner argues in effect that the undersigned's framing of the issue for decision is incorrect. Petitioner cites the following language from Kelley:

> The Vaccine Act does not require petitioners coming under the non-Table injury provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury - regardless of the ultimate diagnosis . . . . If petitioner proves causation by preponderant evidence under the non-Table

> injury provision of the Act, whether he suffers from GBS or CIDP is immaterial.

Kelley at 100. Kelley is both distinguishable from the case at hand and, while the above-quoted statement may be legally correct, in the vast majority of off-Table vaccine cases, its practical application is highly doubtful. First, the diagnostic question in Kelley involved two closely related conditions, GBS[23] and CIDP.[24] After reviewing evidence presented in the case, the reviewing court agreed with petitioner that "GBS and CIDP are conditions on a spectrum, and that distinctions between them are hopelessly blurred." Kelley at 102 (citation omitted). The reviewing judge also found the following language from the undersigned's decision in Althen illuminating:

> Petitioner's expert recognizes that identifying [her] condition is difficult, but believes calling her illness relapsing . . . or [chronic] 'is not a big issue[;] [t]hose are probably the same entity [because] the underlying inflammatory process is undoubtedly the same in each instance, and her condition evidently developed following her . . . [TT and Hepatitis A] vaccinations.

Kelley at 97 (citing Althen v Secretary of HHS, 2003 WL 21439669 at *14) (citations omitted).

Given the "blurred" lines between GBS and CIDP and considering the petitioner's expert's testimony in Althen, one can understand the reasoning behind not requiring the identification of the injury. In addition, and very importantly, petitioner's expert in Kelley provided a medical theory and opinion based upon the neurological injury suffered, whether it was ultimately determined to be GBS or CIDP. However, that is not the situation in this case. Petitioner's treating doctors diagnosed Gerald with a viral encephalitis. Petitioner's expert argues that the diagnosis is incorrect and that he would diagnose Gerald with ADEM. The diagnosis is critical in this case because there is no allegation of a relationship, and to my knowledge no known relationship, between the vaccinations and a viral encephalitis; there is an acknowledged relationship between ADEM and vaccinations. See Tr. at 125 (Dr. MacDonald agreed that immunizations have been "implicated" with ADEM). There is no blurring of the medical lines such as was involved in Kelley. Unlike petitioner's expert in Kelley, Dr. Griesemer did not contend that ADEM and viral encephalitis share the same pathogenesis. Also,

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[23] GBS is an "acute, autoimmune inflammatory destruction of the myelin sheath covering peripheral nerves, causing rapid progressive symmetrical loss of motor function." Kelley at 86, n.1.

[24] CIDP is "[a] gradually progressing autoimmune muscle weakness in arms and legs caused by inflammation of the myelin sheath covering peripheral nerve axons." Kelley at 86, n.2.

unlike the expert in Kelley, Dr. Griesemer did not advance a medical theory and give an opinion based upon a generic injury, his theory and opinion were premised upon a diagnosis of ADEM. See id. at 21-23. Thus, Kelley is clearly distinguishable from the case at hand. Which leads to the second point, the rare practical import of the Kelley finding that naming the injury is not legally required.

The Federal Circuit recently reiterated petitioner's burden in proving an off-Table case in a three-part standard. The first part is presenting evidence of "a medical theory causally connecting the vaccination and the injury." Althen at 1278. The Vaccine Act provides that petitioner's proof may be by the medical records or by medical opinion, but cannot be based upon petitioner's claims alone. §13(a). In virtually all of the off-Table cases, petitioners' presentation is through a medical expert. It is rare that the medical records alone support an off-Table case.[25] The medical expert's testimony linking the vaccine to an injury begins by identifying an injury. That only makes sense since the expert in providing a reliable medical theory must discuss the specifics of the injury to describe its logical relationship to vaccination. If you cannot identify the injury, how can the expert testify to a reliable, logical relationship to the vaccination? In eighteen years of hearing testimony from experts in these cases, no expert has opined to causation without first defining the injury. Kelley, which was heard by the undersigned, was no different in that respect. What was different in Kelley was that the medical expert's opinion focused upon two injuries, GBS and CIDP, and the expert opined that they were variants of the same disease process. What was accepted by the reviewing court was the petitioner's expert's testimony that the two processes are so similar, the lines between them are "blurred," that it did not matter which of the two injuries was ultimately diagnosed - the vaccine caused it. The case at hand it completely different. There is no blurring of the lines between ADEM and viral encephalitis. No expert has testified to any blurring. In addition, it is the petitioner's expert's medical theory in this case that the vaccinations caused Gerald's ADEM, not some generic injury and certainly not the viral encephalitis. Thus, if ADEM is eliminated in this case, Dr. Griesemer's medical theory fails. That is what the undersigned found.

Lastly, petitioner elevates references to the vaccines in the medical records to an unjustified level of evidentiary significance. Petitioner argues that "all" of Gerald's treating physicians "associated" or "attribute" his vaccines to his injury. The definition of "attribute" is to assign to a particular cause or source; the definition of associate is to connect or join together;

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[25] In Capizzano v. Secretary of HHS, Ruling on Remand, 2006 WL 3419789 (Fed. Cl. Spec. Mstr. Nov. 8, 2006), the undersigned stated that "[t]reating doctors rarely, if ever, provide medical theories of causation; they do provide critical circumstantial evidence." Id. at *14. To explain why that is the case, the undersigned quoted from petitioner's post-trial brief, the same counsel representing petitioner in this case, "treating physicians rarely discuss 'theories' in their notations. Theories are not relevant to the clinician's agenda, which is to identify, treat, and heal. If treating physicians needed to list their 'theories' before their opinions became probative in the Vaccine Program, then no medical record would be probative. Clinicians simply don't have the time to indulge in theorizing." Id.

combine; link. American Heritage Dictionary 140,135 (2d ed. 1985). After reviewing the entire record, paying particular attention to each of the records cited in petitioner's Posthearing Memorandum at pages 24-27, it is very clear that Gerald's treating physicians did not "associate" or "attribute" his injury to his immunizations. In fact it only makes sense that they did not given their ultimate diagnosis of a viral encephalitis.

While the undersigned considered all of the medical records that petitioner cited in his Posthearing Memorandum, no attempt will be made to discuss all of them. However, the undersigned carefully noted that not one of these notations in the record is a diagnosis, association or attribution of Gerald's injury to his vaccination. Unlike in Capizzano IV where the treating doctors discuss in the medical records the potential role of the vaccine causing petitioner's illness,[26] none of the treating doctors in this case discussed any relationship between the vaccine and Gerald's injury. At most, the records contain **references** to the vaccine. Most of the citations are to histories. See P. Ex. 3 at 38; P. Ex. 16 at 30; P. Ex. 3 at 5; Id. at 31; P. Ex. 13 at 50; P. Ex. 25 at 47. Others contain a reference to the vaccination under Chief Complaint, see P. Ex. 13 at 7; P. Ex. 9 at 3. Most are simply historical references. See P. Ex. 7 at 5; P. Ex. 12 at 5; P. Ex. 10 at 3; P. Ex. 8 at 25; P. Ex. 25 at 14; and P. Ex. 3 at 25. Finally, some records list DTaP under "allergies." See P. Ex. 9 at 18 and P. Ex. 12 at 2. However, there simply is no way of knowing why these notations of allergies were made or who made them. One must be very careful in giving weight to the mere mentioning of the vaccine in a medical record. As Dr. Griesemer noted, and in the undersigned's experience correctly so, in discussing why he discounted mom's testimony, "[t]hese are not observations that have been made and validated. This is presumably a history taken from mom after all of these experiences." Tr. at 34. Further, he testified that when taking a history "we describe what we are told, we don't give a diagnosis." Id.

Most of these notations in the record were taken from Gerald's mother's observations which she reported to his treating physicians. None of the physicians observed the events that occurred between October 1 and October 9. Petitioner's own expert testified that the observations made in the mother's affidavit may be limited because she does not have a medical background, and he was not sure what weight to give her perspective as a mother. That observation applies equally to the historical information she gave the doctors. Dr. Griesemer also testified that when a notation is made in a medical report that is not an actual observation made by the physician, it is listed in the history portion of the examination report rather than the physical examination portion of the report. Tr. at 28. He also testified, as noted above, that when taking a history "we describe what we are told, we don't give a diagnosis." Id. at 34. The fact that the medical providers made these notations is simply not indicative of causation or that

[26] Capizzano IV, 2006 WL 3419789 at *3 (Fed. Cl. Spec. Mstr. Nov. 8, 2006) ("The treating doctors contemporaneously treated Rose, ran appropriate tests, analyzed the data, noted factors, wrote their observations, and consistent with their role, determined the nature of the injury with an eye towards treating the illness and curing the patient. Based upon their medical analyses, the treating doctors considered the vaccine within their differential diagnoses.")

they associated the vaccines with causing Gerald's injury.

One record, at first glance, gives reason for pause. Petitioner's Exhibit 3 contains progress notes from October 14, 2001. The note states under assessment: "Encephalitis ? DTaP - adverse reaction." Id. at 71. It is not known who is responsible for this assessment. What is known is that the treating doctors finally diagnosed viral encephalitis and treated Gerald as such. There is no diagnosis or discussion of an adverse reaction to the DTaP during the critical treatment period of October 1 to October 18.

In summary, Gerald's treating physicians diagnosed him with a viral encephalitis and not ADEM. Several physicians examined Gerald. Gerald was examined by a pediatric neurologist on October 10 who thought that he may have encephalitis or meningitis. P. Ex. 16 at 6. Gerald was also examined by an infectious disease specialist who thought he may have a viral encephalitis. Id. at 8. Not one of these treating doctors diagnosed Gerald with ADEM nor did they note that ADEM may be a possible diagnosis in the contemporaneous medical records.

The undersigned recognizes, as the respective experts do, that the evidence in this case is not definitive. However, petitioner's effort to raise questions about the viral diagnosis does not make ADEM the preferred diagnosis by default. Dr. MacDonald effectively and persuasively explained why Dr. Griesemer's conclusions are possible, but far from probable. In the end, there is no persuasive reason to retrospectively re-diagnose Gerald. The treating doctors saw him, ran tests, treated him for a virus, noted Gerald's improvement to the treatment and diagnosed him with a viral cause. No doctor, until Dr. Griesemer, diagnosed ADEM. The radiologist did state that the MRI findings **may** be seen in processes such as ADEM, but did not diagnose ADEM. Importantly, the treatment of Gerald did not change in light of the MRI scan and interpretation. In the face of this evidence, it is illogical to conclude that Gerald should be re-diagnosed with ADEM and find that the vaccine was its cause.[27]

[27] Having found that Gerald did not suffer from ADEM, it is not necessary to discuss how vaccines can cause ADEM since petitioner's expert's entire medical opinion that the vaccines Gerald received caused his injury is based on Gerald having ADEM. Further, Dr. MacDonald agreed that vaccinations can cause ADEM, but he did not agree that Gerald had ADEM. Tr. at 125. Petitioner submitted several medical articles discussing ADEM and vaccines. However, having found that Gerald did not suffer from ADEM, it is not necessary to discuss those articles here.

IV. CONCLUSION

Based on the foregoing, the court finds, after considering the entire record in this case, that petitioner is not entitled to compensation under the Vaccine Act. The court found above that this case fails because the medical records and the expert's testimony do not support petitioner's expert's theory that Gerald had post-immunization ADEM. Thus, petitioner failed to prove by a preponderance of the evidence that his injuries were caused-in-fact by the vaccinations he received on October 1, 2001. For the reasons discussed above, petitioner fails to qualify for an award under the Program. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master