OFFICE OF SPECIAL MASTERS

No. 99-25V

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MONICA WATT and WILLIAM WATT biological parents and legal representatives of AMANDA ROSE WATT	*	
Petitioners,	*	**PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

DECISION

GOLKIEWICZ*, Special Master*.

Petitioners in this case, Monica and William Watt, are seeking compensation on behalf of their daughter Amanda Rose Watt (hereinafter "Amanda") under the National Vaccine Injury Compensation Program[1] (hereinafter "the Vaccine Program" or "the Program"). Their Petition alleges that "Amanda suffers a seizure disorder as defined in the Vaccine Injury Table." Petition at 3 (hereinafter "Pet. at ___"). Specifically, petitioners contend that Amanda developed a seizure

[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Vaccine Injury Act of 1986 ("the Vaccine Act" or "the Act"), as amended, 42 U.S.C.A. §§ 300aa-1 et seq. (West 1999 & Supp. 2000). Hereinafter, individual section (§) references will be to 42 U.S.C.A. § 300aa of the Act.

disorder, or infantile spasms, subsequent to the administration of the Diphtheria-Pertussis-Tetanus ("DPT") vaccine.[2] Pet. at 1. Respondent contested petitioners' request for compensation. To collect evidence to answer the questions presented in the case, on July 24, 2000, the Court conducted a hearing. The inquiry devolved to the following two issues:[3]

1. Did Amanda exhibit the first symptoms of her injury within the time period prescribed by the revised Vaccine Injury Table; and, if answered in the affirmative,

2. were the symptoms the onset of acute encephalopathy, as defined by the Act?

After reviewing the entire record, the Court finds that petitioners did not prove by a preponderance of the evidence that Amanda suffered a Table injury (acute encephalopathy) within 72 hours of the DPT vaccination, or in the alternative, that her condition was, in fact, caused by the DPT vaccination. Petitioners, therefore, are not entitled to compensation under the Program.

FACTS

This case presents a factual inquiry into the timing of events surrounding the onset of petitioners' injury. Amanda Rose Watt was born in New York, New York on November 6, 1995. See Petitioners' Exhibit 1 (hereinafter "P. Ex. __"). In accord with Amanda's medical records,

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[2] For purpose of the revised Vaccine Injury Table, which governs this case, a residual seizure disorder is not a listed vaccine-related injury. Therefore, petitioners must show by a preponderance of the evidence that Amanda experienced a listed vaccine-related injury within the time prescribed by the Act. For example, the first onset of an encephalopathy must occur within seventy-two hours (72) hours of the DPT vaccination. See 42 C.F.R. § 100.3. In the alternative, petitioners must show that the DPT in fact caused Amanda's injuries.

[3] The hearing transcript, filed on August 18, 2000, will be referenced herein as "Tr. at __."

petitioners state that she was "healthy at birth" and her subsequent development was considered normal. Petition at 1 ("hereinafter Pet. at ___); P. Ex. 3 at 2; Tr. at 15. Petitioners allege that Amanda began to smile around two months, but sometime thereafter her "development halted." Pet. at 1; Tr. at 15. Amanda's medical records indicate that she received her first DPT vaccination on February 22, 1996, when she was just over three months old. P. Ex. 3 at 1.

Petitioners contend that at approximately 5 p.m. that evening, Amanda "became severely cranky, began crying uncontrollably, and her eyes rolled back in her head." Pet. at 1; Tr. at 13. Within the days following Amanda's DPT vaccination, petitioners allege that "Amanda's symptoms got worse" and they noticed abnormalities in her behavior. On February 26, 1996, for example, Amanda began "startling at all noises." Pet. at 1. She also experienced "upward eye deviation around this same time." Tr. at 15. On March 10, 1996, petitioners noticed Amanda's "eyes rol[l] back in her head;" on March 15, 17, and 20,th petitioners noticed Amanda's eyes were dilated. Pet. at 1. Petitioners allege that these abnormalities continued until age four months. Id. The medical records, however, do not document these reported concerns.

Amanda visited her pediatrician on March 21, 1996, who noted that Amanda was "smiling" and found no medical problems associated with her behavior. Pet. at 2; Tr. at 42-43; P. Ex. 3 at 2. Amanda's mother, Mrs. Watt, kept a detailed journal of Amanda's medical history where she documented each visit to the pediatrician, Amanda's immunizations and her subsequent growth and development. P. Ex. 3 at 5-19. Not all notations in this journal, or "baby book," were made contemporaneously to all the medical events as they occurred. Tr. at 52. The journal records the March 21, 1996 office visit and notes that Amanda's doctor "says she looks fine;" it also describes Amanda as "cranky and lethargic" and "startling at all noises." P. Ex. 3 at

11. However, the pediatrician's notes concerning Amanda's March visit do not report these symptoms. P. Ex. 3 at 2.

Amanda's medical records document the onset of infantile spasms at age five months, beginning in April 1996 when she was initially hospitalized and diagnosed with her condition. P. Ex. 5 at 4. Petitioners describe the events leading up to Amanda's hospitalization as follows: on April 12, 1996, at approximately 8 p.m., Amanda "had a series of 15-20 startles in a row;" on the morning of April 13, 1996, petitioners took Amanda to the emergency room at Morristown Memorial Hospital (MMH) where later that same day, Amanda experienced "a series of 20-30 startles in a row." Pet at 2. Petitioners contend, and the medical records confirm that Amanda was subsequently admitted on April 13, 1996, and she began ACTU therapy. Pet. at 2; P. Ex. 5 at 4. Amanda's pediatrician noted that her mother reported "jerking movements" on April 15, 1996, similar to those "she had begun to notice this week." P. Ex. 3 at 3. Amanda's medical records also confirm that during this hospitalization, Amanda experienced "brief myoclonic jerks." P. Ex. 6 at 4. Amanda was diagnosed with "infantile spasms" and "mild developmental delays" and was discharged on April 22, 1996. P. Ex. 5 at 4; P. Ex. 6 at 3.

Amanda continued to receive ACTH therapy until she became a patient of Dr. Douglas R. Nordli, Jr., M.D., a neurologist and head of Columbia Presbyteria's Comprehensive Epilepsy Center[4] in July, 1996. Id.; P. Ex. 7 at 1. During Amanda's initial office visit, petitioners had an

[4]Dr. Nordli is board certified in psychiatry and neurology with a special qualification in child neurology. In addition, he is board certified in pediatrics, clinical neurophysiology in electroencephalography and evoked potentials, with special qualifications in clinical neurophysiology. P. Ex. 17. He earned an M.D. from Columbia University in 1984. Id. For two years following graduation, Dr. Nordli was a pediatric intern at Babies Hospital, Columbia Presbyterian Medical Center. Id. Then Dr. Nordli spent three years as a resident in child neurology at the Neurological Institute of New York, Columbia Presbyterian Medical Center. Id.

opportunity to discuss Amanda's condition with Dr. Nordli; they reported "upward eye deviation around 2-3 months." P. Ex. 7 at 1. Dr. Nordli's notes from this initial visit also indicate that Amanda's development halted prior to the DPT vaccination, at age two months. P. Ex. 7 at 1. Dr. Nordli reduced the dosage on Amanda's ACTH therapy, but, reinstated it after "she began to experience seizure events often in clusters, on a daily basis;" these events started in January, 1997 and continued through May 1997. P. Ex. 7; Pet. at 2; P. Ex. 8 at 1.

Evidence in the record suggests that Amanda's spasms may have began prior to April, 1996, but nothing evidences a clear date of onset. For example, Amanda's genetic consultation in 1998 indicated that petitioners "had some concerns when Amanda was about four months old." P. Ex. 10 at 1. Likewise, the April 1996 discharge diagnosis indicated that Amanda's parents described her as "well until 1 month prior to admission." P. Ex. 6 at 3. Petitioners reported "poor visual tracking" and that she "stopped smiling and cooing" during the month of March, 1996. Id. In this respect, petitioners' account conflicts with that of Amanda's pediatrician, who indicated that Amanda was "smiling" during her March 21, 1996 office visit. P. Ex. 3 at 2.

Petitioners have discussed Amanda's seizures with various health professionals following her initial hospitalization in April, 1996. P. Exs. 7-10. Although they have voiced concerns about Amanda's behavior when she was four months old, her medical records consistently record the onset of infantile spasms at five months of age. P. Ex. 6 at 3-4; P. Ex. 7 at 1, P. Ex. 8 at 1, P. Ex. 9 at 1; P. Ex. 10 at 1,3. For example, since Amanda's seizures in 1997, she has undergone a PET Brain Scan, a neuropsychological evaluation, and genetic testing. P. Exs. 8, 9 & 10.

Following his residency, he became a postdoctoral clinical fellow in neurology (EEG and Epilepsy). Id. Currently, Dr. Nordli is a neurologist at Children's Memorial Hospital. Id.

Amanda's PET Brain Scan report to Dr. Nordli documents the onset of Amanda's infantile spasms at age five months. P. Ex. 8 at 1. Similarly, Amanda's March 1998 neuropsychological evaluation also records "a history of infantile spasms at approximately 5 months of age."[5] P. Ex. 9 at 1. Mrs. Watt gave her most recent account of Amanda's medical history to Dr. Davis during the 1998 genetic consultation, yet, she made no mention of the events following Amanda's vaccination.[6] P. Ex. 10 at 3. Dr. Davis references Amanda's diagnosis of "infantile hypsarrhythmia" at "5 months of age." Id.

Although Amanda has not experienced a seizure since May 17, 1997, she continues to take medication for her condition (500mg of Vigabatrin, 2x a day; 250mg of Depakote Sprinkles, 2x a day; 2.5 ml of Carnitor, 2x a day; Prilosec (10 mg) 1x a day; and, 3.5ml of Propulsid (1mg/ml) 4x a day). Pet. at 2; P. Ex. 7. Today, at age three, Amanda remains under Dr. Nordli's care. P. Ex. 14.

PROCEDURAL HISTORY

Petitioners filed their claim on January 14, 1999, alleging that Amanda suffered a vaccine-related injury resulting from the administration of the DPT vaccine. In support of their claim, petitioners provided medical records detailing Amanda's history of infantile spasms. P. Exs. 1-13. Petitioners also submitted a letter from Dr. Nordli, indicating that "immunization remains a distinct possibility" for Amanda's encephalopathy. P. Ex. 14. Pursuant to Court Order,

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[5] This neuropsychological evaluation, conducted when Amanda was age two, indicated that her "highest areas of functioning were at a 7-month level on a cognitive scale and 9 month level on the language scale." P. Ex. 15 at 2.

[6] Dr. Davis' follow-up letter to petitioners indicated that she and Ms. Watt "spoke in depth about the fact that . . . the underlying cause of Amanda's seizures is not known . . . ." P. Ex. 10 at 3.

dated May 13, 1999, petitioners were granted additional time to gather expert testimony concerning the cause of Amanda's seizure disorder. Petitioners submitted an expert report by Dr. D.R. Nordli, her neurologist, and a final one year follow-up VAERS (Vaccine Adverse Event Reporting System) report on September 9, 1999. P. Ex. 15 & 16.

Respondent filed her response to petitioners' claim on November 11, 1999, pursuant to Vaccine Rule 4(b).[7] Respondent's report recommended that the Court deny compensation and dismiss petitioners' case. See Respondent's Report at 9 (hereinafter "R. Rpt. at __"). Respondent argued that Amanda's vaccine-related injury did not occur within the limits prescribed by the Vaccine Injury Table. R. Rpt. at 5. Specifically, she argued that the onset of Amanda's injury occurred in March, 1996. R. Rpt. at 5. Citing Amanda's medical records, respondent noted:

> when Amanda was hospitalized in April, 1996, at Morristown Memorial Hospital, the history taken at that time was that the onset of her problems was one month prior to the admission, which would place the onset of her abnormal behavior in March 1996, not immediately after her DPT.

Id. Furthermore, respondent contended that "Amanda's seizures were not caused by the DPT vaccine she received on February 22, 1996." R. Rpt. at 8. In support of her position, respondent cited the report of Dr. Peter Kollros,[8] who concluded "it is clear that there is not evidence in

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[7] Rule 4(b) provides, in part, that "within 90 days after the filing of the petition respondent shall file a report that shall set forth a full and complete statement of respondent's position as to why an award should or should not be granted . The report shall contain respondent's medical analysis of petitioner's claims ." See RULES OF THE UNITED STATES COURT OF FEDERAL CLAIMS, APPENDIX J (rev. Mar. 15, 1992).

[8] Dr. Kollros is board certified in pediatrics and neurology with a special qualification in child neurology. Tr. at 57. He earned an M.D. degree with honors and a Ph.D. degree in pathology from the University of Chicago. Id. Dr. Kollros spent two years at Children's Memorial Hospital, where he did a pediatric internship and residency. Id. Following

Amanda's medical record to support a Table injury. The first mention in physician records of jerking or seizure is in April of 1996." R. Ex. A. Dr. Kollros also opined that "DPT does not cause infantile spasms." R. Rpt. at 8; R. Ex. A.

An expert hearing was conducted on July 24, 2000, to hear the testimony of Dr. Nordli, Amanda's neurologist and Dr. Kollros, respondent's expert in the case. The transcript of this hearing was filed on August 18, 2000, and the case is now ripe for decision.

ANALYSIS

Petitioners can prove they are entitled to compensation under the Program in either of two ways; through a statutorily prescribed presumption or causation-in-fact. First, petitioners may prove Amanda suffered an injury or condition listed on the Vaccine Injury Table, within the statutorily prescribed time period. §11(c)(1)(C)(i). Petitioners are presumptively entitled to compensation if they meet their burden by a preponderance of the evidence.[9] § 13(a)(1)(A). Once established, this presumption is rebutted only by a showing that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B).

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this experience, he went to the University of Michigan for a pediatric neurology residency and continued for an additional year at the University as a lecturer and research fellow. Id. Dr. Kollros is currently a clinical associate professor for pediatrics and neurology at Temple University. Id.

[9] Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact "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, 372-373 (1970) (Harlon, 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).

In the alternative, petitioners may prove causation-in-fact, by demonstrating a causal link between the vaccination and the injury. § 11(c)(1)(C)(ii); see also Grant v. Secretary of HHS, 956 F.2d 1144, 1147-48 (Fed. Cir. 1992) (distinguishing causation-in-fact cases under the Act). The court explained that "a reputable medical or scientific explanation must support this logical sequence of cause and effect." Id. at 1148 (citing Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983). Here too**,** petitioners must meet their burden by a preponderance of the evidence. Id., § 13(a)(1)(A). Petitioners in this case allege that Amanda suffered a Table injury.[10] Pet. at 1.

I. Onset of injury within the time period prescribed by the Vaccine Injury Table

Because this case involves the DPT vaccine, petitioners must prove that Amanda suffered from an acute encephalopathy within 72 hours of receiving the vaccine. 42 C.F.R. § 100.3. After examining the record in this case, the Court finds that petitioners failed to show that the onset of an acute encephalopathy, as it is defined by the Program, occurred within the time prescribed by the Vaccine Injury Table (within 72 hours of the DPT vaccination). 42 C.F.R. § 100.3.

Both experts offered testimony regarding the date of onset of Amanda's infantile spasms; the only clear consensus on the date of onset in the record is April, 1996. P. Ex. 5.; R. Ex. A. From Amanda's initial office visit, Dr. Nordli could not pinpoint the date of onset. Based on her initial visit, Dr. Nordli described her condition as "cryptogenic infantile spasms with early onset-?." P. Ex. 7 at 1. In a supplemental expert report, Dr. Nordli has since noted the onset "at five months of age." P. Ex. 15 at 1. Likewise, Amanda's medical records indicate the onset of

[10] The Court notes that petitioners cannot prevail based on a causation-in-fact theory in this case. In addition to Dr. Kollros' opinion against such a theory, petitioners' own expert, Dr. Nordli does not support the theory. At the July hearing, Dr. Nordli testified that " . . . and I've said it before; I'll say it again: I don't think there is a causal relation between DPT and spasms. That's been carefully shown." Tr. at 50; see also Tr. at 33-35.

infantile spasms occurring at age five months. See e.g., P. Ex. 6 at 3; P. Ex. 8 at 1; P. Ex. 9 at 1. Furthermore, Amanda's follow-up visit to her DPT vaccination (at age four months) did not reflect an onset of infantile spasms. Pet. at 1-2; P. Ex. 3 at 11, Tr. at 42-43. Dr. Nordli explained the lack of a documented onset date stating "its not fair to demand that the pediatrician make the association [with the administration of the DPT vaccination]." He recognized, however, that the onset is difficult to pinpoint from the existing medical records; further, Dr. Nordli largely relied on the parent's reports of the events following the DPT vaccination. Dr. Nordli testified:

> Can we pinpoint it from the medical records, or can you, with a great degree of specificity point to one day from the initial information we collected. And I would say no, you can't. Relying on the parental report is what's, I think, critical.

Tr. at 44. Dr. Nordli explained "[a]nd in medical terms, you know, we're very accustomed to working with that kind of information [parental report], because that's the vast majority of information that we have to work with." Tr. at 24. The Court questioned Dr. Nordli regarding "the lack of specificity" surrounding the date of onset. Tr. at 24. Dr. Nordli explained that absent "objective testing," he could not "pinpoint" the date. Tr. at 24.

The Court questioned Dr. Nordli regarding the "acuteness" of Amanda's encephalopathy. Dr. Nordli explained that the "acuteness relates to the events at the time of the vaccination;" he recognized that the only account of those events is evidenced in the parental reports – "just the report of what the family is describing and, you know, the history of what they are relating to us." Tr. at 48-49.

Despite the testimony from Dr. Nordli, it is not clear when symptoms began. There are references to an onset as early as two months and as late as five months. Tr. at 15; P. Exs. 7 at 1, 8 at 1, 9 at 1. Dr. Kollros' testimony acknowledged what little information existed regarding the

events three days following the DPT vaccination. He stated,

> [t]here is a paucity of data, both in the medical records and in the petition of the mother, for what happened in the time period of the three days after the DPT is given. We know that the mother relates events that occurred in early March during – in the petition, in which she talked about eyes rolling up, the baby not being quite right. And this is given in the context that she was playing with the baby and then this event would happen. And that event could be part of a chronic encephalopathy. It's not really clear to me that it's an acute – part of an acute encephalopathy of the severity that I think the definitions in the table would demand. And it certainly was outside of the three-day time period.

Tr. at 60.

The Court credits Dr. Kollros' opinion and emphasizes a point made by his testimony. The medical records in this case do not support petitioners' allegations that Amanda suffered an acute encephalopathy within 72 hours of her DPT vaccination. Tr. at 61-62. The references in the record to the date of onset of Amanda's infantile spasms consistently document the onset at age five months, which is approximately two months after Amanda's DPT immunization. P. Ex. 7 at 1; P Ex. 8 at 1; P. Ex. 9 at 1. Petitioners' own expert notes that "clear Salaam attacks presented on 4/12/96 when she was five months." P. Ex. 7; see also P Ex. 8 at 1; P. Ex. 9 at 1. Nonetheless, a special master will not rely solely on medical records when deciding the factual issues presented by each claim, rather, the special master must consider the entire record. 42 U.S.C.A. § 300aa-13. Therefore, if the Court were to find for petitioners in this case, it would have to find some other evidence in the record for its decision that Amanda did, in fact, suffer an acute encephalopathy within the time prescribed by the Act. 42 U.S.C.A. § 300aa-13(a)(1).

To that end, the Court considered carefully Amanda's baby book, a very thorough journal, which Ms. Watt used to document petitioners' account of the events surrounding the onset of Amanda's infantile spasms. P. Ex. 3 at 5-19; Tr. at 52. After complete consideration, however,

the Court cannot use this evidence to substantiate petitioners' claim. Because Mrs. Watt did not record all of these medical events contemporaneous to the time in which they occurred, and it is uncertain when the notations were made, the Court rejects the journal as untrustworthy evidence. It is well established that information recorded contemporaneously to the time in which the events occurred "is more believable than that produced years later at trial." See Lawson v. Secretary of HHS, 2000 WL 246234 *7 (Fed. Cl. 2000) (citations omitted); see also Cucuras v. Secretary of HHS, 993 F.2d 1525 (Fed. Cir. 1993).

At the July hearing, the Court asked Ms. Watt "how the notations came about in [the] baby book." Tr. at 52. Ms. Watt explained:

> I would write in my baby book every time I phoned the doctor, or I would put it on my daily calender. So I don't know if I transferred them at some point. I cannot tell you that. But I always made a notation when I called the doctor.

Id. The Court asked Ms. Watt specifically about her notations concerning the Feb. 22, 1996 office visit (the date of Amanda's DPT vaccination). See P. Ex. 3 at 11. In response to the Courts question whether these notations were made contemporaneous to the events on February 22, 1996, Ms. Watt responded:

> I would say most of those – I cannot verify all, but most of those were written at the time I would call, because I always had the baby book in my bag.

Id.

The Federal Circuit has counseled against crediting the conflicting testimony of a fact witness when medical records contemporaneous to the "medical events" support a contrary factual finding. See Cucuras v. Secretary of HHS, 993 F.2d 1525, 1527 (Fed. Cir. 1993); see also Burns v. Secretary of HHS, 3 F.3d 415 (Fed. Cir. 1993). The Federal Circuit specifically held that petitioners did not meet their burden of persuasion when, contrary to parent's testimony,

contemporaneous medical records indicated their child was "perfectly well" until one week following a DPT vaccination. See Curcuras, 993 F.2d at 1527-28. The Federal Circuit considers medical records "trustworthy evidence " in part, because they are "contemporaneous to the medical events." See Cucuras, 993 F.3d at 1528. In this case, the Court finds that the medical records are a far more reliable source of factual information. See Burns v. Secretary of HHS, 3 F.3d 415, 416 (Fed. Cir. 1993) (citing Cucras v. Secretary of HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993)).

The notations in Amanda's baby book were not made contemporaneously to all of the medical events. Tr. at 52. While Ms. Watt implied that the notations at worst were made shortly after the event, there is evidence to the contrary. At P. Ex. 3 at 11, it is noted on February 22, 1996 that there was a possible reaction "to the DPT." However, Ms. Watt testified that she did not make the connection between Amanda's injury and the DPT until seeing Dr. Nordli in July 1996 – five months later. Tr. at 56. Such a gap in time undercuts the reliability of the information being recorded. Thus, Ms. Watt's uncertainty as to when the entries were made plus hard evidence of a substantial time lapse for at least one entry, undermines the evidentiary value of the baby book. Furthermore, the baby book is the sole evidence in the record detailing the medical events that petitioners allege occurred within 72 hours of Amanda's vaccination. Dr. Nordli concedes that there is no evidence in the medical records that confirms petitioners' claim. Tr. at 29. Moreover, petitioners discussed Amanda's medical history with various health professionals prior to filing this action, and yet, Amanda's medical records do not reflect the events occurring in February 1996. P. Exs. 7-9. Of particular note is the history given on June 30, 1998, two years after the vaccination and after Ms. Watt allegedly correlated the vaccination

with Amanda's injuries. Tr. at 56. This detailed examination of the factual events constructed with Ms. Watt's participation fails to support petitioners' current factual allegations, but is in accord with the contemporaneous medical records. P. Ex. 10 at 1-4. The Court cannot reconcile petitioners' factual allegations with the clear, complete and consistent information contained in the medical records. Therefore, the Court accepts the evidence contained in Amanda's medical records, recorded contemporaneously with the medical events, and finds that it far outweighs the petitioners' current account of the onset of Amanda's infantile spasms.

Since the records do not document, as conceded by Dr. Nordli, the onset of a Table encephalopathy within 72 hours of Amanda's DPT vaccination, petitioners' claim must fail.

II Acute encephalopathy, as defined by the Act

Even if the Court were to accept Mrs. Watt's factual allegations as true, petitioners would not prevail. In considering Amanda's medical records, as supplemented by the expert testimony heard during the July expert hearing, the Court finds Amanda did not suffer an acute encephalopathy, as defined by the Act. As Dr. Nordli explained, the medical community defines "encephalopathy" broadly:

> an encephalopathy, in medical terms and the way I commonly use it, and my colleagues do, is that it's a disorder of brain function. You know, coming from a combination of "encephalo," meaning the brain, and "pathy," meaning disease. So any process, disease or disorder that affects the nervous system is truly speaking, an encephalopathy.

Tr. at 7. In contrast, the Program requires that Amanda experience an acute encephalopathy within 72 hours of the vaccination. 42 C.F.R. § 100.3(b)(2)(I). The Qualifications and Aids to Interpretation ("QAI") define acute encephalopathy as "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." 42 C.F.R. § 100.3(b)(2)(i).

Further, the QAI explains that in a child less than 18 months "who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i)(A). Dr. Nordli admitted, however, that "Amanda did not show any evidence of a stupor or an alteration of consciousness with three days of her DPT vaccination." Tr. at 44. Furthermore, "sleepiness irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying and bulging fontanelle" are not evidence of a change in level of consciousness. 42 C.F.R. § 100.3(b)(2)(i)(D). The QAI goes on to state that "seizures themselves are not sufficient to constitute a diagnosis of encephalopathy." 42 C.F.R. § 100.3(b)(2)(i)(E). Thus, petitioners' expert was forced to question the correctness of the QAI, Tr. at 73-75, while conceding that Amanda did not meet the QAI. Tr. at 44.

It goes without saying that the Court's proper role is to interpret the QAI and apply the facts and medicine thereto. It would be in error for this Court to interpret or apply the QAI as others believe they should be written. See Tr. at 74-75 (Dr. Nordli's discussion of how the QAI guidelines should read). As Dr. Kollros stated:

> the [Vaccine Injury] table probably is a very reasonable compromise, you know, given the need to – from a public health point of view, to have immunizations. But if you look at it from an epidemiology point of view, there are probably many people who are compensated – if we were to look at the people who are compensated from an epidemiological point of view, we would be able to pick this up.

Tr. at 76-77.

It is not for the Court to participate in the debate but to apply the law. Applying the law, Amanda did not suffer an encephalopathy as defined by the Vaccine Act. Dr. Kollros' opinion is consistent with that of the QAI; he opined that Amanda did not suffer a Table encephalopathy

within 72 hours of her DPT vaccination. Dr. Kollros expounded, "the vaccine table makes some distinctions about the encephalopathy, which says that it cannot merely be crying, it cannot – inconsolable crying; it cannot merely be crankiness; it cannot merely be a number of things." Tr. at 59. Furthermore, Dr. Kollros acknowledged that "a simple seizure at the time is not really sufficient to meet the definition of an encephalopathy on the [T]able definition." Tr. at 59. Dr. Kollros also noted that "the [T]able definition of encephalopathy says that inconsolable crying is not enough. That is not an unexpected acute side effect of the DPT." Tr. at 62. Dr. Nordli, in contrast, opined that "[s]ome of the symptoms [of encephalopathy] could be crankiness, inconsolable crying, you know, an abrupt change in their behavior." Tr. at 14. This testimony, however, is contrary to the binding QAI and, thus, must be rejected.

Because Dr. Kollros' definition of acute encephalopathy is consistent with the that of the Program, the Court credits his testimony and finds that Amanda's did not suffer an acute encephalopathy within 72 hours of her DPT vaccination. Despite Dr. Nordli's good efforts to support petitioners' claim, Dr. Nordli was forced to concede that this claim fails to meet the QAI's definition of encephalopathy. Tr. at 44. Therefore, petitioners have failed to offer proof by a preponderance of the evidence that Amanda's condition met the Table definition of acute encephalopathy.

CONCLUSION

Petitioners in this case have not provided legally sufficient evidence to meet their burden in this case. It is unfortunate that Amanda undoubtedly suffers from a seizure disorder.

However, petitioners have not offered persuasive proof that the DPT vaccination, which Amanda received on February 22, 1996, either presumptively or actually caused her condition. Petitioners have failed to show that Amanda suffered an acute encephalopathy, as defined by the Act, within 72 hours of her DPT shot. In addition, the experts in this case agree that Amanda's seizure disorder is not the cause-in-fact of her injury. Therefore, for the reasons discussed above, petitioners fail to qualify for an award under the Program. The Clerk is directed to enter judgment accordingly.

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Gary J. Golkiewicz
Chief Special Master