In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 04-{redacted}V

(Redacted version submitted: November 30 , 2006)
To be published[1]

* *	
{redacted}, *	
Grace {redacted}, *	
*	Vaccine Act Entitlement;
Petitioner, *	Causation-in-fact;
*	DTaP/Infantile Spasms
v. *	Causation Issue.
*	
SECRETARY OF HEALTH AND *	
HUMAN SERVICES, *	
*	
Respondent. *	
*	
* *	

DECISION

HASTINGS, ***Special Master*.**

This is an action in which the petitioner, **{redacted}**, seeks an award under the National Vaccine Injury Compensation Program (hereinafter "the Program--see 42 U.S.C. § 300aa-10 *et seq*.[2]), on account of an injury to her daughter, Grace **{redacted}**. For the reasons set forth below, I conclude that petitioner is not entitled to such an award.

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[1]At the request of the petitioner, this decision is issued in redacted form. This decision may be cited as *Grace v. Secretary of Health and Human Services*.

[2]The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq*. (2000 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2000 ed.). I will also sometimes refer to the Act of Congress that created the Program as the "Vaccine Act."

I

THE APPLICABLE STATUTORY SCHEME AND CASE LAW

Under the National Vaccine Injury Compensation Program (hereinafter the "Program"), compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showings that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious long-lasting injury; and has received no previous award or settlement on account of the injury. Finally--and the key question in most cases under the Program--the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table" corresponding to the vaccination in question, within an applicable time period from the vaccination also specified in the Table.[3] If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that, in fact, the vaccination caused the injury in question. See, e.g., *Hines v. Secretary of HHS*, 940 F. 2d 1518, 1525 (Fed. Cir. 1991); *Althen v. Secretary of HHS*, 418 F. 2d 1274, 1278 (Fed. Cir. 2005). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); see also *Hines*, 940 F. 2d at 1525; *Althen*, 418 F. 3d at 1278. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F. 3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Secretary of HHS*, 165 F. 3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, by evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F. 3d at 1278; *Grant v. Secretary of HHS*, 956 F. 2d 1144, 1148 (Fed. Cir. 1992).

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[3]The original version of the Vaccine Injury Table was contained in the statute, at § 300aa-14(a). As will be detailed below, however, the Table has been administratively amended.

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccine brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F. 3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting the petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of a qualified expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program factfinder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

More recently, the Federal Circuit has addressed the causation-in-fact standard in two more rulings, *Capizzano v. Secretary of HHS*, 440 F. 3d 1317 (2006), and *Pafford v. Secretary of HHS*, 451 F. 3d 1352 (2006). Both opinions affirmed the applicability of the *Althen* test, quoted above. The *Capizzano* opinion cautioned Program factfinders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. The *Pafford* ruling, on the other hand, indicated that it is the *petitioner's* burden to demonstrate a defined period after vaccination in which one would expect to see the symptoms of a vaccine-caused injury of the type in question.

II

FACTS AND PROCEDURAL HISTORY OF THIS CASE

A. Facts appearing in the contemporaneous medical records

Grace **{redacted}** was born on November **{redacted}**, 2000. In February and March of 2001, Grace received DTaP (diphtheria, tetanus, and acellular pertussis), polio, and haemophilus influenza B (HiB) vaccinations. On April 9, 2001, Grace received another set of vaccinations, consisting of the DTaP vaccination and an inactivated polio (IPV) vaccination. (Vol. 1, p. 3[4].)

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[4]Petitioner filed her "First Submission of Required Documents" on March 30, 2004; her "Second Submission" on July 2, 2004; her "Third Submission" on August 3, 2004; her "Fourth Submission" on February 3, 2005; and her "Fifth Submission" on February 8, 2005. I will refer to

On April 14, 2001, Grace was taken to see her pediatrician. The pediatrician's office notes indicate that one of Grace's parents at that visit reported that she had been having two-hour "screaming/crying" spells over the past three days. (Vol. 1, p. 3.) The same pediatrician's records also indicate that on April 16, 2001, Grace was still experiencing "excessive crying." (*Id.*) During the evening of April 22, 2001, Grace was taken to a hospital emergency room. There, her parents reported (1) that Grace had not been her "usual self" for ten days, with "screaming," and (2) that "4 days ago" Grace "started having 'seizures'"--*i.e.*, incidents in which she threw her arms up and her eyes rolled back. (Vol. 1, p. 11.) Grace was admitted to the hospital, and another history, taken just a few hours later, at 2:00 a.m. on April 23, 2001, confirmed that Grace began her seizure-like movements about four days beforehand. (Vol. 1, p. 16.)

Grace's hospitalization continued, and her physicians soon diagnosed that she was suffering from "infantile spasms," a specific type of seizure disorder. This grave disorder includes severe developmental delay as well as seizures. Since April of 2001, Grace has continued to suffer from the severe affects of her "infantile spasms" disorder. No cause for that disorder has ever been definitely identified by her treating physicians.

B. Family's reports of additional symptoms

In the course of this Vaccine Act proceeding, Grace's mother (the petitioner) and Grace's grandmother have provided testimony describing symptoms that, according to their memories, Grace displayed during the first two days after her vaccinations of April 9, 2001. The affidavits of both witnesses were filed on August 3, 2004 (Vol. 3), and then both provided oral testimony at the hearing of February 23, 2006.

In her affidavit and hearing testimony, Grace's mother stated that on April 9, 2001, after Grace was given vaccinations around noon, she was sleepy for the rest of the day. (Vol. 3, p. 656; Tr. 6.) The mother testified that beginning about 10 p.m. that evening, Grace began crying incessantly for about three hours. (Vol. 3, p. 656; Tr. 6-7.) The next morning (April 10) Grace "had a significantly decreased level of consciousness," failed to look into her mother's eyes, failed to "recognize" her sister or father, stopped reaching for toys, and did not respond to attempts to engage her. (Vol. 3, p. 656; Tr. 7-11.) On the following day, April 11, Grace "cried on and off for a period of nine hours," and, when awake, was "not responding to anything that was going on around her." (Vol. 3, p. 657.)

Grace's grandmother, **{redacted}**, described Grace's behavior on April 11, 2001, two days after the vaccination, when she babysat for Grace for several hours. She testified that on that day, Grace failed to turn her head or otherwise respond to visual stimuli, voices, or even to hand-clapping. (Vol. 3, p. 658; Tr. 46-48.)

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those submissions as "Vol. 1," "Vol. 2," etc. Respondent has filed exhibits, designated as Ex. A through Ex. H, on several occasions. I will refer to those as Ex. A, Ex. B, etc. "Tr." references will be to the pages of the transcript of the evidentiary hearing held on February 23, 2006.

C. Procedural history

The petition was filed on **{redacted}**, 2004, and was assigned at that time to Special Master John Edwards. On January 12, 2006, the case was reassigned to my docket. I conducted an evidentiary hearing on February 23, 2006. After the hearing, petitioner's counsel requested permission to file a supplemental expert report. That report was filed on October 5, 2006, so that the case is now ripe for a ruling on the issue of "entitlement."

III

ISSUES TO BE DECIDED

In this case, the petitioner seeks an award on Grace's behalf via two different theories. First, petitioner contends that Grace suffered the Table Injury known as "encephalopathy" after her DTaP vaccination of April 9, 2001. Second, she contends that Grace's "infantile spasms" disorder was "caused-in-fact" by that DTaP vaccination. After careful consideration, I conclude that petitioner has *failed* to establish causation under either theory.[5] I will set forth my reasoning in the following sections of this Decision. First, in Section IV, I will explain why I cannot accept, as accurate, certain testimony of Grace's mother and grandmother concerning behavior that Grace allegedly displayed during the first two days after the vaccination in question. Next, in Section V, I will state my reasoning concerning the Table Injury issue. Thereafter, in Sections VI, VII, and VIII of this Decision, I will explain why I must reject petitioner's "causation-in-fact" theory as well.

IV

I CANNOT ACCEPT THE SYMPTOM HISTORY UPON WHICH DR. JACOBSON RELIED

In the course of this Vaccine Act proceeding, Grace's mother and Grace's grandmother have provided testimony describing symptoms that, according to their memories, Grace displayed during the first two days after her DTaP vaccination of April 9, 2001. Specifically, Grace's mother testified that on the day after that vaccination, Grace failed to look into her mother's eyes, failed to "recognize" her sister or father, stopped reaching for toys, and did not respond to attempts to engage her. (Vol. 3, p. 656; Tr. 7-11.) On the following day, Grace, when awake, was "not responding to anything that was going on around her." (Vol. 3, p. 657.) Similarly, Grace's grandmother described Grace's behavior on April 11, 2001, two days after the vaccination, when she babysat for Grace for several hours. She testified that on that day, Grace failed to turn her head or otherwise respond to visual stimuli, voices, or even to hand-clapping. (Vol. 3, p. 658; Tr. 46-48.)

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[5]Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than not." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J. concurring).

Petitioner in this case has relied upon the testimony of an expert witness, Dr. Ronald Jacobson.[6] Dr. Jacobson's written report and oral testimony indicate that the above-described testimony of Grace's mother and grandmother, to the effect that Grace suddenly became almost completely nonresponsive to her environment during the two days post-vaccination, was a factor in *both* his conclusions (1) that Grace suffered a "Table Injury encephalopathy," and (2) that the DTaP vaccination "caused-in-fact" Grace's infantile spasms disorder. (Vol. 4, p. 2; Tr. 62, 102-03.)

However, after listening to and carefully considering this aspect of the testimony of Grace's mother and grandmother, I simply cannot conclude that this testimony was accurate. According to this testimony, Grace suddenly went from her normal self into a state in which she was so profoundly nonresponsive that she did not even react to the sound of hand-clapping near her, a state in which she was so nonresponsive to visual stimuli that she seemed to her grandmother to be like a "blind child." (Vol. 3, p. 658.) Yet Grace was not taken to see a doctor until several days later (April 14), and even then, while the pediatrician recorded that Grace had been crying intensely, the physician's record contains *no mention at all* of any failure to respond to stimuli. This scenario simply seems to me to be extremely unlikely. If Grace had in fact so suddenly become so completely nonresponsive, her family likely would have rushed her to medical attention long before April 14. And if such symptoms had been in fact reported to Grace's pediatrician on April 14, surely that physician would have so noted in his records.[7]

This is not to say that I conclude that these two witnesses were intentionally giving false testimony. I do *not* so conclude. Rather, it seems likely to me that these witnesses, understandably

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[6]Dr. Jacobson is a physician board-certified in both neurology and pediatrics, with a practice in pediatric neurology.

[7]Both Dr. Jacobson and respondent's expert, Dr. Kollros, testified that they would expect that if such symptoms were reported to a pediatrician, the pediatrician would ordinarily record such symptoms in the medical records. (Tr. 104, 150.)

I also note that numerous Program decisions have noted the general principle that contemporaneously-recorded records should ordinarily be given greater evidentiary weight than witness recollections offered long after the event in question. See, e.g., *Cucuras v. Secretary of HHS*, 26 Cl. Ct. 537, 542 (1992), *aff'd*. 993 F. 2d 1525, 1528 (Fed. Cir. 1993); *Beddingfield v. Secretary of HHS*, 50 Fed. Cl. 520, 523-524 (2001); *Estate of Arrowood v. Secretary of HHS*, 28 Fed. Cl. 453, 458 (1993); *Reusser v. Secretary of HHS*, 28 Fed. Cl. 516, 523 (1993); *Murphy v. Secretary of HHS*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F. 2d 1226 (Fed. Cir. 1992), *cert. denied*, 506 U.S. 974 (1992). See also the same principle noted in non-Program decisions such as *United States v. United States Gypsum Co*., 333 U.S. 364, 396 (1947); *Montgomery Coca Cola Bottling Co. v. United States*, 222 Ct. Cl. 356, 615 F. 2d 1318, 1328 (Ct. Cl. 1980). (I do note that there will be occasions when it *is* appropriate to credit witness recollections concerning facts not recorded in the medical records. See, *e.g.*, *Parcells v. HHS*, No. 03-1192V, 2006 WL 2252749, at *5 (Fed. Cl. Spec. Mstr. July 18, 2006) (describing circumstances in which oral testimony may be reliable). In this case, however, I found the witness testimony in question to be insufficient to overcome the weight of the medical records.)

desperate to determine a cause for Grace's grave disorder, and having now focused on the April 9 DTaP vaccination as a possible cause, in "searching their memories" concerning the days immediately following that vaccination, likely have greatly exaggerated their memories of behavior by Grace. Or they have "remembered," as occurring in the immediate post-vaccination period, behavior that actually occurred at a *later* time. To me, it seems understandable that loving family members, desperate to pinpoint a cause for an awful disorder, may in such circumstances be greatly susceptible to exaggeration or to confusing the timing of events.[8]

Moreover, I note that another problem with this testimony of these two witnesses is that it paints the picture of a child who had been normally responsive prior to the vaccination of April 9, 2001, but then suddenly became nonresponsive, a different child. However, this picture is *at odds* with several notations in the medical records, which indicate that even *prior* to the vaccination of April 9, 2001, Grace had *not* been a normally responsive child. Specifically, records of Grace's first hospital stay contain the note of one consulting physician, who wrote on April 29, 2001, that "father states that [patient's] symptoms began after receiving DTP vaccine, but mom states that [patient] was noted to be delayed by herself prior to vaccine." (Vol. 1, pp. 42-43.) Another hospital note, made on April 23, 2001, states that "mom remarks that child has never really focused on herself or father and often has staring episodes." (Vol. 1, p. 16.) A third hospital note, recorded on April 24, 2001, states that "child has not reached any developmental milestones and 'does nothing,' according to mother." (Vol. 1, p. 110.) Similarly, a fourth hospital note, made on May 31, 2001, states: "Marked lethargy, but mother says that is the way [child] was since birth and before spasms." (Vol. 2, p. 507.) And, finally, another record, made on May 18, 2001, states that "parents were concerned that she was not tracking visually at age 2 months." (Vol. 1, p. 373.)

These hospital notes, then, also seem to contradict the theory which petitioner has attempted to advance in this case, *i.e.*, that Grace was a normal child whose behavior suddenly changed the day after the inoculations. These notes add weight to my conclusion that I simply cannot accept, as accurate, the testimony of Grace's mother and grandmother alleging non-responsive behavior by Grace during the first two days after vaccination.

V

ANALYSIS OF "TABLE INJURY" CLAIM

In this case, as noted above, the petitioner's expert, Dr. Jacobson, has offered the opinion that Grace suffered an injury falling within the Table Injury category of "encephalopathy." It is true that

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[8]I also note that at the hearing, Grace's grandmother could not explain how she could pinpoint the day in question, on which she observed Grace being nonresponsive, as April 11, 2001. (Tr. 53-57.) At best, she seemed to be able to say that such day occurred during the "same month" as Grace's hospitalization. (Tr. 57.) This factor added to my reasoning for doubting the accuracy of her testimony.

for petitions, such as this one, filed since March 24, 1997, "encephalopathy" exists as a Table Injury for DTaP vaccinations. I will set forth the relevant Table Injury definition below. [9]

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, * * * the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manification of onset or of significant aggravation after vaccine administration
*	*	*
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP - Hib).	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	4 hours 72 hours Not applicable
*	*	*

[9]The statute itself contains a version of the Vaccine Injury Table that applied to vaccinations administered prior to the enactment of the Program and for several years after that enactment. See § 300aa-14(a). However, the Vaccine Injury Table was administratively modified with respect to Program petitions, such as this one, that were filed after March 24, 1997. See 62 Fed. Reg. 7685, 7688 (1997); *O'Connell v. Shalala*, 79 F. 3d 170 (1st Cir. 1996). That Table modification, along with an earlier administrative modification of the Table in 1995 (see 60 Fed. Reg. 7678 (1995)), significantly altered the "Table Injury" categories with respect to pertussis-containing vaccinations from the version of the Table contained in the statute. The portion of the new Table applicable to this case, listing "encephalopathy" as a Table Injury for the pertussis-containing vaccinations, appears at 42 C.F.R. § 100.3(a)(II)(B) (10-1-97 edition of C.F.R.--all C.F.R. references in this Decision will be to the 10-1-97 edition of the C.F.R.).

(b) *Qualifications and aids to interpretation*. The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

* * *

> (2) *Encephalopathy*. For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.
>
> (i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).
>
> (A) *For children less than 18 months of age* 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. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.
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> * * *
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> (D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):
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> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
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> (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).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

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42 C.F.R. § 100.3 (10-1-97 edition of C.F.R.).

I note that in neither his written reports, nor in his hearing testimony, did Dr. Jacobson make any serious attempt to go through the Table Injury definition of "acute encephalopathy," set forth above, and explain *why* he believes that Grace's condition within the first 72 hours post-vaccination fits within this category. Dr. Jacobson offered, rather, only vague suggestions that Grace's intense crying/screaming behavior during the three days post-vaccination, coupled with the reports of Grace's mother and grandmother describing nonresponsiveness in Grace during that period, mean that her case fits within the Table Injury definition. I must reject Dr. Jacobson's argument, for several reasons.

First, Dr. Jacobson's opinion was based in substantial part upon the reports of Grace's mother and grandmother, described above, concerning alleged behavior of Grace during the two days after the vaccination in question. (See, *e.g.*, Tr. 102-103.) However, for reasons set forth above (pp. 5-7), I cannot accept those reports as accurate. Thus, Dr. Jacobson's opinion, based on an incorrect assumption of facts, is of no value to petitioner.

Second, when I analyze the available medical records and compare them to the Table Injury definition set forth above, it seems clear that, as argued by the respondent's expert, Dr. Peter Kollros[10] (Tr. 113-115, 128-135, 149), Grace's condition during the three days after vaccination certainly does *not* fit within the Table Injury definition of "acute encephalopathy." As set forth above, the Table Injury "acute encephalopathy" definition requires that the infant must have a "significantly decreased level of consciousness lasting for at least 24 hours" (42 C.F.R. § 100.3(b)(2)(i)(A)), a condition that was "sufficiently severe so as to require hospitalization" (42 C.F.R. § 100.3(b)(2)(i)). Grace, however, was *not* brought for any medical attention in the first 72 hours after her vaccination in question. And when Grace was, in fact, brought to see her pediatrician on April 14, 2001, two days after the conclusion of the relevant 72-hour post-vaccination period, the records of that visit offer *no support whatsoever* to the conclusion that she had recently suffered a

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[10]Dr. Kollros, like Dr. Jacobson, is a physician board-certified in neurology and pediatrics, with a practice in pediatric neurology.

24-hour period of significantly decreased consciousness. The record of that visit (Vol. 1, p. 3) does describe a child who had been crying and screaming intensely, but the Table Injury definition specifically states that "unusual screaming" and "persistent inconsolable crying" *do not* demonstrate an acute encephalopathy or a "significant change in * * * level of consciousness" within the meaning of the Table Injury definition. (42 C.F.R. § 100.3(b)(2)(i)(E).) The pediatrician's note states that Grace "refuses food/drink/pacifier *when crying*," (Vol. 1, p. 3, emphasis added) implying that Grace *would* take food, drink, and pacifier when she was *not* crying. (Vol. 1, p. 3.[11]) As Dr. Kollros pointed out (Tr. 115, 134), the fact that Grace was taking food and drink at times indicates that she was not in a continuous state of diminished consciousness for 24 hours at a time. And, most importantly, the record at the April 14 visit simply makes no mention of any behavior by Grace that might indicate a significantly decreased level of consciousness, even though *both* experts acknowledged at the hearing that if Grace's mother had reported on April 14 any such behavior, the pediatrician likely *would* have recorded such reports in his note. (Tr. 104, 150.)

Accordingly, for all the reasons set forth above, I conclude that petitioner has *failed* to demonstrate that Grace suffered a Table Injury.

VI

SUMMARY OF "CAUSATION-IN-FACT" ANALYSIS

The second issue is whether petitioner has prevailed via her second theory, that of "causation-in-fact". Based upon all the evidence of record in this case, I conclude that petitioner has *failed* to demonstrate that it is "more probable than not" that Grace's infantile spasms disorder was caused by her DTaP vaccination of April 9, 2001. My reasoning behind this conclusion can be divided into two different lines of analysis. First, I find it unlikely that Grace in fact experienced the alleged symptoms, during the first two days after vaccination, described by her mother and grandmother, upon which Dr. Jacobson based his opinion. Second, I simply find the analysis of Dr. Kollros concerning this causation issue to be more persuasive than that of Dr. Jacobson.

My analysis on the first point has already been set forth above, in Section IV of this Decision. My analysis concerning the second issue will be set forth immediately below, in Section VII.

VII

I FOUND THE ANALYSIS OF DR. KOLLROS TO BE MORE PERSUASIVE THAN THAT OF DR. JACOBSON

As explained above, the first reason why I cannot credit petitioner's "causation-in-fact" contention is that I cannot accept, as accurate, the testimony of Grace's mother and grandmother describing certain symptoms, which were allegedly displayed by Grace during the first two days after

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[11]Grace's mother confirmed at the hearing that Grace *did* take food when not crying. (Tr. 37.)

her DTaP vaccination of April 9, 2001. Dr. Jacobson has *not* testified in this proceeding that he could offer a vaccine-causation opinion based solely upon the facts contained in the medical records, *without* assuming the additional symptoms about which the mother and grandmother testified.

However, it is possible that, if asked, Dr. Jacobson might still offer the opinion that Grace's disorder was vaccine-caused based only upon the facts demonstrated in the medical records--*i.e.*, that Grace began a period of intense crying about two days after vaccination, then had the onset of her seizures about nine days after vaccination. Therefore, I have considered whether, assuming that Dr. Jacobson *could* offer such an opinion, the record of this case would support the validity of such an opinion. I conclude that such an opinion would still *not* be persuasive, because I find the general approach of Dr. Kollros to this causation issue to be more persuasive than that of Dr. Jacobson. There are several reasons for this conclusion, which I will set forth separately below.

A. Dr. Jacobson's reliance on IOM report concerning DTP (not DTaP) vaccine

As noted above, Dr. Jacobson has opined that Grace suffered an encephalopathy as a result of the DTaP vaccination of April 9, 2001, which encephalopathy resulted in Grace's infantile spasms disorder. In reaching his conclusion that the DTaP vaccination can cause the infantile spasms disorder, Dr. Jacobson relied primarily on a 1994 report issued by the Institute of Medicine (hereinafter "IOM").[12] In that report, an IOM committee reviewed the evidence concerning the issue of whether the *DTP* (*not* the *DTaP*) vaccination may cause chronic (*i.e.*, long-term) neurologic injury. The committee concluded that the evidence was consistent with a causal relation between the DTP vaccine and certain kinds of chronic neurologic dysfunction in those individuals who experienced a "serious acute neurologic disorder" within seven days after receiving the DTP vaccine. (Vol. 5, p. 15.) Based upon that IOM report, and also on his own experience with two patients, Dr. Jacobson concluded that the *DTaP* vaccine, which Grace received, can cause the infantile spasms disorder, and likely did cause Grace's disorder. There are significant flaws, however, in Dr. Jacobson's reasoning, as Dr. Kollros pointed out.

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[12]The Institute of Medicine is the medical arm of the National Academy of Sciences. The National Academy of Sciences ("NAS") was created by Congress in 1863 to be a advisor to the federal government on scientific and technical matters (see *an Act to Incorporate the National Academy of Sciences*, Ch. 111, 12 Stat. 806 (1863)), and the Institute of Medicine ("IOM") is an offshoot of the NAS established in 1970 to provide advice concerning medical issues. Further, when it enacted the Vaccine Act in 1986, Congress specifically directed that the Institute of Medicine be requested to conduct studies concerning potential causal relationships between vaccines and illnesses. See the *National Childhood Vaccine Injury Act of 1986*, Pub. L. No. 99-660, 100 Stat. 3755 (1986), section 312(e)(2)(A), and section 313(a)(2)(A). In the intervening years, the IOM has formed committees which have prepared numerous reports concerning issues of possible relationships between vaccinations and injuries. Both the 1994 IOM report, upon which Dr. Jacobson relied, and the earlier 1991 IOM report, also discussed in this Decision, were such reports.

1. The distinction between the DTaP and the DTP vaccines

The first problem is that the 1994 IOM report concerned the *DTP* vaccine, not the *DTaP* vaccine. The DTP vaccine contained, in addition to the diphtheria and tetanus elements, the *whole-cell* pertussis vaccine. Grace, however, received a newer type of vaccination, the *DTaP* vaccination. That vaccination contains, in addition to the diphtheria and tetanus elements, the newer *acellular* version of the pertussis vaccine, which does not contain some of the toxins contained in the older whole-cell vaccine. The DTaP version, in general, is believed by medical scientists to be much improved, and to be much less likely than the DPT vaccine to cause neurologic reactions or other harmful side effects. Dr. Kollros explained this difference between the DTP and DTaP vaccinations (Ex. A, p. 3; Tr. 116-119, 156), and respondent also filed certain exhibits supporting the conclusion that the DTaP vaccine is much less likely to cause neurologic or other effects. (See Ex. E, Ex. G.)

The theory of Dr. Jacobson, then, seems to be that any evidence concerning possible harmful effects of the *DTP* vaccine can be automatically extrapolated to apply to the *DTaP* vaccine. However, he simply failed to explain *why* that would be so. He failed to point to any evidence that the *DTaP* vaccine, which was specifically designed to be substantially safer that the DTP vaccine, is capable of causing *any* type of serious brain injury, much less the infantile spasms disorder specifically.

Accordingly, I found Dr. Jacobson's reliance on the 1994 IOM report to be unpersuasive for this reason. Similarly, I note that in addition to referring to the 1994 IOM report, Dr. Jacobson also stated that he based his opinion on the cases of two individuals whom he had treated during his career as a neurologist. (Tr. 76.) However, he actually described only one such case, in which a child with a well-controlled infantile spasms disorder had a recurrence of spasms after receiving a DTP vaccination. (Tr. 76-77.) However, as Dr. Jacobson acknowledged (Tr. 80), this previous case, said to have occurred around 1981 or 1982, clearly involved the *DTP* vaccine; the DTaP vaccine was not introduced until years later.

Therefore, I also found Dr. Jacobson to be unpersuasive in his reliance on this one cited case, since he has failed to explain why his experience involving the *DTP* vaccine is relevant to this situation involving the *DTaP* vaccine.

2. The lack of a "serious acute neurologic disorder" with seven days of vaccination

Even if one were to ignore the distinction between the DTP and the DTaP vaccinations, Dr. Jacobson's "causation-in-fact" reasoning would fail for a second reason. That is, in the 1994 IOM report upon which Dr. Jacobson relies, the IOM committee concluded that the available evidence was consistent with a causal relation between the DTP vaccine and certain kinds of chronic neurologic dysfunction in those individuals who experienced a "*serious acute neurologic illness*" within seven days after receiving the DTP vaccine. (Vol. 5, p. 15.) Dr. Jacobson's theory, thus, is seriously flawed, because he failed to even *attempt* to demonstrate that Grace suffered a "serious acute neurologic illness," as that term was used in the IOM report, within seven days of her DTaP

vaccination of April 9, 2001. To the contrary, I conclude that Grace did *not* suffer such a "serious acute neurologic disorder," within seven days of her vaccination.

A careful look at the 1994 IOM Report in its entirety clarifies what the 1994 IOM committee meant by the words "serious acute neurologic illness." In my view, the committee was referring to a specific list of neurologic events that was set forth in the National Childhood Encephalopathy Study ("NCES") described in the 1994 IOM report. In other words, the phrase "serious acute neurologic illness" referred to the five neurologic events listed by the 1994 IOM committee at the bottom of Vol. 5, p. 6. And Grace clearly did *not* manifest one of those specific five injuries *within seven days* of her DTP vaccination of April 9, 2001. To be sure, Grace *did*, of course, experience the onset of the fifth listed illness, infantile spasms, but she clearly did *not* experience the onset of those spasms *within seven days* of her vaccination in question.

Accordingly, even if one ignored the distinction between the DTaP and DTP vaccines, Dr. Jacobson's reasoning would still fail for this second fundamental reason.

3. "Infantile spasms" as a distinct neurologic disorder

Finally, Dr. Jacobson's reliance on the 1994 IOM report, as the primary basis of his opinion concerning causation-in-fact, fails for yet another reason. That is, while the 1994 IOM committee did find evidence supporting a causal relationship between the DTP vaccine and "the forms of chronic nervous system dysfunction described in the NCES," Dr. Jacobson failed to note that the IOM did *not* treat the *particular type* of neurologic disorder known as "infantile spasms" the same as *other* types of "chronic nervous system dysfunction." Rather, as Dr. Kollros noted (Tr. 119-120), the IOM treated "infantile spasms" as a *distinct* type of neurologic disorder, in the series of reports that the IOM produced in the early 1990's concerning the issue of whether the DTP vaccine causes chronic neurologic injury. And, in the IOM's 1991 report (the 1994 IOM report cited by Dr. Jacobson was a follow-up report concerning one aspect of the more comprehensive 1991 report), the IOM committee concluded specifically that the available evidence *does not* indicate a causal relationship between the DTP vaccine and the *infantile spasms disorder*. (See the excerpt from the 1991 IOM report filed as respondent's Ex. H on March 30, 2006, specifically the conclusion set forth at page 77 thereof.)

In other words, even if one could accept Dr. Jacobson's logic in treating the DTP and DTaP vaccines as equivalent, and his reliance on the 1990's work of the IOM, his theory would still fail, since he ignored the portion of the IOM work that is *most relevant* here--*i.e.*, the specific conclusion that there is *no* causal relationship between the DTP vaccine and the *particular disorder* known as infantile spasms.

B. Evidence of prior neurologic abnormality

Another reason for rejecting Dr. Jacobson's theory is that he seems to assume that Grace was a neurologically normal infant prior to the DTaP vaccination of April 9, 2001. However, a close

review of the record casts considerable doubt on the premise that Grace was neurologically normal prior to that vaccination.

Specifically, in several places Grace's medical records contain notations that Grace's mother herself stated that Grace had abnormalities *prior* to the vaccination in question. First, records of Grace's first hospital stay contain the note of one consulting physician, who wrote on April 29, 2001, that "[f]ather states that [patient's] symptoms began after receiving DTP vaccine, but mom states that [patient] was noted to be delayed by herself prior to vaccine." (Vol. 1, pp. 42-43.) Another hospital note, made on April 23, 2001, states that "mom remarks that child has never really focused on herself or father and often has staring episodes." (Vol. 1, p. 16.) A third hospital note, recorded on April 24, 2001, states that "child has not reached any developmental milestones and 'does nothing,' according to mother." (Vol. 1, p. 110.) Similarly, a fourth hospital note, made on May 31, 2001, states: "Marked lethargy, but mother says that is the way [child] was since birth and before spasms." (Vol. 2, p. 507.) And, finally, another record, made on May 18, 2001, states that "parents were concerned that she was not tracking visually at age 2 months." (Vol. 1, p. 373.)

In this regard, I note that Dr. Kollros acknowledged that, judging only by the medical records of Grace's pediatrician during her first 4 ½ months of her life, one could not conclude with certainty that Grace's early development was abnormal. (Tr. 120-22, 141.) But he also testified that with the benefit of hindsight, and considering the later statements of Grace's mother cited in the previous paragraph, he could fairly say that Grace *probably* was developmentally delayed even prior to her DTaP vaccination of April 9, 2001. (Tr. 141-142.)

Therefore, this conclusion, that the overall record makes it seem likely that Grace was developmentally delayed prior to the vaccination, gives me one more reason for rejecting Dr. Jacobson's conclusion that Grace's overall infantile spasms disorder, involving developmental delay as well as seizures, was a new condition caused by that vaccination.

C. Medical record notations concerning causation

It is noteworthy that in the recent *Capizzano* opinion, the U.S. Court of Appeals for the Federal Circuit stressed 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 shows that the vaccination was the reason for the injury.'" 440 F. 3d at 1326 (emphasis added, citation omitted). Similarly, in several recent cases, judges of this court have, in resolving Vaccine Act causation issues, relied heavily upon the statements of treating physicians contained in the vaccinee's medical records. *See*, *e.g.*, *Zatuchni v. Secretary of HHS*, 69 Fed. Cl. 612, 623 (2006); *De Bazan v. HHS*, 70 Fed. Cl. 687, 697 (2006); *Kelley v. HHS*, 68 Fed. Cl. 84, 100 (2005).

Accordingly, in this case I have carefully reviewed the medical records of Grace's treatment, in order to see whether those records shed any substantial light upon the issue of the cause of Grace's

infantile spasms, in the form of statements by her treating physicians. The short answer is that the medical records simply do *not* seem to provide any substantial help.

The parties have not pointed to any medical records that they believe to be relevant concerning this issue. Upon my own review, the only medical record that clearly indicates a conclusion as to the cause of Grace's disorder is the note made by Dr. Jacobson himself, who did treat Grace very briefly, in June of 2002; that record points to a "vaccine-induced reaction." (Vol. 1, p. 491.) But, again, having listened carefully to Dr. Jacobson's explanation of his reasoning behind that conclusion, I have not found it persuasive, for the reasons already set forth.[13]

Besides Dr. Jacobson's own notation, in a few medical records Grace's physicians mention briefly the issue of the cause of Grace's infantile spasms disorder, sometimes speculating as to possible causes *without* mentioning a vaccination as a possibility. See, *e.g.*, Vol., p. 18 ("structural vs. metabolic causes vs. genetic"); Vol. 1, p. 374 (describing the infantile spasms as "cryptogenic"-- *i.e.*, of unknown cause, and mentioning a "migrational disorder" as a possible cause); Vol. 2, p. 507 ("possible metabolic disorder"); Vol. 2, p. 541 ("no specific metabolic etiology is apparent"). The fact that these treating physicians did *not* seem to consider the vaccination as a possible cause perhaps adds some slight weight to the respondent's view of Grace's case, *i.e.*, that there is no good reason to conclude that the vaccination was the cause. But, on balance, my review of the medical records, in search of hints as to the views of Grace's treating physicians concerning the causation issue, basically provides very little help concerning this particular causation issue.

D. Other Vaccine Act "causation-in-fact" rulings concerning infantile spasms

One other point is worth a brief mention. A number of Vaccine Act cases have involved situations in which it was alleged that a child's infantile spasms disorder was caused by a *DTP* vaccination. In all but one of the published decisions that I have located involving such allegations, the Vaccine Act factfinder concluded that the available evidence did *not* support a conclusion that the DTP vaccine can cause "infantile spasms." See, e.g. *Thompson v. HHS*, No. 99-436V, 2003 WL 21439672 (Fed. Cl. Spec. Mstr. Millman, May 23, 2003); *Perez v. HHS*, No. 00-328V, 2003 WL 431593 (Fed. Cl. Spec. Mstr. Golkiewicz, Jan. 14, 2003); *Raj. v. HHS*, No. 96-294V, 2001 WL 963984 (Fed. Cl. Spec. Mstr. Golkiewicz, July 31, 2001); *Grady v. HHS*, No. 95-173V, 2000 WL 1772473 (Fed. Cl. Spec. Mstr. Millman, Nov. 16, 2000); *Jenkins v. HHS*, No. 90-3717V, 1999 WL 476255 (Fed. Cl. Spec. Mstr. Wright, June 23, 1999); *Hoag v. HHS*, No. 94-67V, 1998 WL 408783 (Fed. Cl. Spec. Mstr. Golkiewicz, Apr. 22, 1998), *aff'd*, 42 Fed.Cl. 238 (1998); *Jackson v. HHS*, No. 90-1903V, 1995 WL 120210 (Fed. Cl. Spec. Mstr. Hastings, Mar. 3, 1995); *Woodcock v. HHS*, No.

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[13]According to Dr. Jacobson's own testimony, Dr. Jacobson served briefly as a consultant during Grace's initial hospitalization in April of 2001, and then later was consulted for one visit in June of 2002. He was never a regular treating physician of Grace. Moreover, as Dr. Jacobson himself explained, the June 2002 visit was *not* for ordinary treatment purposes, but occurred because the **{redacted}** family was looking into the possibility of seeking compensation for a vaccine-related injury, and believed that Dr. Jacobson might be supportive of that goal. (Tr. 96.)

90-1030V, 1992 WL 92169 (Cl. Ct. Spec. Mstr. Baird, Apr. 10, 1992); *Shelley v. HHS*, No. 90-604V, 1991 WL 239093 (Cl. Ct. Spec. Mstr. Hastings, Oct. 29, 1991).[14]

To be sure, the fact that the special masters reached those conclusions in those cases certainly does not constitute "evidence" concerning the factual issue before me in this case. I have made my factual ruling in this case based solely upon the evidence introduced into the record of *this* case. But it is at least worthy of note that other special masters, faced with causation-in-fact theories similar to that advanced by Dr. Jacobson in this case, rejected the petitioners' claims in those cases as well.

VIII

PETITIONER'S CASE FAILS THE *ALTHEN* TEST

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccine brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F. 3d at 1278 (citations omitted). This statement in *Althen* can be interpreted as establishing a four-part test for proving "causation-in-fact" in Vaccine Act cases--that is, the first three parts being those three enumerated in the first sentence of the *Althen* excerpt set forth above, with the fourth element being the requirement, contained in the second sentence of the excerpt, that the evidence *not* show that the injury was caused by "factors unrelated to the vaccine." Interpreting this formulation as such a four-part test, I conclude that the petitioner's attempt to demonstrate causation-in-fact in this case clearly *fails* that *Althen* test, because petitioner has failed to satisfy *each* of the first three elements thereof.

As to the first two elements, I conclude that petitioner has failed to provide either "a medical theory causally connecting the vaccination as the injury" or "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." As demonstrated at pp. 12-14, I simply could not find merit in Dr. Jacobson's theory that the DTaP vaccine *can* cause the infantile spasms

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[14]The one exception was *Bunting v. HHS*, 931 F. 2d 867 (Fed. Cir. 1991). That case involved an unusual situation in which the respondent failed to supply an expert witness. The court of appeals, noting that the *only* expert witness in the case supported the petitioner's causation-in-fact claim, concluded that a reasonable fact-finder must rule in the petitioner's favor in that case.

disorder, for several reasons. For example, as fully explained above, Dr. Jacobson's theory ignored the difference between DTP versus DTaP vaccinations. And Dr. Jacobson also ignored the fact that the infantile spasms disorder has been found *not* to be caused by the *DTP* vaccine, in the very series of IOM reports upon which Dr. Jacobson purports to rely.

The third element of the *Althen* test, set forth above, requires "a showing of a proximate temporal relationship between vaccination and injury." That is, under this third element of the *Althen* test, the petitioner must demonstrate that the first symptom of Grace's infantile spasms disorder occurred in a time frame that would be consistent with causation by the vaccination in question.[15] Petitioner in this case, however, has failed to do so. To the contrary, Dr. Jacobson failed even to *attempt* to explain during what period after vaccination he would expect to see a patient's first spasms, in the event of a vaccine-caused infantile spasms disorder.

Accordingly, it is clear that petitioner's causation theory in this case fails under the test set forth in *Althen*.

IX

CONCLUSION

The record of this case demonstrates plainly that Grace **{redacted}** and her family have been through a tragic and painful ordeal. The entire family is certainly deserving of great sympathy. Congress, however, designed the Program to compensate only the families of individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or causation-in-fact evidence, to a listed vaccination. In this case, as described above, no such link has been demonstrated. Accordingly, I conclude that the petitioner in this case is *not* entitled to a Program award.[16]

George L. Hastings, Jr.
Special Master

[15]In other words, the petitioner must demonstrate the existence of a "scientific temporal relationship" as discussed in *Pafford v. HHS*, 64 Fed. Cl. 19, 29-30 (2005).

[16]In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.