In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 98-782V**

**(Filed: October 30, 2000)**

| | | |
|---|---|---|
| * * * * * * * * * * * * * * * * * * * * * * * * * * * * | | |
| ALLISON GIBSON and DARLENE GIBSON, as Guardians and Next Friends of EMILY N. GIBSON, Minor, | * | |
| Petitioners, | * | |
| v. | * | **TO BE PUBLISHED** |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |
| * * * * * * * * * * * * * * * * * * * * * * * * * * * * | | |

***Mark A. Anderson, Fort Worth, Texas, for petitioners.***

***Claudia Barnes Gangi, Department of Justice, Washington, D.C., for respondent.***

**DECISION**

**HASTINGS,** ***Special Master.***

This is an action in which the petitioners, Allison Gibson and Darlene Gibson, seek an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"),[1] on account of an injury suffered by Emily Gibson. For the reasons stated below, I conclude that petitioners are not entitled to such an award.

[1]The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (1994 ed.). Hereinafter, all "§" references will be to 42 U.S.C. (1994 ed.).

## I

## FACTS

Emily Gibson was born on July 7, 1994. At birth she was noted to have a cleft lip and cleft palate condition, which was later treated surgically. Emily received DPT vaccinations on September 7, 1994, December 12, 1994, January 26, 1995, and October 10, 1995.

On February 3, 1995, after several days of fever, vomiting, and diarrhea, Emily suffered a seizure, and was hospitalized. She was found at the time to be suffering from hyponatremia, meaning a low level of sodium in her blood, which was thought to have caused the seizure.

Emily experienced no further seizures, or other remarkable health problems, until October 12, 1995, which was two days after her 15-month DPT "booster" immunization. On that day, Emily again experienced a seizure and was hospitalized, and again the sodium level in her blood was found to be low, apparently causing the seizure. A search for the cause of her low blood sodium was undertaken, and it was determined that Emily was suffering from SIADH, or "Syndrome of Inappropriate secretion of Anti-Diuretic Hormone." This means that the hypothalamus portion of her brain was inappropriately secreting excessive amounts of anti-diuretic hormone, which was causing her to retain water, which retention in turn caused her blood sodium level to plummet.

Subsequent monitoring of Emily has revealed that she suffers from *chronic* SIADH. However, with medical management her SIADH seems at the present time to be under control, so that she is an active six-year-old who goes to school, does not suffer from mental retardation, and does not regularly suffer from seizures.

## II

## STATUTORY BACKGROUND; ALLEGATIONS HERE

Under the Program, compensation awards are made to individuals who have suffered injuries after receiving certain vaccines listed in the statute. There are two separate means of establishing entitlement to compensation. First, if an injury specified in the "Vaccine Injury Table," originally established by statute at § 300aa-14(a) and since modified administratively (as will be discussed below), occurred within the time period from vaccination prescribed in that Table, then that injury may be *presumed* to qualify for compensation. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a). If a person qualifies under this presumption, he or she is said to have suffered a "Table Injury." Alternatively, compensation may also be awarded for injuries not listed in the Table, but entitlement in such cases is dependent upon proof that the vaccine *actually caused* the injury. § 300aa-13(a)(1); § 300aa-11(c)(1)(C)(ii).

In this case, petitioners' claim is that the condition from which Emily suffers, known as "SIADH," was caused by a DPT (diphtheria, pertussis, tetanus) vaccination that Emily received on

October 10, 1995. That vaccination is one listed in the Vaccine Injury Table, and petitioners allege that Emily is entitled to an award via two separate theories. First, they allege that Emily suffered an injury falling within the Table Injury definition of "encephalopathy," and that the encephalopathy in turn caused her SIADH. Alternatively, they allege that Emily's SIADH was "actually caused" by her vaccination.

I will deal with these alternative theories of causation in parts III and IV of this Decision, below.

## III

## "TABLE INJURY" THEORY

As noted above, petitioners' first allegation is that Emily suffered the Table Injury known as "encephalopathy" with respect to her DPT vaccination that she received on October 10, 1995. To begin my discussion of this allegation, I note that § 300aa-14(a) of the statute contains the *original* version of the Vaccine Injury Table. That original version of the Table applied to Program petitions filed during the first few years of the Program, and listed "encephalopathy" as a Table Injury for the DPT vaccine, if incurred with three days of the administration of the vaccine. § 300aa-14(a)(I)(B). This statutory Table also provided a definition of the term "encephalopathy," at § 300aa-14(b)(3).

However, the statute enacting the Program provided that the Vaccine Injury Table could be modified administratively by the Secretary of Health and Human Services. § 300aa-14(c). And, in fact, on two occasions that Secretary has promulgated administrative modifications of the Table. See 60 Fed. Reg. 7678 (1995); 62 Fed. Reg. 7685 (1997); *O'Connell v. Shalala*, 79 F. 3d 170 (1st Cir. 1996). It is the latest modified version of the Table, promulgated in 1997, that applies to this case, since this petition was filed on October 8, 1998, after the effective date of the 1997 version of the Table. See § 300aa-14(c)(4); 62 Fed. Reg. 7685, 7688. That version of the Table still retains "encephalopathy" as a Table Injury for the DPT vaccination, but contains a definition of that term that is substantially more narrow than the definition of encephalopathy provided in the original statutory version of the Table.

The version of the Vaccine Injury Table applicable to petitioners' claim here--*i.e.*, the claim that Emily suffered a "Table Injury encephalopathy" after her DPT vaccination--provides a lengthy definition of the term "encephalopathy." 42 C.F.R. § 100.3(b)(2). The first part of that definition provides that a vaccine recipient is considered to have suffered an encephalopathy falling within the Table Injury category only "if such recipient manifests, within the applicable time period, an injury meeting the description below of an *acute encephalopathy* * * *." 42 C.F.R. § 100.3(b)(2) (first sentence) (emphasis added). The regulation then goes on to provide a definition of the term "acute encephalopathy," stating that "an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." *Id*. at § 100.3(b)(2)(i)(A). In turn, the regulation provides a definition of "significantly decreased level of consciousness," as follows:

> (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):
>
> (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).

*Id*. at § 100.3(b)(2)(i)(D). Finally, and crucial here, the regulation provides that the applicable *time period* with respect to a "Table Injury encephalopathy" is 72 hours after a vaccination. *Id*. at § 100.3(a)(II).

In other words, under the applicable regulation, to qualify under the Table Injury encephalopathy category an "acute encephalopathy," meaning a 24-hour period of "significantly decreased level of consciousness" as described above, must be manifested within 72 hours of the vaccination. *Id*. at § 100.3(b)(2).

The question here, then, is whether Emily suffered a period of "significantly decreased level of consciousness," lasting at least 24 hours, within the first 72 hours after her vaccination on October 10, 1995. A close look at the record shows clearly that she did not. The record contains extensive records of Emily's condition at the hospital after she arrived there about an hour after the beginning of her seizure episode on October 12, 1995. The most relevant records pertaining to the first three days of that hospitalization are contained at Ex. 10, pp. 96, 101-107, 112-125. These records do *not* show any extended period in which Emily was unresponsive to people or other stimuli, as required at 42 C.F.R. § 100.3(b)(2)(i)(D). To the contrary, while Emily was described as "unresponsive" by the medical technicians who took her to the hospital (see Ex. 11, p. 1), she is described as "responsive upon arrival" at the hospital (Ex. 10, p. 112). She is also described, on the same day, as "reacts to stimulation of exam." (Ex. 10, p. 114.) In short, in the hospital records that I have examined, there is simply no evidence at all of an extended period of "significantly decreased level of consciousness" during the 72-hour post-vaccination period. And petitioners have failed to point me to any medical records, or any other evidence, that describes such a period of decreased consciousness during the first three days after Emily's vaccination.

To be sure, at the evidentiary hearing, the petitioners' expert, Dr. Roger Knapp, described a period *later on* during Emily's extensive hospitalization in October of 1995,[2] during which the child was nonresponsive to her parents and other stimuli. Dr. Knapp did not point to specific medical records in this regard, but, in response to my question, he stated that this period of nonresponsiveness took place about October 20, 1995. (Tr. 44.) However, even assuming that Emily did have a period of "significantly decreased level of consciousness" around October 20, 1995, that would not qualify her as having suffered a Table Injury, since that episode did not occur within the first 72 hours post-vaccination.

Accordingly, I must conclude that Emily did not suffer an "encephalopathy" falling within the Vaccine Injury Table.[3]

## IV

## "ACTUAL CAUSATION" THEORY

As to petitioners' alternative theory of "actual causation," the analysis is somewhat more complicated, but again I find that petitioners quite clearly have failed to present a viable case, for reasons to be detailed below.

### *A. Applicable legal standard*

I note initially that in analyzing a contention of "actual causation," the presumptions available under the Vaccine Injury Table are, of course, inoperative. The burden is on a petitioner to show that in fact the vaccination in question more likely than not caused the injury in question. *See, e.g., Hines v. Secretary of HHS*, 940 F. 2d 1518, 1525 (Fed. Cir. 1991); *Carter v. Secretary of HHS*, 21 Cl. Ct. 651, 654 (1990); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F. 2d 731 (Fed. Cir. 1991); *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646, 650-51 (1989). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." *Shaw*, 18 Cl. Ct. at 651; *Hasler v. United States*, 718 F. 2d 202, 205-06 (6th Cir. 1983), *cert. denied*, 469 U.S. 817 (1984); *Novak v. United States*, 865 F. 2d 718, 724 (6th Cir. 1989).

---

[2]Emily was hospitalized from October 12 through October 19, 1995, then discharged on the 19th. On the next day, October 20, however, she was readmitted to the hospital, and was not discharged until November 4, 1995. (See Ex. 10.)

[3]I note that Dr. Knapp opined generally that Emily's condition amounted to an "encephalopathy," but Dr. Knapp never even referred to the relevant Table definitions of "acute encephalopathy" and "significantly decreased level of consciousness." I found that Dr. Knapp's testimony was outweighed by the contrary testimony of respondent's expert Dr. Barry Bercu, as well as by the weight of the medical records discussed above. Moreover, I note that upon cross-examination, Dr. Knapp acknowledged that in Emily's medical records made in October of 1995, there are no references to Emily's injury as constituting an "encephalopathy." (Tr. 34.)

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).

***B. Summary of parties' theories***

I will begin by briefly summarizing the theories of the two opposing experts. Petitioners' basic theory of this case, presented through their expert, Dr. Knapp, is that toxic elements in the pertussis portion of the DPT vaccine damaged Emily's brain, resulting in her SIADH. Of course, as explained above in part III of this Decision, I have rejected petitioners' claim that Emily suffered an "encephalopathy" falling within the applicable "Table Injury" category. But that conclusion does not automatically mean that I must also reject Dr. Knapp's *actual causation* theory--in theory, a factfinder could find that the vaccine did damage Emily's brain, even though her symptoms within the *initial 72-hour Table time period* after vaccination did not fall within the strict definition of "acute encephalopathy" contained at 42 C.F.R. § 100.3(b)(2). Thus, I will summarize Dr. Knapp's "actual causation" theory in the following two paragraphs.

Dr. Knapp begins his theory of the case by noting that substantial evidence exists for the proposition that the pertussis portion of the DPT vaccine can on rare occasions cause significant neurologic damage, including encephalopathy (brain injury), to a vaccinee. Dr. Knapp then adds in the facts that SIADH is known to often be caused by neurologic problems, and that Emily's SIADH was diagnosed after she suffered a seizure just two days after her DPT vaccination of October 10, 1995. Dr. Knapp also points to a medical article which portrays two instances in which individuals experienced episodes of SIADH after suffering the pertussis *disease* (not the pertussis vaccination). He theorizes that if the pertussis organism in its "wild," disease-causing form can cause SIADH, then it follows that the whole-cell pertussis vaccine, which contains a killed form of the entire pertussis organism, could also cause SIADH. Finally, Dr. Knapp notes that Emily's treating physicians, including himself, have never definitively determined any specific cause for Emily's SIADH.

Putting these factors together, Dr. Knapp finds it likely that the DPT vaccination damaged Emily's brain, thereby causing her SIADH.

Respondent's expert Dr. Barry Bercu, on the other hand, opined that Emily's SIADH is very *unlikely* to have resulted from her DPT vaccination. First, Dr. Bercu believes that there is simply a gross lack of any evidence to suggest that the pertussis vaccine *can* cause SIADH. He explained that he has searched the medical literature and has found no reports whatever of SIADH occurring after DPT vaccination. He also found no reports associating the DPT vaccine with any type of dysfunction of the hypothalamus, which is the part of the brain that is associated with SIADH. Dr. Bercu sees no scientific justification for concluding that the pertussis vaccine can cause SIADH simply based on the fact that a single individual--*i.e.*, Emily Gibson--had an episode of SIADH shortly after a DPT vaccination.

Moreover, Dr. Bercu also emphasized that there is very strong evidence that the hypothalamus portion of Emily's brain was already abnormal long *before* the DPT vaccination in question. He noted that Emily clearly has suffered from growth hormone deficiency, indicating a malfunctioning hypothalamus, and that this deficiency clearly predated her October 1995 DPT vaccination episode by many months. He also noted that Emily at birth suffered from a severe cleft lip/cleft palate condition, and that such conditions are commonly associated with abnormalities of the hypothalamus. Further, he opined that Emily's seizure episode in February of 1995, some eight months before the DPT vaccination in question, is substantial evidence that Emily may have been suffering from undetected SIADH even at that earlier time.

In sum, Dr. Bercu opined that given the complete lack of evidence that the DPT vaccine *can* cause SIADH or other hypothalamic dysfunction, coupled with the fact that Emily clearly had hypothalamic dysfunction, and maybe even actual SIADH, long prior to the DPT vaccination in question, it is not reasonable to conclude that her chronic SIADH was vaccine-caused.

### *C. Analysis*

After careful consideration of the entire record, I conclude that petitioners have failed to demonstrate that it is "more probable than not" that Emily's chronic SIADH was caused by her DPT vaccination.[4] The short summary of my reasoning is that I found the testimony of Dr. Bercu to be substantially more persuasive than that of Dr. Knapp.[5] I will elaborate below.

#### *1. The evidence does not demonstrate that the DPT vaccine can cause SIADH*

The first major point is that I agree with Dr. Bercu that there simply does not exist sufficient evidence to justify the conclusion that the DPT vaccine *can* cause SIADH at all, much less that it *did* cause Emily's chronic SIADH. To be sure, there does exist a body of evidence indicating that the pertussis element of the DPT vaccine may on rare occasions cause significant brain damage/neurologic dysfunction. Dr. Knapp merely alluded to this evidence (see Ex. 20, p. 2[6]) without going into it, but I have studied that evidence in great detail in the course of other Program cases. See, *e.g., Liable v. Secretary of HHS*, No. 98-120V, 2000 WL 1517672, at *2-4 (Fed. Cl.

---

[4]Petitioners have 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).

[5]I note also that, as a pediatric endocrinologist (endocrinology is the study of the body's internal secretions), Dr. Bercu has credentials which are somewhat superior, as to the particular issue involved in this case, to those of Dr. Knapp, a pediatrician.

[6]Petitioners filed Exs. 1 through 9 with the petition, and additional, consecutively-numbered exhibits on a number of occasions thereafter. Respondent filed Exhibits A and B on May 16, 2000, and Exhibits C through M on May 24, 2000. "Ex." references will be to those exhibits.

Spec. Mstr. Sep. 7, 2000). However, that evidence concerns episodes of neurologic dysfunction that are *extremely dissimilar* to the specific problem of SIADH that has plagued Emily Gibson. SIADH involves a specific type of dysfunction of a specific part of the brain, the hypothalamus. And my review of the medical literature in *Liable* and similar cases uncovered no instances of DPT-related episodes of SIADH or any dysfunction of the hypothalamus. Similarly, Dr. Bercu explained in this case that he has searched the medical literature and has found no reports whatever of SIADH occurring after DPT vaccine, nor any reports associating DPT vaccine with any type of dysfunction of the hypothalamus. Nor could Dr. Knapp identify any such reports. Thus, like Dr. Bercu, I see no scientific justification for concluding that the pertussis vaccine can cause SIADH, simply based on the fact that a single individual (Emily) had an episode of SIADH two days after a DPT vaccination. In other words, while Dr. Knapp's theory that the pertussis vaccine damaged Emily's hypothalamus does not seem wholly impossible, since there is evidence that the vaccine can damage the human brain in other, more devastating ways, there just does not exist sufficient evidence from which I could reasonably conclude that Emily's DPT vaccination more likely than not caused her SIADH.

In this regard, I note that Dr. Knapp did point to a medical article reporting two individuals who experienced SIADH after suffering from the pertussis *disease* (not a pertussis *vaccination*). (See Ex. 20, attached item number 14.) Dr. Knapp stated the theory that if the pertussis organism in its "wild," disease-causing form can cause SIADH, then it is plausible that the pertussis *vaccine*, containing a "whole-cell" version of the same organism,[7] can cause the same outcome. However, I found Dr. Bercu to be persuasive when he rebutted this theory. Dr. Bercu opined that even assuming that the pertussis *disease* can cause SIADH--a theory that is certainly not "proven" simply by two case reports--it is unreasonable to jump to the conclusion that anything the pertussis *disease* can cause, the pertussis *vaccine* can cause. After all, the vaccine is specially designed to prompt the human immune system to develop immunity against the pertussis disease *without* at the same time triggering any ill effects on the vaccinee.

In sum, the first major point is that I agree with Dr. Bercu that there simply does not exist sufficient evidence to justify the conclusion that the DPT vaccine *can* cause SIADH at all, much less that it *did* cause Emily's condition of chronic SIADH.[8]

---

[7]Until very recent years, the only type of pertussis vaccine in general use was the "whole-cell" pertussis vaccine, which contains the entire pertussis organism in a killed form. In the last several years, a new type of "acellular" pertussis vaccine has become available, and is now being substituted for the whole-cell pertussis vaccine in most DPT inoculations in this country. However, there appears to be no dispute that the DPT vaccination received by Emily Gibson on October 10, 1995, included the whole-cell pertussis vaccine. (Combined vaccinations containing the acellular pertussis vaccine are normally described as "DTaP" vaccinations, not "DPT," to distinguish them from the "DPT" vaccinations containing the whole-cell pertussis vaccine.)

[8]I note that in *Liable, supra*, I concluded that it may be reasonable to causally attribute a vaccinee's chronic neurologic dysfunction to a pertussis vaccination in certain circumstances. Specifically, I concluded that if a neurologically-intact vaccinee (1) suffers, within seven days after a pertussis vaccination, a neurologic episode that would have qualified as a "serious acute neurologic

### *2. Strong evidence exists of a pre-existing cause for Emily's SIADH*

A second important consideration is that, as Dr. Bercu also emphasized, there exists very strong evidence that Emily's hypothalamus, the part of the brain associated with SIADH, was already abnormal long before the DPT vaccination in question. He noted that Emily clearly has suffered from growth hormone deficiency, indicating a malfunctioning hypothalamus, and that this deficiency clearly predated her October 1995 SIADH episode by many months. For example, the significant drop in Emily's growth rate, the indicator of growth hormone deficiency, began prior to her first birthday, while the vaccination in question was not administered until she was 15 months of age. Further, Dr. Bercu also noted that Emily at birth suffered from a severe cleft lip/cleft palate condition, and that such "mid-line defects" are commonly associated with abnormalities of the hypothalamus.

Dr. Knapp did not attempt to refute either of two above points, concerning Emily's growth hormone deficiency and the fact that mid-line defects are commonly associated with hypothalamic abnormalities. But these points provide strong evidence that Emily's hypothalamus was already abnormal, in at least some respects, long before her DPT vaccination in question. And, as Dr. Bercu

---

illness" under the National Childhood Encephalopathy Study (NCES); (2) goes on to experience chronic neurologic dysfunction of the type described in the NCES; and (3) no other cause for that dysfunction can be identified; then it is appropriate to causally attribute the chronic neurologic dysfunction to the vaccination. 2000 WL 1517672 at *12. In this case, petitioners have not argued that I should apply that causation theory or any similar reasoning to Emily's case. However, because Emily did suffer an extended seizure two days after a DPT vaccination, I will briefly address why I do not find that the theory adopted in *Liable* applies to Emily's case.

Initially, it appears that Emily likely did suffer, two days after her DPT vaccination on October 10, 1995, a neurologic episode that would have qualified as a "serious acute neurologic illness" under the NCES, since she suffered a seizure that probably did last at least 30 minutes. (See 2000 WL 1517672 at *3.) However, her case fails to fulfill elements (2) and (3) of the theory set forth above. As to element (2), Emily has not experienced the type of chronic neurologic dysfunction of the type described in the NCES. While she has suffered some seizures, they are apparently triggered only if her blood sodium level drops, and are controlled by control of that sodium level. She has not displayed the type of significant neurologic dysfunction (*e.g.*, uncontrolled seizures disorders, severe developmental delays, diffuse brain damage, etc.) observed in the children followed by the NCES. (See, *e.g.*, Madge, *et al*., "The National Childhood Encephalopathy Study: A 10-year follow-up. A report of the medical, social, behavioral and educational outcomes after serious, acute, neurological illness in early childhood," chapters 3 through 10. *Developmental Medicine and Child Neurology* 1993; Supplement No. 68.35(7):1-118.) As to element (3), in Emily's case significant evidence of a non-vaccine cause for her chronic condition does exist, since Emily clearly did have a significant abnormality of her hypothalamus that clearly *predated* her DPT vaccination. (For discussion of this point, see pp. 9-10, *infra*.)

Accordingly, I conclude that Emily's case does *not* fit within the causation theory that I articulated in *Liable.*

argued, the existence of other hypothalamic abnormality prior to Emily's vaccination makes it seem more likely that the *SIADH-producing abnormality* in Emily's hypothalamus *also* pre-existed her DPT vaccination of October 10, 1995.

Moreover, another point made by Dr. Bercu is also important. Dr. Bercu pointed to the seizure that Emily experienced in February of 1995, a seizure that, like her seizures of October 12, 1995, was produced by a low blood sodium level.[9] He opined that, with the benefit of hindsight, it seems quite possible that the February seizure, like the October seizure, was also a product of SIADH, although it was not recognized as such at the time. To be sure, Dr. Bercu acknowledged that one cannot be *certain* that Emily had SIADH in February, because all of the tests necessary to confirm that were not done at that time. Therefore, it is *possible* that, as Dr. Knapp argues, Emily's low blood sodium level in February, and thus her seizure, was due to something completely different from her later SIADH condition. However, I again found Dr. Bercu to be persuasive in arguing that given Emily's later confirmation of chronic SIADH, with the benefit of hindsight it seems *likely* that her February seizure was also related to her chronic SIADH condition. And, of course, if the chronic SIADH preceded the October 10 vaccination, it obviously was not caused by that vaccination.

Next, an argument stressed by Dr. Knapp merits a brief discussion. Dr. Knapp noted that in support of his opinion in this case, Dr. Bercu pointed to three medical articles, respondent's Exs. C, F, and G. The former two articles describe two human children who suffered from both cleft palate and SIADH, and the latter article reports an animal study showing an association between cleft palate and SIADH. At the hearing, petitioners' counsel and Dr. Knapp made much of the fact that scientifically, an association between mid-line defects and SIADH in humans cannot reasonably be inferred from only two case reports and an animal study. This point has merit. But it is noteworthy that these three articles, which possibly *suggest* an association between mid-line defects and SIADH, take on more weight in the context of the apparent existence of *additional* evidence indicating an association between mid-line defects and *other*, non-SIADH hypothalamic defects.[10] More importantly, it is not Dr. Bercu's burden to show that Emily's SIADH is causally associated with her mid-line defect. Rather, it is the *petitioners'* burden to show that her SIADH is vaccine-caused. Thus, while Dr. Knapp is correct that these three articles certainly do not by themselves demonstrate that SIADH is related to mid-line defects, respondent need not demonstrate such an association in order to prevail in this case.

---

[9]It may be noted that Emily's February seizure occurred eight days after her third DPT vaccination on January 26, 1995. However, petitioners have not alleged that the February seizure had anything to do with the January 26 vaccination.

[10]As noted above, Dr. Bercu testified at the hearing that it is medically accepted that there is an association between mid-line defects and other, non-SIADH defects in the hypothalamus, although he did not detail the evidence supporting such an association. Dr. Knapp did not rebut this assertion by Dr. Bercu.

### *3. Other opinions contained in the medical records contradict petitioners' theory*

Thirdly, and finally, I note that indications in the medical records concerning the views of *other* of Emily's treating physicians, as to the cause of her SIADH, tend to support the opinion of Dr. Bercu rather than that of Dr. Knapp. For example, a neurologist who treated Emily, Dr. Miller, noted that while Emily's parents may believe that the temporal relationship between Emily's DPT vaccination and her SIADH is important, "I think that there is no supportive evidence" for a causal relationship. (Ex. 10, p. 29.) Another treating physician, Dr. Dickson, a pediatrician, also noted that he had heard of the parent's concern about the vaccination possibly causing the SIADH, but told them "that there is more likely a higher correlation with her cleft lip and cleft palate * * * and that there is no causal relationship between it [the SIADH] and her receiving immunizations." (Ex. 21, p. 9.) Lastly, two treating physicians, the pediatrician Dr. White and the pediatric endocrinologist Dr. Willcutts, wrote jointly as follows:

> In summary, Emily is a 21 month old female of short stature, whose history of hyponatremic seizures from SIADH along with midline developmental defects and failure to thrive are very worrisome for pituitary disease or dysfunction. It is possible that her poor caloric intake or systemic disease could be contributing to her condition. Nonetheless, as mentioned during her hospital admission in October, 1995, it is very unlikely that her episodes of SIADH are idiopathic.

(Ex. 4, p. 61.) While their use of the word "idiopathic" is somewhat confusing, this excerpt as a whole seems to indicate that these two physicians found that the fact that Emily's SIADH was accompanied by "midline developmental defects" *is by itself an "explanation" of her SIADH*, so that they would not say that Emily's SIADH is idiopathic (*i.e.*, without known cause). Thus, they seem to agree with Dr. Bercu that both Emily's SIADH and her mid-line defects are likely related to each other--*i.e.*, likely both the result of abnormal prenatal development.

Thus, the only three expressions of opinion concerning the cause of Emily's condition that I have found in the medical records seem to generally indicate agreement with Dr. Bercu's view of Emily's case. In contrast, I could find no indications of support by other treating physicians for Dr. Knapp's theory.

In short, because (1) there is no substantial support for the theory that the DPT vaccine can cause SIADH, (2) there exists substantial evidence pointing to a pre-existing hypothalamic defect as a cause for Emily's SIADH, and (3) the opinions of Emily's other treating physicians seem to support the view of Dr. Bercu, I conclude that petitioners have failed to demonstrate that Emily's SIADH was vaccine-caused.[11]

---

[11]I note that there exist two different legal approaches to "actual causation" under the Program, a dichotomy that emerged in a Program case known as *Wagner*. The two different approaches are explained in detail in *Wagner v. Secretary of HHS*, 37 Fed. Cl. 134 (Fed. Cl. 1997) (hereinafter *Wagner I*) and *Wagner v. Secretary of HHS*, No. 90-2208V, 1997 WL 617035 (Fed. Cl.

## V

## CONCLUSION

The story of the SIADH condition of Emily Gibson is an unfortunate one. She and her family are certainly deserving of sympathy for the difficulties caused by that impairment. Congress, however, designed the Program to compensate only those individuals who can demonstrate either the existence of a "Table Injury" or satisfactory evidence of a causal link between an injury and a listed vaccination. And in this case the petitioners have failed to so demonstrate, for the reasons discussed above. Therefore, I conclude that petitioners are not entitled to a Program award.[12]

_____

George L. Hastings, Jr.
Special Master

---

Spec. Mstr. Sept. 22, 1997) (hereinafter *Wagner II*), and will not be repeated here. To summarize the divergence of analysis between the two opinions, in *Wagner II* I set forth the view that in ruling upon a claim of "actual causation," a Program factfinder is authorized to consider *all* the evidence of record; in *Wagner I*, on the other hand, a judge of this court concluded that in ruling upon an "actual causation" claim the factfinder is *forbidden* to consider evidence concerning a possible non-vaccine cause of the injury if that possible cause constitutes an "idiopathic" factor"--*i.e.*, one of unknown cause.

In this case, as explained above, part of Dr. Bercu's reasoning was that there exists considerable evidence of a non-vaccine cause for Emily's SIADH--*i.e.*, a pre-existing abnormality in Emily's hypothalamus. It is possible that this non-vaccine cause could be considered an "idiopathic" factor. Therefore, I wish to note that while the complete analysis set forth above at pp. 7-11 constitutes my analysis of this case under a *Wagner II* approach, even under a *Wagner I* approach I would reach the same outcome. That is, even if I were to ignore the evidence as to the possible non-vaccine cause of Emily's SIADH, I would still conclude that petitioners had failed to carry their burden of demonstrating that the SIADH was "more likely than not" caused by her vaccination, simply for the reasons set forth under part IV(C)(1) of this Decision at pp. 7-8.

[12]I do note that, despite the petitioners' ultimate lack of success on this claim, I find that this case was brought "in good faith" and upon a "reasonable basis." Accordingly, petitioners will be entitled to an amount for attorneys' fees and costs incurred in this action pursuant to § 300aa-15(e). This amount will be awarded in a supplemental decision, after the judgment "on the merits" becomes final. See Vaccine Rule 13.