



the testimony of Mr. Robert Williams, David's father,<sup>(2)</sup> and Dr. Thomas Schweller. Dr. Max Wiznitzer testified for the respondent. At the hearing, the issue was raised of whether petitioner had satisfied the Act's requirement that the petitioner incurred in excess of \$1,000 in unreimbursable vaccine-related expenses pursuant to § 300aa-11(c)(1)(D)(i). Numerous pleadings have since been filed by the parties regarding this issue.

## II. Factual Background

The record in this matter contains the following evidence:<sup>(3)</sup>

Mrs. Williams gave birth to David on April 19, 1981, the seven-pound, two-and-one-half-ounce product of an uneventful pregnancy. Medical records indicate David had APGAR scores of eight at one minute and nine at five minutes.<sup>(4)</sup> David visited the pediatrician on four occasions prior to September 8, 1981, and other than a notation indicating he had colic, David remained healthy and met his developmental milestones on time.<sup>(5)</sup> P. Ex. 7 at 54-58. On June 23, 1981, David received his first DPT vaccination. He suffered only a slight fever, irritability and decreased nursing for a period of 24 hours following the inoculation. P. Ex. 1 at 7.

Because of an ear infection, David's mother took him to the doctor on September 7, 1981, and the doctor placed David on antibiotics. P. Ex. 10 at 117. Mr. Williams testified David was not unusually cranky that night. Tr. at 17. The next day, September 8, 1981, David received his second DPT vaccination. Although David's mother died before the evidentiary hearing in this matter, she had previously filed an affidavit with the petition regarding the events in question. In her affidavit, Mrs. Williams averred:

Within one or two hours of inoculation David started crying loudly and would not stop for over 48 hours. He was running a temperature of 102.6 F. . . . Over the next six hour period there was nothing I could do that would comfort my child and stop his crying. Previously, swinging in the baby swing or taking him for a drive in the car, in a carseat, would both stop his crying and put him to sleep. Neither of these methods worked.

He would not vigorously nurse as was his habit nor did he drop to sleep while nursing as was also his habit. Prior to the vaccination he had been a very vigorous nurser. I could feel that he was very tense and not relaxed.

David did not sleep at all, for two days after the vaccination, except for perhaps a half an hour at about 4:00 a.m. on September 8, 1990 [sic]. There was nothing I could do to get him to go to sleep.

The next day, on September 9, 1981, David continued with his loud crying. His eyes were glassy. I was concerned because he was still not nursing vigorously. I estimate that he was nursing half as much as he had previously nursed. He was still unable to sleep and there was nothing I could do to comfort, calm or soothe my baby.

At approximately 11:00 p.m. on September 9, 1981, David started shaking his head from side to side without stopping. Then he began to shake his arms and draw his legs up to his body. His right arm and his left leg would jerk in almost a synchronized motion and then his left arm and right foot would jerk in a similar fashion. The jerking of David's body and the continual shaking of his head from side to side continued for nearly a day. His crying seemed like a panic cry. I thought the jerking of his body and shaking of his head was a convulsion.

At 3:00 a.m. on September 10, 1981 (the night of September 9, 1981) I took David to the emergency room at Kaiser Bellflower. They were unable to calm him. They told me to continue the Ampicillin for his ear infection, to give him tepid baths to calm him down and to put him in a room and let him cry himself to sleep. I gave him the baths, but would not let him cry in a room alone. They prescribed Auralgan ear drops.

On September 10, 1981, I again returned to Kaiser at approximately 5:15 p.m. His temperature was 36.8 C; although I thought he felt hot. I believe they gave him an injection of something to calm him down. He calmed down for about an hour, although they told me he should have been calm for five or six hours. They prescribed Phenergan Forte to calm him which I gave to him as prescribed. The doctor told me David's pain was due to the ear infection, but I have since learned that the medical record for this visit gave the diagnosis as a "DPT reaction".

At about 10:15 p.m., P.D.T., on September 10, 1981, I went back to Kaiser Bellflower to the pediatric "sick baby" clinic because I was concerned that David was still crying and jerking. They could not do anything to stop his crying, so we went home. The doctors told me that he was jerking because he was crying and taking air into his stomach.

On September 11, 1981, I telephoned his doctor at Kaiser Bellflower twice as David was still crying and he felt hot to me.

On September 14, 1981, I again telephoned David's doctor because he was still reacting to the vaccine. His eyes were glassy and he still had a temperature.

P. Ex. 1 at 7-10. Mrs. Williams also averred that, due to David's severe reaction, medical personnel administered a half dose of DPT at his third immunization and, for his fourth vaccination, only the DT portion of the vaccination. Id. at 10.

After the vaccination, Mrs. Williams noticed changes in David. She averred:

As David grew up, it soon became apparent to me that he was not developing normally; not crawling or playing like other toddlers his age. Although he is of average or above average intelligence, he suffers from numerous learning disabilities.

Id. at 11.

Although not the primary care-giver of their children at the time, Mr. Williams nevertheless has a distinct memory of the events that occurred following David's September 8, 1981, vaccination. When he came home from work the evening of September 8, Mr. Williams remembers, "David's eyes were as big as dollars and did not look normal. They were glazed over. He was crying and screaming and neither I nor my wife could console him or make him stop." P. Ex. 2 at 13. Mr. Williams also believes David appeared to hyperventilate that evening. Tr. at 10. According to Mr. Williams, David cried until 4:00 a.m. or 5:00 a.m. the next morning, when he finally cried himself to sleep for a short time. P. Ex. 2 at 13; Tr. at 10-11.

On the next evening, Mr. Williams recalls, David's condition worsened. Mr. Williams remembers David "making his arms and legs stiff and shaking slightly and then relaxing" in addition to crying and hyperventilating. Tr. at 11-12. In his affidavit, Mr. Williams described the unusual movements as "shaking his head back and forth like he was in a panic" and "shaking his hands like he was trying to cool them down." P. Ex. 2 at 13-14; Tr. at 34. Mr. Williams remembers these episodes continued for two

or three days and then tapered off.<sup>(6)</sup> Tr. at 14.

Mr. Williams described David as healthy and meeting his developmental milestones appropriately before the September 8 DPT vaccination.<sup>(7)</sup> Tr. at 7. Mr. Williams believes he first noticed David's slow development when David started trying to learn how to walk, run and ride a bicycle.<sup>(8)</sup> According to Mr. Williams, David appeared slower than the neighborhood children in all those areas. Mr. Williams testified his wife discussed these issues with David's pediatrician. Tr. at 41-42. Mr. Williams testified he became concerned about David's development during preschool and kindergarten, when David began "lagging behind in his physical coordination and definitely lagging behind in his speech development." Tr. at 18-19. David's articulation also remained unclear. Tr. at 19. In addition, Mr. Williams testified, David's eyes, which had appeared normal prior to the vaccination, crossed slightly after the vaccination and "the right eye tended to look left and he was always twisting his head to try to see straight." Tr. at 21-22.

According to Mr. Williams, David currently appears to be weaker on the right side of his body, his right eye remains weak, his mouth turns down on the right side, and he tends to wear his right shoe out more quickly. Tr. at 22. David has received speech and vision therapy and also participated in an orthopedic program to aid in his coordination. Tr. at 21.

### **Record evidence**

Medical records corroborate that Mrs. Williams took David to the Kaiser Hospital on several occasions in the three days following his DPT vaccination. P. Ex. 9 at 111-13. Records indicate Mrs. Williams took David to the Kaiser emergency room at 4:15 a.m. on September 10, 1981. P. Ex. 9 at 111. The notation indicates a complaint of crying. The record notes that David was on Ampicillin for his left otitis media and was displaying "mild distress." He was apparently seen by a physician's assistant and sent home. *Id.* at 111. A notation made during a visit on September 10 at 5:15 p.m. indicates David was crying and irritable. The physician recorded his impression as "DPT reaction," and prescribed Phenergan.<sup>(9)</sup> *Id.* at 112. Later that evening, at a 10:30 p.m. visit, medical records note "reaction to shots" as the presenting medical problem. A description notes "quiet boy sucking breast" and doctors recorded an impression of a questionable reaction to Actifed<sup>(10)</sup> or the DPT vaccine. *Id.* at 113.

The records also note two telephone calls made by Mrs. Williams to the doctor's office on September 11, reporting a continued "bad reaction" to David's DPT immunization. *Id.* at 114. Again on September 14, Mrs. Williams called the doctor's office to report that David's reaction to his September 8 immunization was continuing. *Id.* at 115. An additional school record prepared in 1990 indicates that Mrs. Williams gave a history that she thought David had experienced convulsions during his reaction to DPT, "[b]ut Kaiser ER said no." P. Ex. 19 at 418.

### **Expert testimony**

Petitioner presented the testimony of Dr. Thomas Schweller, a board certified pediatric neurologist. Dr. Schweller believes, to a reasonable degree of medical certainty, that David suffered an encephalopathy within 72 hours of his DPT vaccination on September 8, 1981. Dr. Schweller bases his opinion on the following evidence:

1. Marked irritability with persistent, inconsolable crying;
2. Altered level of alertness, with glassy stare;

3. Poor feeding; and

4. Jerking of the extremities and drawing up of the legs, highly suggestive of seizures.

P. Ex. 26 at 2.

Dr. Schweller testified that the unusual body movements David exhibited, consisting of arm and leg shaking with the right arm and left leg jerking simultaneously and then the left arm and right leg, may indicate an incomplete physical expression of a generalized seizure due to the immaturity of the brain. <sup>(11)</sup> Tr. at 57-61. He emphasized that depression of consciousness, often seen in an encephalopathy, need not be present in all encephalopathies and, indeed, encephalopathies caused by certain toxic agents result in agitation rather than depression. Tr. at 61-72. Dr. Schweller discounted the possibility that David's pain from his ear infection caused his irritability because David's response to this particular ear infection appeared different, and the abrupt change in his behavior did not occur until after the DPT vaccination on September 8, 1981. Tr. at 63. He believes David's glassy stare, seizure activity and level of "constant agitated, screaming for two days with periods of rest and then return to agitation," removes David's case from the typical scenario. Tr. at 106.

Dr. Schweller believes David suffered a clear encephalopathy following his DPT vaccination and that from that point in time David had abnormalities involving motor skills, cognitive abilities and language. Tr. at 119, 121. Dr. Schweller noted that after the DPT vaccination, David had problems with coordination, clumsiness, vision, eye muscle imbalance, language development, right hand use and writing ability. <sup>(12)</sup> Dr. Schweller believes these problems, which became apparent after the DPT vaccination, constitute sequelae of his vaccine-related encephalopathy and that the continuum they established indicate a causal relationship with the DPT inoculation. <sup>(13)</sup> Tr. at 123-25.

Dr. Schweller testified children such as David often possess a relatively high intelligence <sup>(14)</sup> but have other developmental problems. He testified:

If you have a diffuse injury, you would expect a global problem in all area[s]: motor, intellectual, language. If the nature of your injury is multifocal rather than diffuse, you might expect to have certain holes in your intellectual system. So your general intelligence may be fine but you may have difficulties in other areas.

Tr. at 94. Dr. Schweller believes David's current functioning suggests he has been left with some deficits that appear to be focal in nature. He explained that an injury to the brain from a DPT vaccination would "not necessarily injure all areas of the brain to the same degree." Tr. at 95. Dr. Schweller testified the acute stage of David's encephalopathy resolved within about three days. He explained:

I think that there's a spectrum of encephalopathy. You can have an encephalopathy occur over a period of hours if you have a toxic exposure . . . [and] return to normal. You can have an encephalopathy that can last for days to weeks if you have an inflammatory process in the brain, such as an encephalitis. You can have an individual who has an infarct to the brain or is in a motor vehicle accident that has a permanent and continuous encephalopathy. So I don't think that you can necessarily say that there is one time frame for all encephalopathies.

Tr. at 101. However, as Dr. Schweller explained, while the acute phase will pass, it does not necessarily mean no residual damage remains. Dr. Schweller analogized the situation to a prize fighter knocked out from a blow to the head. While the brain makes an attempt to compensate and there may be the physical

appearance of recovery, there remains often some degree, perhaps not immediately measurable, of residual damage. Tr. at 102. As well, Dr. Schweller pointed out one would not have to have impairment of all of the brain's systems in an encephalopathic process. Rather, only certain systems may be affected. Tr. at 103.

Respondent presented the testimony of Dr. Max Wiznitzer, a board certified pediatric neurologist. Dr. Wiznitzer testified, to a reasonable degree of medical certainty that he believes David did not suffer an encephalopathy within three days of his vaccination. He believes the medical records do not support a diagnosis of encephalopathy, but merely a child who was irritable and upset. He believes the factual testimony and affidavits are inconsistent with the medical records. He further asserted that the physicians who treated David would have noted in the medical records if he had been encephalopathic. Tr. at 130-34. Dr. Wiznitzer believes David's irritability was due to either (1) an ear infection (2) a possible reaction to a medication David was administered for his ear infection (3) being tired from medication for his ear infection or (4) a simple local reaction to the DPT vaccination.<sup>(15)</sup> Tr. at 122-23. Dr. Wiznitzer later conceded that emergency room records of 5:15 p.m. on September 10, 1981, indicate David's ears, nose and throat were clear. Tr. at 169; P. Ex. 9 at 113. Moreover, at the 10:30 p.m. visit to the emergency room, a physician indicated that the tympanic membrane was improved. Dr. Wiznitzer conceded that "if the eardrums are getting better that that [sic] has to be a diminishing contributor to any irritability." Tr. at 169.

Dr. Wiznitzer also believes the abnormal movements described by Mr. and Mrs. Williams did not constitute seizures but rather resulted from agitation due to being upset. Tr. at 135-37. Dr. Wiznitzer found the hyperventilation and crying David reportedly exhibited inconsistent with a diagnosis of seizures. Tr. at 138. Dr. Wiznitzer conceded, however, that an infant might cry during a partial seizure. A partial seizure involves jerking on one side of the body. Tr. at 158. However, the stiffening and relaxing that Mr. Williams described, as well as the head shaking from side to side, do not indicate seizure activity, according to Dr. Wiznitzer. Tr. at 139.

Dr. Wiznitzer believes the DPT vaccination in question did not cause David's current problems. First, he asserts, there is an absence of medical record evidence of an encephalopathy. Moreover, "you have to have an acute encephalopathy of sufficient degree to cause a prolonged alteration in mental status that should be easily identifiable by any clinician who sees the child." Tr. at 141-42. Dr. Wiznitzer expects David would have been difficult if not impossible to arouse and significantly hypotonic if he had been encephalopathic. Moreover, he expects the physicians who cared for David in the emergency room would have determined he was encephalopathic. Finally, he would expect to have some residual observable on neurological examination for at least six to twelve months if David had suffered an encephalopathy.<sup>(16)</sup> Tr. at 141-43. Dr. Wiznitzer believes David should have had significant hypotonia during the latter portion of infancy if he had suffered a DPT-related encephalopathy. Tr. at 143. In addition, Dr. Wiznitzer would expect significant feeding difficulties for several weeks following a moderate encephalopathy. David, on the other hand, gained weight by the time of his well-baby doctor's visit on December 1, 1981. Tr. at 144; P. Ex. 7 at 65.

Dr. Wiznitzer conceded that Dr. Schweller was accurate when he described that one might see anything from "a severe spastic quadriplegia to a very mild spasticity. . . ," following a brain insult depending on the severity of the brain injury. Tr. at 144-45. However, Dr. Wiznitzer believes certain symptoms would be present following even a mild case of an acute encephalopathy, including spasticity and hyperreflex. David, on the other hand, exhibited only coordination and tone difficulties, according to Dr. Wiznitzer. Tr. at 145. Dr. Wiznitzer testified if David's present neurologic condition had been caused by an encephalopathy occurring at the time of his DPT vaccination, he "would have expected at the minimum to find motor problems during the rest of infancy, and even that was not reported or recorded in the

records." Tr. at 152. Dr. Wiznitzer does not believe David's visual problems could have been related to his DPT vaccination because "there wasn't an encephalopathy acute enough to cause the kind of brain damage that would cause children to have an acute crossing of the eyes."<sup>(17)</sup> Tr. at 145-46.

Dr. Wiznitzer believes David's problems stem from a genetic defect. Tr. at 148. He believes David's clinical picture is a much more mild version of his brother, Brian's, and problems such as they have tend to run in families.<sup>(18)</sup> Tr. at 147. Dr. Wiznitzer testified David's current developmental language disorder, motor coordination difficulties and attention span problems are described in the medical literature as occurring in certain children who are genetically predisposed to having such problems. *Id.* He conceded, however, that clumsiness, dyspraxia, developmental language disorder and attention span problems also occur with children who have suffered encephalopathy. Tr. at 152-53.

Dr. Wiznitzer concedes that David currently suffers from a mild to moderate encephalopathy, but he believes David's encephalopathy has existed since birth. Tr. at 160-61. When asked why David's problems were not recognized earlier, he testified:

You couldn't diagnose this at birth. . . . One example would be children don't talk at birth. It would be very hard to diagnose a language disorder if they're not talking at that time. Number two, children do not have voluntary motor activity at birth. It would be very hard to pick up problems with motor coordination if you don't have voluntary motor activity. Newborn babies have willy-nilly extremity movements that are not under the control of the cerebral hemisphere, they're under much more primitive intercontrol. Number three. How are you going to gauge attentional problems in a newborn? . . . You can't measure it at that point in time. Because you can't measure it at that point in time, you have to measure it when it's there. It's different if he was born -- had a moderate or severe encephalopathy and then was left with hypotonia after that time which has gradually evolved into this picture.

Tr. at 161-62.

### **III. Discussion**

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation in fact. Petitioners must prove one or the other in order to recover under the Act. 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, 372-73 (1970) (Harlan, J., concurring) (quoting F. James, *Civil Procedure* 250-51 (1965)). Mere conjecture or speculation will not establish a probability. *Snowbank Enter. v. United States*, 6 Cl.Ct. 476, 486 (1984).

The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. § 300aa-14(a). The Table lists encephalopathy as a compensable injury that creates such a presumption if the onset occurs within 72 hours of the vaccine's administration. § 300aa-14(a)(I)(B), (D). The presumption may be overcome by an affirmative showing that a factor unrelated to the vaccine's administration caused the injury.<sup>(19)</sup>

#### **Encephalopathy**

The Vaccine Injury Table's Aids to Interpretation define an encephalopathy, in part, as follows:

The term "encephalopathy" means any acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least six hours in the level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent inconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

§ 300aa-14(b)(3)(A).

As an initial matter, respondent suggested in closing that I should not rely at all on Mrs. Williams' affidavit in support of this case. Tr. at 185-86. Although Mrs. Williams' unfortunate death prevented respondent's ability to cross-examine her, I see no reason not to consider her affidavit in my role as fact finder in this case. Indeed Mrs. Williams' account of David's course following his DPT vaccination is corroborated not only by Mr. Williams' testimony, but also by medical documentation. Moreover, as David's primary care giver, she was in the best position to record the events that occurred following his inoculation. Her untimely death does not preclude the special master from considering her affidavit. Moreover, the fact that Mrs. Williams took David to the emergency room several times in the 72 hour period following his inoculation would tend to support her contentions that David was alarmingly unwell following his vaccination.

The Vaccine Rules expressly provide that the Federal Rules of Evidence have no applicability in this forum. Vaccine Rule 8(b). Rather, all "relevant, reliable evidence" should be considered, "governed by principles of fundamental fairness to the parties." *Id.* I find Mrs. Williams' statements in her affidavit both relevant and reliable. When viewed with the medical documentation and corroborated by the testimony of Mr. Williams, I find her affidavit presents an entirely consistent, reliable, and accurate interpretation of the events following the vaccination in question.<sup>(20)</sup>

David received his vaccination on September 8, 1981. Over the next 48 hours he remained extremely irritable, evidenced by hours of inconsolable crying. During this time he failed to eat normally, his eyes appeared glassy, he appeared to hyperventilate, his sleep patterns changed, and he exhibited signs of seizure activity. Within 48 hours of David's DPT immunization, Mrs. Williams showed such concern for her son's condition that she rushed him to medical professionals on three separate occasions. Medical professionals who saw David during one of the visits to the emergency room believed that David was suffering a "DPT reaction." Thereafter, David only received a half dose of DPT for his third vaccination and did not receive the pertussis portion of his fourth DPT inoculation.

Dr. Schweller explained that the severity of an encephalopathy may vary, resulting in varying degrees of subsequent impairment. Dr. Wiznitzer, on the other hand, believes that even for mild residua of encephalopathy, the symptoms would necessarily have been severe enough that David would have been stuporous and that his condition would have been immediately recognizable by health care professionals. He further believes that had David suffered an encephalopathy, the residua would have been evident by two to three years of age.<sup>(21)</sup> In fact, however, Mr. Williams testified he noticed problems in David's development as early as when he was learning to walk.

Dr. Wiznitzer believes David was just irritable and cranky from his DPT vaccination. He believes David's current problems stem from a genetic defect. I simply did not find Dr. Wiznitzer's analysis compelling in this regard. Dr. Wiznitzer relied heavily on the fact that medical professionals who saw

David in the 72 hours following his vaccination did not diagnose him as encephalopathic. He implied that Mrs. Williams took her child to the emergency room three times following his DPT vaccination because she was a hysterical, overprotective mother. Ironically, in cases where an encephalopathy is alleged and a child is not taken to the hospital, it is respondent's typical refrain that if the child was not sick enough to seek further medical attention, the child could not have been suffering an encephalopathy. Medical records suggest hospital personnel certainly believed David was suffering a DPT reaction. Further, while medical personnel apparently did not observe any seizures and did not diagnose encephalopathy at the time, Dr. Schweller has testified, and I find convincing, that David suffered a mild encephalopathy. Based on the testimony and the record herein, it appears that hospital personnel did not appreciate the seriousness of David's condition.

Although Dr. Wiznitzer's ultimate analysis rests on a theory that David had a pre-existing, genetic encephalopathy, he could not point to a single manifestation of that encephalopathy prior to the events following the vaccination in question. In sum, I found Dr. Schweller's testimony more compelling than that of Dr. Wiznitzer. In light of the above, and considering the entire record herein, I find the evidence preponderates in favor of a finding that David suffered an encephalopathy within 72 hours of his December 8 DPT vaccination. Further, I find a preponderance of the evidence does not suggest David's encephalopathy was due to factors unrelated to the administration of the vaccine in question.

### **Sequela**

The Vaccine Act requires that in order to enjoy a presumption of causation, not only must a Table injury occur within 72 hours of the vaccination in question, but any subsequent injury or death for which a petitioner seeks compensation must be a sequela of the injury. § 300aa-14(a)(I)(E). "Sequela" is defined in the American Heritage Dictionary as "[s]omething that follows, [especially] a pathological *condition resulting from a disease*." The American Heritage Dictionary 1119 (2nd ed. 1985) (emphasis added). In the medical sense, sequela is defined as "any lesion or affection *following or caused by* an attack of disease." Dorland's Illustrated Medical Dictionary at 1509 (27th ed. 1988) (emphasis added). Both definitions imply a progression of events, one leading to the next. As has been noted by the U.S. Court of Federal Claims, the Vaccine Act provides compensation for the sequela of a Table injury as long as a petitioner offers "some logical, direct causal link" between the Table injury and the resultant sequela. Hossack v. Secretary of HHS, 32 Fed. Cl. 769, 776 (1995). "It is not a difficult burden, and requires far less than medical certainty." Id.

Petitioner has presented compelling evidence that David's subsequent condition, including his motor and visual problems and learning disabilities, constitute sequelae of his Table injury. Mr. Williams testified that he noticed changes in David's gaze and eye coordination immediately after the vaccination. Mr. Williams also testified that David walked clumsily at first, his articulation consistently remained unclear, and his speech developed late. Mr. Williams testified that he became more concerned about David's developmental progress during preschool and kindergarten when he noticed that David lagged behind other children in his development.

Dr. Schweller testified that an encephalopathy of the sort David suffered and his current physical disabilities of motor, language, vision, and development problems "logically go together." I find compelling his analysis of a prize fighter being knocked out who subsequently recovers to some degree without immediately discernable outward manifestations of the masked residual damage. Far less compelling was Dr. Wiznitzer's opinion that none of David's current problems could be in any way related to a vaccine-related encephalopathy, because such an encephalopathy would have had to be overwhelming in order to cause the deficits from which David currently suffers.

On the basis of all the evidence before me, I find the evidence preponderates in favor of a finding that all

of David's current intellectual, motor, visual and language deficits are sequelae of a presumptively vaccine-related encephalopathy. It would seem completely illogical that, as Dr. Wiznitzer seems to suggest, there can be gradations along a continuum of severity of encephalopathy, but that with respect to any resulting residua, permanent sequelae of an encephalopathy would necessarily have to be global and devastating. Dr. Schweller's conclusion is much more reasonable, in my view. David suffered a relatively mild encephalopathy and his residual symptoms are correspondingly milder than in many cases. In David's case, they are confined primarily to gross and fine motor problems, language deficits, a learning disability and visual problems.

In the final analysis, after weighing the evidence and considering the expert testimony offered in support of the parties' respective positions, I find the preponderance of evidence tips the scales in favor of petitioner. I find that more likely than not, David suffered an encephalopathy within three days of his September 8, 1981, vaccination, and his current deficits are sequelae of his vaccine-related injury.

### **Six Month Rule**

A petitioner under the Program must show that the injury complained of lasted for more than six months. § 300aa-11(c)(1)(D)(i). Respondent argues that petitioner has not met this burden. Tr. at 188. Apparently, respondent presumes that a person must suffer immediately discernable residua of an acute encephalopathy which last six months. *Id.* I simply do not agree. There have been many cases in which a vaccine-related injury has been found and sequelae such as developmental delays and/or learning disabilities are not noticeable until several years later. *See, e.g., Fuller v. Secretary of HHS*, No. 90-3709V, 1996 WL 65734 (Fed. Cl. Spec. Mstr. Jan. 31, 1996); *Jordan v. Secretary of HHS*, No. 91-1542V, 1993 WL 106729 (Fed. Cl. Spec. Mstr. Mar. 25, 1993); *Brown v. Secretary of HHS*, No. 90-904V, 1992 WL 191100 (Cl. Ct. Spec. Mstr. July 27, 1992); *Thomas v. Secretary of HHS*, No. 90-2022V, 1991 WL 263730 (Cl. Ct. spec. Mstr. Nov. 22, 1991), *aff'd* 27 Fed. Cl. 384 (1992). In this regard, I find compelling Dr. Schweller's prize fighter analogy in which the consequences of the underlying injury remain masked for a period of time. Similarly, in this case, I find that David's current deficits more likely than not constitute residual effects of his presumptively vaccine-related injury. Accordingly, I find David's injury lasted for the requisite period of six months.

### **\$1,000 in pre-petition, unreimbursable, vaccine-related expenses**

Finally, respondent argues that petitioner failed to document the expenditure of more than \$1,000 in pre-petition, unreimbursable, vaccine-related expenses pursuant to § 300aa-11(c)(1)(D)(i).<sup>(22)</sup> Respondent's Response to Petitioner's Submissions in Support of Unreimbursable Expenses, filed Aug. 22, 1995; Respondent's Response to Petitioner's June 24, 1996 Submission, filed Aug. 9, 1996. Petitioner filed documentation to support the \$1,000 requirement on April 10, 1995, May 22, 1995, January 16, 1996, and October 4, 1996. *See*, P. Exs. 30, 31, 32, 37.

To satisfy the statutory requirement, petitioner needs to show that he incurred an amount greater than \$1,000 in unreimbursed vaccine-related expenses prior to the tolling of the relevant statute of limitations. *Black v. Secretary of HHS*, 93 F.3d 781 (Fed. Cir. 1996). Further, as petitioner points out in his September 13, 1995, filing, the statute does not limit the expenses which satisfy this requirement to medical expenses, or even to expenses which may be compensated under § 300aa-15. *See, e.g., Hutchings v. Secretary of HHS*, No. 94-388V, 1994 WL 413273 (Fed. Cl. Spec. Mstr. July 20, 1994).

Petitioner also asserts that a careful reading of the statutory provisions indicates that the unreimbursable vaccine-related expense need not be *solely* for the vaccine-related injury, but rather the statutory language requires that the expense be "due in whole *or in part*" to the vaccine-related injury. § 300aa-11

(c)(1)(D)(i)(emphasis added). Petitioner's Reply, filed September 13, 1995, at 3. Petitioner argues, "The \$1,000 requirement was meant as [a] rough measure of the seriousness of an individual's vaccine-related injuries. Congress did not intend it to be a technical barrier to compensating persons with significant injuries." *Id.* Petitioner urges that the provisions in § 300aa-11(c)(1)(D)(i) should be read intentionally broadly in concert with Congress' intentions.

Respondent makes several arguments with respect to petitioner's proof on the \$1,000 issue. First, respondent argues petitioner has not demonstrated by a preponderance of the evidence that David's visual problems are vaccine-related. Because a large part of the claimed unreimbursable expenses are related to David's visual therapy, a resolution of this issue is essential. As noted above, Dr. Schweller believes that David's visual problems stem from the same root as the other residua of David's vaccine-related injury. He testified that individuals with some degree of spasticity, such as David exhibited as a child, tend to have visual problems as well. David was never noticed to have crossed eyes before his vaccination. That this particular problem became apparent following the vaccination, along with the clumsiness in walking and coordination, and problems in language development and writing abilities, suggests they stem from the same cause. I found Dr. Schweller's testimony in this regard very compelling and find there is a preponderance of the evidence that David's visual problems are sequelae of his vaccine-related encephalopathy.

Next, respondent argues that even if petitioner were able to establish the vaccine-relatedness of David's vision therapy expenses, petitioner has failed to provide adequate documentation of these expenses. Respondent apparently questions the veracity of Mr. Williams' statements that he was not reimbursed for Dr. Cox's vision therapy fees by Kaiser Permanente. Respondent notes that the plan submitted by petitioner is undated, and further, that its provisions with respect to visual care do not necessarily, on their face, preclude the provision of vision therapy. Petitioner has asserted that Kaiser Permanente has found vision therapy to be experimental in nature and excluded expenses therefrom from coverage.

Mr. Williams attests that after numerous hearings on the issue and partial reimbursement from David's school district, a total unreimbursable amount of \$835.96 was incurred for vision therapy sessions and related travel between May 1, 1990, and September 26, 1990. P. Ex. 32 at 5. As an initial matter, I found Mr. Williams to be completely forthright and credible during his testimony before me at the evidentiary hearing on entitlement in this matter. As discussed above, I find that David's vision problems are sequelae of his vaccine-related encephalopathy, and, further, that petitioner would not have incurred the vision therapy costs but for the vaccine injury.

While respondent has requested petitioner supplement the records with tax returns from the relevant years and further explanation regarding the visual therapy bills and whether any other collateral sources of payment were available, I do not find any further information is necessary. Petitioner has produced a wealth of documentation on the \$1,000 issue. I believe Mr. Williams' averments that he has not been reimbursed, nor will the insurance company agree to reimburse him, for vision therapy. These amounts, then, I find to be properly included in the \$1,000 amount.

As noted, petitioner only need show that he incurred an amount greater than \$1,000 in relevant unreimbursed expenses prior to the expiration of the relevant statute of limitations to satisfy the statute. Black v. Secretary of HHS, 93 F.3d 781 (Fed. Cir. 1996). Because the Black decision made it clear that unreimbursable expenses incurred on or before January 31, 1991, are includable in the \$1,000 amount, the cost of \$290.27 for two pairs of eye glasses for David, purchased on January 31, 1991, is also includable in the \$1,000 amount. See P. Ex. 37. These unreimbursed expenses for vision therapy and the purchase of prescription glasses total more than the \$1,000 required to fulfill the Act's requirements. However, I will review the additional items petitioner has listed as satisfying the \$1,000 requirement.

Mr. Williams attests in November 1986, David's kindergarten teachers informed him and his wife that David was having great difficulty with tasks involving both gross and fine motor skills. The teachers recommended he be evaluated for developmental delay in these areas. P. Ex. 32 at 2. The Williamses then relayed the concerns of the teachers to David's pediatrician, Dr. Fredericks. Dr. Fredericks referred David for an occupational therapy evaluation in November 1986, and following the evaluation, treatment for occupational therapy was instituted for David by Ms. Sung. P. Ex. 32 at Tab A. According to Mr. Williams, both Dr. Fredericks and Ms. Sung suggested David be enrolled in tumbling, swimming, and dancing classes to improve his gross motor skills. P. Ex. 32 at 3. Petitioner states he incurred \$442.91 in unreimbursable expenses for these classes from 1986 to 1988. Id. at ¶ 8; P. Ex. 31 at 1-2.

Respondent objects to these costs on the grounds that the doctor's note offered in support of this expense provided no detail regarding which specific types of activities petitioner should engage in and does not set forth the suggested duration of those activities. Resp. Response, filed August 22, 1995, at 7-8. In support of the costs for lessons and classes, petitioner has submitted Dr. Frederick's November 1986, referral for an occupational therapy evaluation, which does not specifically mention any particular classes or activities he recommended for David. However, I have no doubt that Mr. and Mrs. Williams had a conversation with Dr. Fredericks and with Ms. Sung about what activities would best address David's gross motor deficiencies.

Respondent further argues that David's sister also engaged in similar activities, diminishing the likelihood that these classes were actually recommended specifically to benefit David's vaccine-related injury. Id. at 6. Petitioner counters as follows:

Children with and without disabilities receive tumbling, swimming, and dancing lessons. One of the primary reasons children receive such lessons is to improve their coordination. For many children such lessons are also a desirable opportunity to socialize with other children and learn the skills involved. . . .

David, however, received the lessons in part to address his lack of coordination. Coordination is a gross motor skill and David's deficit in gross motor skills was vaccine injury related. David, therefore, received the lessons "in part" as a result of his vaccine-related injury.

Petitioner's Reply Re: Unreimbursable Expenses, filed September 13, 1995, at 6 (emphasis in original). This argument has merit. For example, if a family of a vaccine-injured retarded child built a fence around their yard in order to keep the child safely within the confines of an area subject to parental supervision, the cost of the fence would be includable in the \$1,000 statutory amount even though many families choose to build fences around their yards. Similarly, here, many children engage in activities such as swimming and dancing. However, David's pediatrician and occupational therapist specifically recommended these activities for David to benefit his gross motor deficiencies. While David may have participated in *some* activities as a healthy child which would have had the incidental benefit of improving his gross motor skills, petitioner asserts that *these particular classes and activities* were selected for David to benefit his gross motor development at the suggestion of his physician and occupational therapist. Simply because there may be overlap in the activities of a normal child as opposed to a child who has developmental deficits, I find that, as petitioner asserts, these particular activities were chosen *at least in part due to David's vaccine-related injury*. As such, they fall within the purview of costs includable in the \$1,000 statutory amount. [\(23\)](#)

Mr. Williams attests that the family purchased a total of \$236.05 in toys to address David's fine motor skill deficiencies. P. Ex. 32 at 3. Again, respondent argues that a note filed by petitioner from the doctor fails to support the allegation that the expenses are vaccine-related. Resp. Response, filed August 22, 1995, at 6-7. I have found above that David's deficiencies in gross motor skills constitute sequelae of his

vaccine injury. Based on Mr. Williams' statement, and for the same reasons stated above with respect to the activities chosen to benefit David's developmental problems, I find the cost of the specific toys listed are reasonably includable in the \$1,000 statutory requirement as well. Mr. Williams purchased these items in an effort to address David's specific deficiencies and they are thus includable in the statutory amount.

In sum, I find petitioner has substantially exceeded the \$1,000 statutory amount for vaccine-related expenses.

#### **IV. Findings of Fact**

1. As the father of his minor son, petitioner has the requisite capacity to bring this action. § 300aa11(b)(1)(A).
2. Petitioner has not previously collected an award or settlement of a civil action in connection with any alleged injury sustained by David due to the administration of the DPT vaccine in question. § 300aa-11(c)(1)(E); P. Ex. 1 at ¶ 21; P. Ex. 2 at ¶ 11; Petition at ¶ 16.
3. David received a vaccine listed in the Vaccine Injury Table. § 300aa-11(c)(1)(B)(i)(I); P. Ex. 6 at 110.
4. Said vaccine was administered in the United States, in Bellflower, California. § 300aa-11(c)(1)(B)(i)(I); Tr. at 8.
5. There is a preponderance of the evidence that David suffered an encephalopathy as defined by the Vaccine Injury Table with onset within 72 hours of the administration of the DPT vaccination on September 8, 1981, and that his current condition is a sequela of that injury.
6. There is a preponderance of the evidence that petitioner expended in excess of \$1,000 in unreimbursed medical expenses as a result of a vaccine-related injury.
7. There is not a preponderance of the evidence that David's injury is due to a factor unrelated to the immunization in question.

#### **V. Conclusion**

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioner is entitled to compensation in this case under the Vaccine Act. An order setting forth the schedule for resolving the damages portion of this case will be issued separately.

**IT IS SO ORDERED.**

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Elizabeth E. Wright

Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C.A. §§ 300aa-1 through -34 (West 1991 & Supp. 1997)). References shall be to the relevant subsection of 42 U.S.C.A. § 300aa.
2. David's mother, Mrs. Patricia Williams, died subsequent to the filing of this petition.
3. The evidence in the record consists primarily of exhibits submitted as part of the petition filed in this case ("P. Ex. \_\_\_\_"), respondent's exhibits filed in this matter ("R. Ex. \_\_\_\_"), plus evidence taken at the evidentiary hearing in this matter ("Tr. at \_\_\_\_").
4. An APGAR test measures heart rate, respiration, muscle tone, responsiveness to stimulation, and skin color. Generally, two tests are performed at exactly one and five minutes after birth. The maximum score is ten. The Merck Manual 1858 (15th ed. 1987). The score taken at one minute is an index of asphyxia, while the five minute score is an index of the likelihood of death or neurological residua. Nelson Textbook of Pediatrics 362 (13th ed. 1983). The accuracy of the score for the prediction of long-term outcome, however, is inconsistent. R. Summitt, Comprehensive Pediatrics 370 (1990).
5. Medical records indicate David's hearing and vocalizations were appropriate at two months of age, and that he was following to midline, raising his head 45 degrees while prone and rolling side to back. P. Ex. 7 at 56. By four months of age, the date of his September 8, 1981, DPT vaccination, records note David took objects to his mouth, held his head steady while sitting and laughed aloud. P. Ex. 7 at 58.
6. Mr. Williams did not accompany his wife when she took David to the hospital in the days following his vaccination. Tr. at 16.
7. Mr. Williams testified David has an older brother, Brian, born July 3, 1974, who is severely developmentally delayed and retarded. As a result, the Williams were particularly attuned to David's development. Tr. at 8.
8. Mr. Williams testified when David finally learned to walk, sometime past one year of age, he seemed clumsy and fell more often than other children. Tr. at 19.
9. Phenergan is an antihistamine also used as a sedative. Tr. at 77; 1996 Physicians' Desk Reference at 2775.
10. Actifed is a nasal decongestant. 1996 Physicians' Desk Reference for Nonprescription Drugs at 808.
11. Dr. Schweller conceded David's symptoms of continuous crying throughout a generalized seizure, as Mr. Williams described, constitutes an atypical presentation of a seizure. But Dr. Schweller opined the terms "atypical" and "partial" accurately describe David's seizures. During those types of seizures, the victim remains somewhat conscious and could be alert and responsive. Tr. at 84.
12. Dr. Schweller believes David's vision problems are the result of his vaccine-related injury because,

among other things, individuals with some degree of spasticity tend to have strabismus-type problems. Tr. at 89.

13. Dr. Schweller believes no relationship exists between David's disabilities and those of his brother, Brian. He explained Brian's injuries materialized at birth and were "very different in their course." Tr. at 96-97.

14. Doctors have estimated David's IQ at 119 for overall intelligence, which places him in the high average range.

15. Dr. Wiznitzer surmises that David's leg hurt from the DPT vaccination and that he was crying as a result. Tr. at 133-34.

16. Dr. Wiznitzer testified David's neurological exams were essentially normal on December 1, 1981, March 19, 1982, August 16, 1982, and May 23, 1983. Tr. at 143; P. Ex. 7 at 65, 67, 68.

17. As to David's eyelid drooping, Dr. Wiznitzer would expect to see "failure of adequate closure of that eye. . . ." Tr. at 146-47.

18. Dr. Wiznitzer stated Brian had significant cognitive problems as well as hypotonia, language deficits and coordination problems. Tr. at 147.

19. <sup>19</sup> § 300aa-13(a)(1)(B). Other prerequisites to compensation include: (1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine. § 300aa-11(c)(1)(D)(i); (2) that the petitioner incurred in excess of \$1000 in unreimbursable vaccine-related expenses. § 300aa-11(c)(1)(D)(i); (3) that the vaccine was administered in the United States. § 300aa-11(c)(1)(B)(i)(I); (4) that the petitioner did not previously collect a judgment or settlement in a prior civil action. § 300aa-11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative. § 300aa-11(b)(1)(A).

20. Even if the Federal Rules of Evidence were applicable here, I would find that Mrs. Williams' statements in her affidavit clearly fall within an exception to the hearsay rule. Fed. R. Evid. 804(a)(4); 804(b)(5). I find her statements trustworthy in this context. As noted, the mere fact that Mrs. Williams took David to the emergency room three times in one 24 hour period suggests that she was acutely distressed and concerned about David's symptoms and would remember them clearly.

21. This testimony, however, belies Dr. Wiznitzer's assertion that an encephalopathy must have immediately apparent sequelae. He testified babies who suffer birth hypoxia and are encephalopathic as a result may not exhibit developmental delay for several years, when they are called upon to perform higher cortical functions.

22. The statutory provision requires petitioner to have "incurred unreimbursable expenses due in whole or in part to [a vaccine-related injury] in an amount greater than \$1,000." § 300aa-11(c)(1)(D)(i).

23. Several special masters have applied a "but for" test in determining whether an expense should be includable in the \$1,000 statutory amount. See, e.g., Ashe-Robinson v. Secretary of HHS, No. 94-1096V, 1997 WL 53450 (Fed. Cl. Spec. Mstr. Jan. 23, 1997)(cost of health club membership includable); Ferguson v. Secretary of HHS, No. 93-376V, 1995 WL 642693 (Fed. Cl. Spec. Mstr. Oct. 19, 1995)(cost of travel expenses to find employment includable); Hutchings v. Secretary of HHS, No. 94-388V, 1994 WL 413273 (Fed. Cl. Spec. Mstr. July 20, 1994)(cost of driver to drive injured petitioner

to work includable). However, the "but for" test should not be viewed as eliminating from possible inclusion in the \$1,000 costs for an item a person *might choose to purchase or spend for even if he or she were not injured*. For example, in Ashe-Robinson, supra, the chief special master allowed costs for an injured person to join a health club. Many healthy people obviously join health clubs. In the example cited above, many families choose to build fences around their yards. Here, as well, many children take tumbling classes. The determining factor is not that the person would under no other circumstances engage in the activity or spend money on a particular item or service, but that *because of* the vaccine-related injury, such particular item, activity or service was purchased specifically to address the vaccine-related injury.