OFFICE OF SPECIAL MASTERS
No. 90-1347V
(Filed: January 20, 1998)

BETSY GOODWIN, mother and legal guardian of MARKUS RAY GOODWIN,	
Petitioner,	**TO BE PUBLISHED**
v.	
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	

John M. Rankin, Jr., Brentwood, Tennessee, for petitioner.

Elizabeth Kroop, Department of Justice, Washington, D. C., for respondent.

DECISION

HASTINGS, Special Master.

This is an action seeking an award under the National Vaccine Injury Compensation Program (see 42 U.S.C. § 300aa-10 *et seq*.[(1)]) on account of an injury to petitioner's son, Markus Ray Goodwin. For the reasons stated below, I conclude that petitioner is not entitled to such an award.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program (hereinafter the "Program"), compensation awards are made to individuals who have suffered injuries thought to be caused by certain 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 an injury thereafter; 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 link, either temporal or causal, between the vaccination and the injury. One method by which the petitioner may establish this link is by demonstrating the occurrence of what has been described as a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in § 300aa-14(a) -- the "Vaccine Injury Table" -- corresponding to the vaccination in question, and that either the first symptom of the onset of that injury, or the first symptom of a significant aggravation of that injury, occurred within an applicable time period after the vaccination, also specified in the Table. If so, the "Table Injury" is, in effect, presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is shown affirmatively 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).

As relevant here, one vaccination listed in the Vaccine Injury Table is the "DPT" inoculation (*i.e.*, diphtheria, pertussis, and tetanus), and two of the "Table Injuries" listed for that vaccination are "encephalopathy" (*i.e.*, brain injury) and "residual seizure disorder." The Table further provides that in order for the vaccine recipient to qualify for an award, the first symptoms of either such injury, or the first symptoms of a "significant aggravation" of either such injury, must have been exhibited within *three days* of the inoculation. § 300aa-14(a)(I)(B) and (D).

Alternatively, if no injury falling within the Table can be shown, the petitioner may gain an award by showing instead that the vaccine recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii).

II

BACKGROUND FACTS

Markus Ray Goodwin, son of the petitioner, Betsy Goodwin, was born on December 3, 1978, after a gestation period of just 28 weeks (12 weeks less than a normal gestation period of 40 weeks). (Ex. 3a.[(2)]) Markus at birth weighed only two pounds, 4 3/4 ounces. (Exs. 3a, 8a.) Due to his extreme prematurity and low birth weight, Markus experienced severe medical complications in his early weeks of life. Markus spent the first three months of his life in the hospital. (Ex. 8a.) According to the medical summary recorded at his discharge after that extended hospital stay, it "did not look like [Markus] would live for the first two or three days." (Ex. 3a.) Among other problems, Markus was initially slow to breathe, requiring resuscitation, and had repeated instances of "apnea," in which he simply stopped breathing, along with "respiratory distress syndrome," and periodic "cyanotic spells." (Ex. 3a; Ex. C at 1.)

After Markus was discharged from the hospital, he received his pediatric care from Dr. Rufus Clifford. The notes of his pediatric care for the first three months after hospital discharge (March through May of 1969) do not seem to reflect anything highly unusual, although those notes are brief and poorly legible. (Exs. 6b, 6c.)

On Friday, June 6, 1969, Markus developed a fever, lethargy, and vomiting.[(3)] On the next day, June 7, he was taken to the office of Dr. Clifford, who recorded "some spitting" in his notes, but nevertheless gave Markus his third DPT inoculation. (Exs. 6c, 42.) On June 9, Markus was again taken to see Dr. Clifford, who recorded that "baby has been sleeping all time, vomiting * * * will not wake up for last 2 days." (Ex. 6c.) Dr. Clifford was concerned enough to admit Markus to the hospital that day for evaluation.

Dr. Markus was admitted to the local Maury County hospital on June 9, for evaluation. There, Dr. Clifford observed Markus to be experiencing seizure activity. (Exs. 7a, 8a.) Markus was discharged from that hospital on June 11 so that he could be admitted to the larger Vanderbult University Hospital on June 12. (Ex. 8a; see also pages marked 6A, 6B, and 6C near the end of the attachments to Ex. 36.) He remained at the latter hospital until June 20, 1969, when he was discharged with the diagnosis of a seizure disorder of unknown cause and "communicating hydrocephalus," meaning excessive fluid within the skull. (Exs. 8a, 8e, 8g.)

Tragically, since his hospitalization in June of 1969, Markus has proved to be the victim of a devastating neurological disorder. He has continued to suffer from seizures and is profoundly retarded in both mental and physical development.

III

ISSUES FOR DECISION

In this case, there is no dispute that Markus received a Table-listed vaccination (DPT) in the United States, has manifested a severe neurologic disorder, and has not received any award or settlement on account of such disorder. The issues requiring resolution here are whether petitioner has established the necessary link between Markus' neurological disorder and his DPT inoculation, via either of three possible theories: (1) that Markus suffered either the first symptom of the *onset*, or the first symptom of a *significant aggravation* of the "Table Injury" known as "residual disorder" within three days of his DPT inoculation on June 7, 1969; (2) that Markus suffered either the first symptom of the *onset* or the first symptom of a *significant aggravation* of the Table Injury known as "encephalopathy" within three days of that same inoculation; (3) that Markus' neurological disorder was "caused-in-fact" by that DPT vaccination.

I conclude that petitioner has failed to establish entitlement to a Program award by any of these potential avenues. I will organize my discussion of that conclusion as follows. First, in part IV of this decision, I will discuss the expert testimony in this case, and explain why, in general, I credited the testimony of the respondent's experts over that of the petitioner's expert. Then, in parts V, VI, and VII, I will explain how, applying my general analysis of the case contained in part IV to each of the potential entitlement theories of petitioner, I must reject each of those theories.

IV

GENERAL ANALYSIS

A. Summary of experts' respective views

All three experts who testified at the evidentiary hearing[(4)] in this case--*i.e.*, pediatric neurologists Dr. Lawrence Ch'ien for petitioner and Dr. Arnold Gale for respondent, and pediatric neuroradiologist Dr. Charles Fitz for respondent--agree that prior to his DPT inoculation on June 6, 1969, Markus suffered--though unbeknownst to anyone at the time--from both communicating hydrocephalus and periventricular leukomalacia (hereinafter "PVL"), two abnormal brain conditions which resulted from his premature birth. They agree that at least a significant percentage of infants (though they differ on the percentage) with those two conditions will ultimately suffer from seizure disorders and/or other significant neurological deficits. The experts part company, however, as to other aspects of the case.

Dr. Ch'ien stated the opinion that Markus' hydrocephalus and PVL would not be adequate explanations for the devastating neurological condition that has in fact afflicted Markus; he believes that some

additional neurological insult must have further damaged Markus' brain. He relies upon the fact that Markus experienced his first clear seizure about two days after his DPT vaccination, and also upon the affidavits of Markus' parents filed in this proceeding, which indicated that Markus cried and screamed unconsolably and experienced unusual drooling after receiving that vaccination.[(5)] Dr. Ch'ien also points to the fact that during the three-month period between his hospital discharge in early March through early June, the records of Markus' pediatric care do not indicate any concern about the infant's progress. Based upon these factors, Dr. Ch'ien opines that the DPT vaccination given on June 7, 1969, likely caused considerable additional damage to Markus' brain, resulting in his tragic course since that time.

Dr. Fitz and Dr. Gale, on the other hand, expressed strong disagreement with Dr. Ch'ien's general theory of the case. Dr. Gale, a pediatric neurologist, gave the more extensive testimony. He opined that Markus was undoubtedly the victim of hypoxic/ischemic encephalopathy caused by his premature birth. Dr. Gale explained that in an extremely premature baby such as Markus--especially those born during the 1960's, before improvements in medical techniques to deal with premature birth--the trauma of the birth process itself, along with the stress of living outside the womb at such a premature stage, causes bleeding in an infant's brain. This bleeding, he testified, can and very often does cause both of the conditions from which Markus suffered--hydrocephalus and PVL. (Hydrocephalus is a condition involving excessive cerebrospinal fluid within the skull. PVL is a condition involving destruction of the white matter of the brain around the ventricles.) Dr. Gale stated that the difficulties caused by a birth of 12 weeks prematurity are so great that in 1969, only a minority of such infants would even have escaped death. He further testified that of those infants who survived such extreme prematurity in 1969, a majority would prove to suffer from very severe neurologic abnormalities as a result.

Because of these severe consequences of prematurity, Dr. Gale testified, the unfortunate course of Markus is fully explained by his prematurity. Dr. Gale explained that often with such infants, the extent of their neurologic problems is not manifested until about the age of six months, the very age that Markus had obtained at the time of his DPT inoculation on June 7, 1969. Further, Dr. Gale testified, a crucial factor here is that the initial symptoms of the dramatic downturn in Markus' health in 1969 took place *the day prior* to his DPT inoculation. That is, Markus first displayed vomiting, fever, and lethargy on June 6, 1969. These are classic symptoms, Dr. Gale testified, of Markus' hydrocephalus, resulting from the intracranial pressure caused by the excessive fluid in the skull. Dr. Gale acknowledged that these symptoms worsened during the first two days after the inoculation, and that Markus likely did suffer from seizure activity during that period. But Dr. Gale believes strongly that worsening was wholly coincidental to the inoculation. He believes that the increased lethargy, vomiting, and fever were merely a continuation of the same symptoms that had begun on June 6, due to the hydrocephalus that had certainly existed since Markus' birth. And the seizures, Dr. Gale opined, were most likely the product of the hydrocephalus and/or the PVL damage to Markus' brain, which also long pre-existed the inoculation.

The opinion of Dr. Fitz, an expert at interpreting images (*e.g.*, CT and MRI scans) of infant brains, was substantially in accord with that of Dr. Gale. Dr. Fitz finds it unquestionable that Markus had both hydrocephalus and PVL long prior to his DPT inoculation, almost certainly as a result of his prematurity. Dr. Fitz confirmed that many victims of PVL in fact later do manifest seizure disorders, and he believes it likely that in Markus' case, his course would have been exactly the same had he not received the DPT vaccination. To buttress that opinion, Dr. Fitz explained that if Markus had experienced a new episode of brain damage (encephalitis) at age six months, as Dr. Ch'ien opined, evidence of that, in the form of observable damage to the brain's gray matter, would have been observable on the CT image of Markus' brain taken in 1994. In fact, Dr. Fitz, testified, that image showed no such damage, but instead showed only abnormalities typical of PVL damage due to prematurity.

B. General analysis of expert testimony

After carefully considering the testimony of the three experts at the hearing, as well as the rest of the record, my conclusion is that the analysis of Drs. Gale and Fitz was considerably more persuasive than that of Dr. Ch'ien. My general impression was that Drs. Gale and Fitz seemed to be more comfortable with their analysis than Dr. Ch'ien was with his, and better able to answer questions about and defend their views. In addition, there are several other more specific reasons for my conclusion in this regard.

One very important factor is that the opinions of Drs. Gale and Fitz fit much better with the key fact that the set of neurological symptoms that landed Markus in the hospital on June 9 actually began on *June 6, prior* to the DPT inoculation in question. I found very persuasive Dr. Gale's testimony that given the facts that (1) Markus was in fact diagnosed with hydrocephalus during the June 12 hospitalization and (2) he manifested classic symptoms of hydrocephalus-induced intracranial pressure (vomiting, lethargy, fever) beginning on June 6, it seems very likely that the symptoms that Markus manifested on June 7 through 10 were also symptoms of the hydrocephalus, rather than any new, intervening brain injury.

In contrast, Dr. Ch'ien, in both his written reports as well as his initial oral testimony, seemed to ignore the symptoms on June 6 or to assume that no significant symptoms began until June 7. For example, in his first written report, Dr. Ch'ien stated that Markus "experienced no significant problem during the period leading up to his DPT shot." (Ex. 44, p. 2.) To be sure, Dr. Ch'ien, when confronted at the hearing with the fact that the lethargy, vomiting, and fever began on June 6, stated that assuming such fact would not change his opinion. But he did not explain convincingly *why* the symptoms on June 7 through 9 should not be considered to be a continuation of the symptoms on June 6.

Further, on a number of individual points where there was some conflict between the analysis of the respective experts, I found Drs. Gale and Fitz to be more persuasive than Dr. Ch'ien, further buttressing my conclusion that the overall view of the case of the former two experts should be credited over that of Dr. Ch'ien. For example, Dr. Ch'ien asserted that the fact that Markus' pediatrician on June 7 did not discover a bulging fontanelle in the infant means that Markus was not suffering from increased intracranial pressure at that time. But Dr. Gale effectively refuted that assertion, explaining that while a bulging fontanelle definitely does indicate increased intracranial pressure, the mere lack of that finding certainly does not exclude the possibility that a lesser amount of intracranial pressure does exist. In the overall circumstances of the case, I find to be much more likely Dr. Gale's view that the lethargy, vomiting, and fever that existed on June 6 was indeed a sign of intracranial pressure caused by the hydrocephalus.

As another example, Dr. Gale pointed out that one of Dr. Ch'ien's arguments rested upon an overly simplistic view of the differing roles of white matter and gray matter in the brain, and Dr. Ch'ien at the hearing admitted that his distinction was somewhat simplistic. (Tr. 61.) As to this point, I found that Drs. Gale and Fitz persuasively testified that while PVL nominally refers to diminution of white matter, PVL is also very frequently associated with mental retardation, contrary to the thrust of Dr. Ch'ien's argument.

In addition, Drs. Gale and Fitz were convincing in their portrayal of the consequences of Markus' extreme prematurity of birth, in the context of the fact that his birth took place nearly 30 years ago, prior to the availability of modern techniques for dealing with prematurity. Dr. Gale testified that a majority of infants born 12 weeks prematurely in the late 1960's did not survive, and that a majority of the survivors would end up, as did Markus, with extreme neurological abnormalities. Dr. Ch'ien did not contest this point. Even Dr. Ch'ien acknowledged that of infants with hydrocephalus and PVL as a result of prematurity, at least 30% would be expected to later develop a seizure disorder as a result. Dr. Gale testified that in his experience the percentage would be more than 50%.

Also, Dr. Ch'ien argued that the fact that Markus did not seem to manifest any major neurological difficulties in the period from March through May of 1969 indicated that the brain damage from the

prematurity was not great. But Dr. Gale pointed to Markus' difficult course through his *first* three months of life--*i.e.*, December 1968 through February of 1969--as evidence that Markus was in fact severely neurologically compromised. And Dr. Gale also pointed out that it is very common for serious neurological problems not to be actually recognized until about age six months, when in fact those problems resulted from prenatal factors or birth trauma. Again, Dr. Ch'ien never effectively refuted these points.[(6)]

Yet another strong point in the testimony of respondent's experts was the testimony of Dr. Fitz, a superbly qualified pediatric neuroradiologist, concerning the CT image made of Markus' brain in 1994. Dr. Fitz opined, in both his initial written report and his hearing testimony, that such CT image was *inconsistent* with Dr. Ch'ien's view of the case. That is, Dr. Fitz explained that if Markus had experienced a new episode of brain damage (encephalitis) at age six months, as Dr. Ch'ien opined, evidence of that, in the form of observable damage to the brain's gray matter, would have been observable on the CT image of Markus' brain taken in 1994. In fact, Dr. Fitz, testified, that image showed no such damage, but instead showed only abnormalities typical of PVL damage due to prematurity. Dr. Gale also offered testimony in support of this point, explaining that if a DPT inoculation at age six months had in fact further damaged Markus' brain, he would have expected to see gray matter changes observable upon the CT scan, as well for Markus to have manifested much more severe neurological symptoms, such as coma, within a very short time after the inoculation. And once again, Dr. Ch'ien offered no effective rebuttal on this point.

Finally, I note that certain expressions of one or more of the physicians who treated Markus in the early days of his tragic neurologic course tend to support the opinions of respondent's experts, rather than the opinion of Dr. Ch'ien. To be sure, most records of that time indicate that Markus' problems were of "unknown" origin. However, in a note made on March 18, 1970, an unknown physician at the Vanderbilt University Hospital recorded the "impression" that Markus' retardation was "resultant from neonatal incidents." (Ex. 10d.) On the same date, a separate document, apparently prepared by a Dr. W. Garrett[(7)] of that same hospital, mentioned Markus' "delayed development" followed by the phrase "2º neonatal incidents." The notation "2º" likely means "secondary to," thereby again indicating the view that Markus' neurologic problems resulted from "neonatal incidents." And since the "neonatal" period by definition refers to the period from birth to the 28th day of life,[(8)] and Dr. Gale explained that trauma of prematurity includes brain damage sustained from the beginning of the birth process *through* the neonatal period, it is obvious that the impressions recorded at these two notes (which do not mention any vaccination as a possible cause) are consistent with the views of Dr. Gale and Fitz, rather than those of Dr. Ch'ien.

In short, for the reasons set forth above, my general conclusion as to the differing approaches of the experts in this case is simply that the analysis of the respondent's experts seems to be decidedly more probable than that of Dr. Ch'ien. I conclude that the symptoms that Markus displayed during the three-day period after his DPT vaccination on June 7, 1969, likely were simply *a continuation* of the symptoms that he first manifested on June 6, and were caused by his pre-existing hydrocephalus and PVL, which were in turn caused by his premature birth. I conclude that Markus' tragic neurological course would likely have been the same had he not been vaccinated on June 7.

These general conclusions, of course, clearly mean that I must reject petitioner's claim. In the interest of full clarity, however, I will proceed, in the following portions of this decision, to deal separately with each of the specific theories of proof raised by petitioner's presentation of evidence in this case.

V

"SEIZURE DISORDER" ISSUES

As noted above, one of the "Table Injuries" asserted by petitioner is "residual seizure disorder." § 300aa-14(a)(I)(D). It is undisputed in this case, of course, that Markus did suffer a seizure disorder. That seizure disorder would constitute a Table Injury under the Program, then, if either the first symptoms of the onset of that disorder, or the first symptoms of a "significant aggravation" of that disorder, took place within the three-day period following Markus' DPT injection on June 7, 1969. § 300aa-11(c)(1)(C)(i). And it is further undisputed that, as Dr. Gale acknowledged at the hearing, Markus likely did suffer seizure activity within that crucial three-day period. Therefore, the initial question becomes whether the seizure activity that Markus displayed on about June 9, 1969, constituted either his first seizures or the first symptoms of a "significant aggravation" of his seizure disorder.

Whether the June 9 seizures were Markus' *first* seizures is certainly subject to question, but on the record here, I cannot conclude that they were. During his neonatal period, Markus had suffered apneic episodes (*i.e.*, cessation of breathing), and, at the evidentiary hearing, Dr. Gale opined that these episodes probably, though not definitely, constituted seizures. (*E.g.*, Tr. 102-03, 135-40.) Dr. Ch'ien was not available to refute this testimony. Petitioner's post-trial brief argues that Dr. Ch'ien's previous testimony (at Tr. 18-19) implies Dr. Ch'ien's view that these episodes were not seizures. However, this certainly not at all clear from that testimony. I find that Dr. Gale's testimony stands essentially unrebutted on this point, so the record supports a conclusion that the June 9 seizures were *not* Markus' *first* seizures.[(9)]

However, the record also supports the conclusion that if the June 9 seizures were not Markus' *first* seizures, then they nevertheless *were* the first manifestation of a *significant aggravation* of Markus' seizure disorder. That is, even assuming that Markus did suffer some seizures during his first few weeks of life, he had not suffered any for months. The new onset of seizures on or about June 9, then, certainly constituted a significant worsening of his seizure disorder, qualifying as a "significant aggravation" of that disorder under the teaching of *Whitecotton v. Secretary of HHS*, 81 F.3d 1099 (Fed. Cir. 1996).

Thus, there *does* exist a "Table Injury" in this case under the "seizure disorder" category, pursuant to the "significant aggravation" analysis. The question becomes, then, whether the respondent has demonstrated that such "significant aggravation" was "due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B). I conclude that respondent has in fact done so, for the reasons set forth at part IV(B) of this Decision. As set forth there, I have concluded that the symptoms that Markus displayed during the three-day period after his DPT vaccination on June 7, 1969, including his seizures, likely were a continuation of the symptoms that he first manifested on June 6, and were caused by his pre-existing hydrocephalus and PVL that were in turn caused by his premature birth. I have concluded that his tragic neurological course would likely have been the same had he not been vaccinated on June 7. In other words, I have concluded that the "significant aggravation" (*i.e.*, significant worsening) of Markus' seizure disorder, the first symptoms of which were manifested during the three-day period after his DPT inoculation on June 7, 1969, was more probably than not "due to factors unrelated to the administrative of the vaccine." Those factors, specifically, were Markus' pre-existing PVL and hydrocephalus.[(10)]

VI

"ENCEPHALOPATHY" ISSUES

As noted above, another of the "Table Injuries" asserted by petitioner is "encephalopathy." It is undisputed in this case that Markus has in fact suffered an encephalopathy.[(11)] (Of course, Drs. Gale and Fitz opine that Markus suffered a *single* encephalopathic process, at around the time of his birth, due to the prematurity, whereas in Dr. Ch'ien's view a *separate* encephalopathic event took place after the DPT inoculation, in which additional damage was done to Markus' brain.) That encephalopathy, then, would be compensable under the Program, if either the first symptoms of the "onset" of that encephalopathy, or the first symptoms of a "significant aggravation" thereof, took place within the three-day period

following Markus' DPT injection on June 7, 1969. § 300aa-11(c)(1)(C)(i).

The initial question becomes, therefore, whether the symptoms that Markus displayed during the three-day post-vaccination period in June of 1969, constituted the first symptoms of *the onset* of an encephalopathy. I conclude that they did not, again for the reasons set forth above at part IV(B) of this Decision. As explained there, I found that Markus suffered the onset of a hypoxic- ischemic encephalopathy at around the time of his birth. More importantly, I was unable to accept Dr. Ch'ien's theory that Markus manifested symptoms of a new, separate brain injury during the three-day period after his June 7 vaccination. Rather, I found that the symptoms displayed during the three-day period were very likely symptoms of the pre-existing encephalopathy that dated back to Markus' birth.

The next question, then, is whether symptoms displayed during the three-day post-vaccination period were the first manifestations of a *significant aggravation* of Markus' encephalopathy. *See Whitecotton*, 81 F.3d 1099. I conclude that they were. My analysis on this point is identical to that stated above, with respect to the issue of a "significant aggravation" of Markus' *seizure disorder*. That is, this case certainly does fulfill the first three steps of the four-part "significant aggravation" test set forth in *Whitecotton*. *Id*. at 1107. Under *Whitecotton's* first three steps, I in effect must determine whether the *current* encephalopathic condition of the vaccine recipient is significantly worse than was that person's condition immediately *prior* to the administration of the vaccination. That is certainly the case here. Then, under *Whitecotton's* fourth step, I must next determine whether the "first symptom or manifestation" of that significant worsening of the condition took place within the Table-prescribed time period. Certainly, in this case, the symptoms that Markus experienced on June 7 through June 9, 1969, were, in fact, the first symptoms of the worsening of Markus' condition that has taken place between the time of his June 7, 1969, vaccination and the present.[(13)] Therefore, Markus' case fulfills the *Whitecotton* criteria for a "significant aggravation" of his encephalopathic condition.

However, the question then becomes whether the respondent has demonstrated that this "significant aggravation" of Markus' encephalopathy was "due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B). I conclude that respondent has in fact done so, for the reasons set forth at part IV(B) of this Decision. As set forth there, I have concluded that the symptoms that Markus displayed during the three-day period after his DPT vaccination on June 7, 1969, very likely were merely a continuation of the symptoms that he first manifested on June 6, and were caused by his pre-existing hydrocephalus and PVL, which were in turn caused by his premature birth. I have concluded that his tragic neurological course would likely have been the same had he not been vaccinated on June 7. In other words, I have concluded that all aspects of Markus' encephalopathy, including the symptoms that were exhibited from June 6 through June 9 and the seizures that were manifested about June 9 were, more probably than not, "due to factors unrelated to the administration of the vaccine." Those factors, specifically, were Markus' pre-existing PVL and hydrocephalus.

VII

"CAUSATION-IN-FACT" ISSUE

As noted above, in addition to the Table Injury categories, "causation-in-fact" is an alternative method of establishing entitlement to a Program award. And, of course, Dr. Ch'ien's testimony in this case, if accepted, would support a showing under that potential avenue of proof. Accordingly, I have also considered whether petitioner has presented a meritorious "causation-in-fact" theory in this case.

It should be noted, initially, that in analyzing a contention of "causation-in-fact," the presumptions available under the Vaccine Injury Table are, of course, inoperative. It is clear that the burden is on the petitioner to show that in fact the vaccination in question more likely than not caused the injury. *Hines v.*

Secretary of Dep't. of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Carter v. Secretary of Dep't. of HHS*, 21 Cl. Ct. 651, 654 (1990); *Strother v. Secretary of Dep't. of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991); *Shaw v. Secretary of Dep't. 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." *Strother*, 21 Cl. Ct. at 370; *accord*, *Hines*, 940 F.2d at 1525; *Carter*, 21 Cl. Ct. at 654; *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). Temporal association alone is *not* sufficient. *Strother*, 21 Cl. Ct. at 370; *Shaw*, 18 Cl. Ct. at 650-651; *Carter*, 21 Cl. Ct. at 654. Moreover, "similarity of petitioner's injury to injuries listed on the Table does not show causation in fact. Encephalitis, seizure disorders, and other Table injuries can have causes other than administration of a vaccine." *Strother*, 21 Cl. Ct. at 370.

It is clear in this case, however, that the petitioner has not been able to carry her burden with respect to "causation-in-fact." Rather, as explained above at part IV(B) of this opinion, Dr. Ch'ien was unable to persuade me that it is likely that Markus' DPT vaccination was the cause of any of his chronic neurological difficulties. To the contrary, Drs. Gale and Fitz convinced me that it is far more likely that Markus' hydrocephalus and PVL, which were in turn caused by his premature birth, were the cause of all of his tragic course.

VIII

CONCLUSION

The story of the neurological course of Markus Ray Goodwin is a tragic one. The record of this Program proceeding, however, simply does not show that a Program award is appropriate in this case. Therefore, I conclude that petitioner is not entitled to a Program award.[(14)]

George L. Hastings, Jr.

Special Master

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

2. Petitioner has filed, at various times, exhibits numbered 1 through 46. Respondent filed designated Exhibits A through F. "Ex. __" references will be to those exhibits. (The lower-case letters after references to petitioner's exhibits denote the specific page within the exhibit.) "Tr." references will be to the pages of the transcript of the evidentiary hearing held on August 19, 1997.

3. It was specifically recorded by one consultant on June 13, 1969, that these symptoms began on June 6. (Ex. 8h.) Further, it was recorded on June 12 that the symptoms began on "Friday last" (Ex. 8c), and a look at a perpetual calendar (see the attachment to this Decision) indicates that the previous Friday was

June 6. Note also that the notation of Dr. Clifford on June 7 of "some spitting" may well indicate that some vomiting--*i.e.*, "spitting up"--had been reported to him. *See also* Exs. 8a, 8g.

4. In addition to Dr. Ch'ien, who testified as petitioner's expert at the hearing, petitioner also filed the written opinions (*see* Ex. 34 as well as an unnumbered affidavit filed on March 26, 1993) of Dr. Montouris, a neurologist who has treated Markus. However, while petitioner was offered the opportunity to present oral testimony from Dr. Montouris, petitioner ultimately elected not to do so. Thus, although I have given consideration to Dr. Montouris' written opinion, because she was not available to *explain* her views, and because I found the explanations of Drs. Gale and Fitz for the respondent to be persuasive, I was not able to accord much weight to Dr. Montouris' opinion.

It may also be noted that early in the course of the proceeding, petitioner supplied by "fax," in conjunction with a status conference, a brief opinion by Dr. Roger Morrell. However, soon thereafter petitioner elected not to utilize Dr. Morrell, and his opinion was never formally filed in the case. Moreover, based upon my experience with Dr. Morrell on other Program cases, I do not consider Dr. Morrell to be an honest witness and I would accord no weight to his opinion in any event.

5. Those affidavits appear at Exs. 15, 32, and 33. They describe certain symptoms--*e.g.*, the crying, screaming, and drooling--that are not reflected in the contemporaneous medical records, but I have assumed that those affidavits reflect generally accurate histories of Markus' symptoms.

6. It may be noted that Dr. Ch'ien absented himself from the evidentiary hearing before Dr. Gale's testimony, and thus was simply unavailable to refute many of Dr. Gale's points. This was unfortunate, but it should be noted that I allowed the parties to establish the date and time of the hearing by their own agreement, and petitioner simply never sought to present any rebuttal testimony after the presentations of Drs. Gale and Fitz. In addition, many of Dr. Gale's points were outlined prior to the hearing in his extensive written reports, and thus could have been addressed in Dr. Ch'ien's direct testimony. Moreover, as a full review of this Decision will demonstrate, the ultimate dispositive point in this case is the respondent's argument that the PVL and hydrocephalus resulting from prematurity constitute "factors unrelated" fully accounting for Markus' injury. This argument was clearly set forth in the respondent's written reports filed prior to the hearing. Dr. Ch'ien in fact did attempt to refute that argument in his hearing testimony, but was simply unpersuasive in that attempt.

7. The name of the doctor appears possibly to be "W. Garrett," but is in fact not terribly clear.

8. *See, e.g.*, Dorland's Illustrated Medical Dictionary (27th ed. 1988), p. 1104.

9. I note also that even assuming the June 9 seizures were Markus' *first* seizures, and that therefore he suffered the first symptoms of the *onset* of his seizure disorder (rather than an aggravation of that disorder) within the Table time frame, nevertheless petitioner's case would still fail, because respondent has carried the burden of demonstrating that Markus' condition was "due to factors unrelated to the administration of the vaccine."

10. I also note that the PVL and hydrocephalus are *not* "idiopathic, unexplained, unknown, hypothetical, or undocumentable" factors. See § 300aa-13(a)(2)(A). Rather, we *do* know the cause of those two conditions--namely, Markus' premature birth.

11. The statute encompassing the Program provides, in effect, its own definition of the term "encephalopathy," at § 300aa-14(b)(3)(A). That definition is as follows:

The term "encephalopathy" means any significant 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 6 hours in 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 unconsolable 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.

This statutory section, then--particularly, its first sentence-- provides an extremely broad definition of the term "encephalopathy," being satisfied essentially whenever the brain has a significant "abnormality" or an "impairment of function."(12)

12. For purposes of this case, I leave aside discussion of the statutory requirement that the abnormality or impairment of function be an "acquired" one. See, *e.g., Devlin v. Secretary of HHS*, No. 90-1533V, slip op. at pp. 9-10 (Fed. Cl. Spec. Mstr. March 17, 1993), 1993 WL 566059.

13. Of course, in fact Markus exhibited the first signs of a *major* turn for the worse in his encephalopathy on *June 6, 1969*, one day *prior* to his DPT inoculation here in question. The symptoms exhibited on June 7-9, as I have stressed, were likely merely a continuation of the symptoms exhibited on June 6. However, under *Whitecotton*, as I understand it, the first inquiry here is simply whether Markus' encephalopathic condition is worse today than it was at the moment prior to the inoculation in question. That is so. The second inquiry, then, *ignoring* any *prevaccination* symptoms, concerns the occurrence of the first symptoms of the worsening that took place *between the time of the inoculation and the present*. Thus, in this case, the symptoms that Markus displayed on June 7-9, although likely merely the continuation of symptoms that began on June 6, must be considered under *Whitecotton* as the first symptoms of the worsening of Markus' condition that occurred between the time of the inoculation and the present.

14. I do note that, despite the petitioner's ultimate lack of success on this claim, I find that this case was brought "in good faith" and upon a "reasonable basis." Accordingly, petitioner 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.