OFFICE OF SPECIAL MASTERS

No. 91-1594V

(Filed: May 2, 2000)

LORI BARTON, Parent and Next Friend of DUSTIN L. BARTON	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Robert T. Moxley, Cheyenne, Wyoming for Petitioner.

Michael P. Milmoe, with whom also was Elizabeth Kroop, U.S. Department of Justice, Washington, D.C., for Respondent.

French, Special Master.

DECISION

This case arises under 42 U.S.C. §300aa-et seq., the National Vaccine Injury Compensation Act. Petitioner, Lori Barton, filed her case on November 18, 1991 on behalf of her son, Dustin L. Barton, alleging that as the result of an adverse reaction to a DPT vaccination, administered on January 18, 1989, Dustin sustained vaccine related injuries, namely, a residual seizure disorder and other related neurological deficits. Further, Petitioner claims that Dustin's sudden death, during a violent seizure, was causally related to his DPT vaccination.

Respondent defends on two grounds. Respondent argues that the facts claimed are

not documented in contemporaneous medical records. And further, that Dustin's neurological condition and death, more likely than not, were due to periventricular leukomalacia (hereinafter, PVL), a factor unrelated to the vaccine.

PROCEDURAL HISTORY

Two evidentiary hearings were held. The first, confined to factual matters only, was held on September 28 and 29, 1993 in Albuquerque, New Mexico. At the close of the September hearing, the court found that Petitioner had established the requisite factual basis for her claim. The court was satisfied that the neurological injury was set forth in the Vaccine Injury Table and that the symptoms occurred within the requisite time frame specified for an on-Table case. The court's findings are set forth in a bench ruling on pages 461-471 of the Transcript of Proceedings of September 28 and 29, 1993 (hereinafter Tr. I__). The court directed the parties to proceed to the next phase, the presentation of expert opinion. The hearing of experts was hampered by many delays, but finally held in Albuquerque, New Mexico, on August 7, 1997. Petitioner presented the testimony of Dr. Marcel Kinsbourne, a pediatric neurologist, and the testimony of Dr. Roy D. Strand, a neuroradiologist. Respondent presented the expert testimony of Dr. Rita Lee, a pediatric neurologist. Post-hearing proceedings for closing arguments were scheduled, but on October 25, 1997, before closing arguments could be heard, Dustin died unexpectedly as the result of a seizure. [1] The postmortem examination concluded that the cause of death was related to his seizure disorder.

Whereas Petitioner's claim had been pursued as an on-Table injury, the fact of Dustin's death required a different method of proof. Death in and of itself does not qualify as a Table injury and Petitioner is required to establish, by a preponderance of the evidence, that death was a sequela of a prior vaccine-injury. The claim was converted to a death case.

This case met with agonizing delays. The parties had difficulties in obtaining the required expert reports and critical autopsy materials, including slides of the brain, needed for expert analysis. In March of 1999, Mister Milmoe was substituted as counsel for Respondent. Respondent sought and was granted several extensions of time to enable a complete review of the evidence. In the meantime, Petitioner filed motions for summary

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[1] Prior to March 10, 1995, Residual Seizure Disorder was included as a Table injury. Statutory and regulatory amendments removed Residual Seizure Disorder from the Table for all cases filed after March 10, 1995. This case was filed prior to the effective date of the amendments and is not subject to the revisions.

judgment, and further delays, caused by ensuing motion practice, handicapped the progress of this case.

On August 4, 1999, with Respondent's new attorney at the helm, Respondent requested yet another hearing. Respondent argued that because the issue of death had not been addressed as a sequela of the alleged vaccine injury, the court should allow an additional evidentiary hearing to address the cause of death. Petitioner argued that the Medical Examiner had attributed the cause of death to the seizure disorder, an on-Table injury, and that the case had been already unduly and unfairly prolonged, a complaint to which the court was sympathetic. In consideration of the outrageous delays in this case and in consequence of Mrs. Barton's own tragic and imminent illness, the court was disinclined to add further delays. The court is not required by law to grant a hearing for every request, (§12 (d)(2)(D)). The court denied Respondent's request for a formal hearing and ordered, instead, written opinions, a simpler and more expeditious procedure allowed by the Vaccine Act. Id.

The court agreed to permit Respondent to seek additional information from pathologists as to whether Dustin's death, presumed to have been the result of an on-Table seizure disorder, might possibly have been due, instead to PVL. Respondent engaged three pathologists as rebuttal witnesses, Dr. Lucy Rorke, Dr. Marcus Nashelsky, and Dr. Mario Kornfeld. Respondent submitted also a supplemental opinion statement from Dr. Rita Lee, Respondent's pediatric neurologist, who testified at the hearing of experts. A total of five supplemental reports were filed for the record. (Dr. Rorke submitted two.) Petitioner relied upon the oral testimony of her expert, Dr. Kinsbourne, and on the record as it then stood.

Concluding that the record now contained sufficient evidence on which to determine the merits of the claim, the court closed the record and informed the parties that a decision would be forthcoming based on the record unless the parties could find grounds for a settlement agreement. Efforts to negotiate failed. On February 10, 2000, the court filed its Decision in favor of Petitioner, finding that Respondent had failed to establish a factor unrelated to the vaccine, and that although PVL may have contributed to the ultimate outcome, the evidence was more convincing that the vaccine was its predominant cause. Two days before the deadline for appeal, Respondent filed a Motion to Reconsider.

MOTION TO RECONSIDER

Respondent's Motion to Reconsider, filed on March 8, 2000, argued that the supplemental evidence filed by Drs. Rorke, Nashelsky, and Kornfeld, constituted new evidence, and that denial of an adversarial hearing was an abuse of the court's discretion.

Petitioner objected, arguing that the issues had been fairly framed and that further hearings would unfairly and unnecessarily prolong this case. Valid grounds existed to support both positions. Although Respondent argued otherwise, the supplemental evidence, in fact, was not "new" evidence but constituted evidence that had been in existence and was fully available for analysis at the evidentiary hearing. Respondent had been provided ample time and leeway to be apprised of the issues. The supplemental evidence supplied by the experts contained, unfortunately, merely conclusory statements without explanation or analysis that would convince the court that the PVL was responsible for Dustin's clinical course and death. For example, the joint report of the pathologists Nashelsky and Kornfeld, although they had both been involved with the autopsy itself, merely restated their conclusion that the PVL was the more likely cause. Moreover, they acknowledged that they could not rule out the possibility of a vaccine-related cause. Their evidence, therefore, was unconvincing and legally inadequate. Dr. Lee, in like manner, added nothing that had not been addressed in the evidentiary hearing, and merely reaffirmed her original position bolstered now by Drs. Nashelsky and Kornfeld's conclusion statement. Only Dr. Rorke offered further details.

Dr. Lucy B. Rorke, provided a scholarly, detailed list of autopsy findings; she failed to explain their significance. In other words, the so-called "new" evidence provided general conclusions only without basis, without applying the details to Dustin's clinical presentation, and without explanation sufficient to warrant adoption of Respondent's theory of causation. Dr. Rorke rejected consideration of Petitioner's factual claims, making her own credibility call as to whether the court should accept the eyewitness account of the onset of symptoms. Her opinion statement appeared less objective than the court would have preferred. The evidence, in short, was found wanting. Respondent's motion to reconsider amounted to a request for "another bite of the apple."

One factor, however, led the court to accede to Respondent's request. Apparently, the severity of PVL, varies considerably. Petitioner's expert, Dr. Kinsbourne, had testified that Justin's PVL appeared to be mild based the following factors: No signs or symptoms were observed prior to the administration of the vaccine; no evidence existed to suspect that the child's PVL was extensive or severe; PVL is not expected to cause a sudden onset of seizures at age six months; PVL rarely causes seizures unless the lesions are severe and extensive; and that if spasticity is confined to the lower extremities, as was true in Dustin's case, and does not affect materially the upper extremities, it is more likely than not that the injured will not display cognitive delays. Respondent's expert, Dr. Lee, admitted that PVL does not inevitably cause severe sequelae in all cases. [2] For these reasons, Dr. Kinsbourne

[2] Dr. Lee stated that "one thing that is really quite predictive is the extent of the child's spasticity, so that if only the legs are involved, you have a very good chance of having normal or near normal intelligence." Tr. II at 110.

is convinced that the vaccine, not the PVL was the more likely cause of Dustin's seizure disorder and his death. His opinion was based on the sudden acquisition of symptoms that would be inconsistent with the expected outcome of Dustin's mild PVL.

In an abundance of caution, and in all fairness, the court recognized, as Respondent pointed out, that Dr. Kinsbourne had not addressed directly the details which Dr. Rorke set forth in her supplemental statement. Respondent argued that Dr. Kinsbourne should be offered the opportunity to reconsider his position, if appropriate, as to the significance of those findings and to consider their possible effect, if any, on the outcome of Dustin's injuries. On March 9,2000, the court withdrew its earlier Decision and having heard from all of Respondent's experts on the subject, the court requested further testimony from Petitioner's expert addressing the role of PVL in Dustin's death. At the court's direction, Dr. Kinsbourne submitted his response. He found no evidence that would change his opinion. His reasoning will be set forth hereafter. In consequence, the court now considers the evidence sufficiently complete and ripe for decision.

STATUTORY REQUIREMENTS

The statutory scheme for vaccine cases brought under 42 U.S.C.§300aa provides that if a petitioner establishes that the onset of an injury set forth in the Vaccine Injury Table found in §14 of the Act, or that the first symptom or manifestation of a significant aggravation of an underlying condition was sustained within the prescribed time frame (in the case of a DPT vaccination, 72 hours), causation can be presumed. Respondent thereafter may rebut that presumption by establishing that the injury, more likely than not, was due to a factor or factors unrelated to the vaccine. §13 of the statute provides, however, that the phrase "factors unrelated to the administration of the vaccine"--

> (A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and
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> (B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

Death, in and of itself, does not constitute a Table injury, and may not be presumed to be the result of the administration of a vaccine simply because it occurred within the statutory time frame for the injury. Case law provides that death must be shown to be causally related to a prior Table injury.

FACTS

At this point, the court will present the factual basis for what has proved to be a complicated case. A preponderance of the evidence leads the court to find that the following sequence of events is an accurate and reliable description of the facts.

Dustin was born on July 14, 1988, five and one-half weeks premature, and suffered some of the effects common to prematurity. There were, however, no observed abnormalities. Petitioner's Exhibit (hereinafter P.Ex) A at 15. He was discharged three days later without medication and with this notation: "Baby breathing easily, no respiratory] distress or other [symptoms]. Feeding well." P.Ex. C at 15. The first four visits to his doctor were unremarkable. P.Ex. B at 1-4. In spite of his five-and-one-half week-prematurity, no evidence of neurologic abnormality was identified during the first two months of life. The foregoing facts are not challenged.

The contemporaneous medical records, however, do not document the subsequent events surrounding the onset of post-vaccinal symptoms claimed by the eyewitness accounts. Respondent, therefore, challenges the following alleged facts.

The court considered carefully Respondent's arguments that the court must give superior weight to the medical records when they differ from the oral testimony. In this particular case, the court concludes that the eyewitness accounts constitute a more accurate description of events. The oral testimony was highly credible, more reliable, and is supported by external evidence sufficient to convince the court of its accuracy. The following facts are so found. The court's reasoning for finding credibility will be set forth as well.

The medical records in this case were significantly incomplete. The medical records did not contradict the oral testimony, but were simply lacking in relevant details caused, in part, by the failure of the treating physician to consider as significant the concerns that the child's care givers, related to him. Dr. Marek, Dustin's treating pediatrician, dismissed their concerns and failed to document them. He believed Dustin's mother was overreacting, and Dustin's symptoms following his vaccination reaction were never recorded.[3] Mrs. Barton testified that the pediatrician considered her to be a "hysterical mother." Not until another doctor observed the child and diagnosed a seizure disorder did the pediatrician recognize the child's symptoms as serious. After the Bartons got a second doctor's opinion, the ensuing medical records begin to acknowledge Dustin's strange movements as something other than "startles," or "chills," or merely "a habit" into which

[3] A few months later,however, a consulting doctor recorded a medical history that corroborates the events and symptoms claimed.

the infant had fallen. (These were the doctor's explanations for these movements). In fairness to the doctor, Dr. Marek filed a letter dated September 10, 1991, acknowledging Petitioner's claims that they had, in fact, notified him of their concerns but that he did not document them in his records. The following is their account. To repeat, the court finds that the events occurred in the manner and at the times described.

The first DPT shot was administered on September 15, 1988, when Dustin was two months old. The second DPT shot was given on November 16 at age four months. The medical records for November 1988 state that Dustin had no reaction following his first two sets of immunizations. That statement is refuted by the evidence in later records. After the first shot, Dustin exhibited extended bouts of inconsolable, excessive, severe, and prolonged screaming that persisted for hours -- specifically, through the entire first night. He seemed to recover, however, and his development appeared to be unimpaired. The second shot, given at the November 16, 1988 checkup, was followed by a reaction similar to the one described after the firstshot, including low grade fever with high- pitched, totally inconsolable screaming bouts that lasted for many hours followed by other bouts of intermittent screaming that continued for weeks. On both occasions, after shot number one and shot number two, the doctor was informed by telephone, but he dismissed the reactions as normal, reassuring the family that the crying was merely colic. He did not observe the child at this time.

On January 18, 1989, at six months of age, after concluding that Dustin was a "well child," the doctor ordered the administration of the third DPT vaccination although his mother and grandmother questioned the wisdom of subjecting the child to what they feared might be a third adverse reaction. At this visit, Dr. Marek noted that Dustin was beginning to hold up his head with some regularity. Within 24 hours of his third DPT shot, Dustin developed again a low grade fever, but this time he demonstrated additional, more ominous neurological signs including reduced responsiveness, loss of milestones, loss of head control, slowed development, and an abrupt and dramatic change in personality. His legs became stiffened although his head was notably floppy.[4] He no longer looked at things, most typically staring off into space and squinting his eyes. It became apparent that whereas prior to his shot there was evidence that he was tracking and following, after the shot, he was no longer seeing. He no longer watched the revolutions of a ceiling fan or grabbed at his play gym, or had direct eye contact.[5] A family friend testified that one day he was "ok"; and the next day (after the third shot) he was not! Transcript of hearing of

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[4] His mother stated that his legs, in fact, were hard to bend.

[5] It is not possible to determine whether the child's vision was 100% normal prior to the third DPT shot, but the evidence supports a finding that he was seeing prior to January 18, 1989, and that he stopped seeing immediately after the shot.

September 28 and 29, 1993 (hereinafter Tr. I) at 267.

The infant began also to demonstrate sudden manifestations of recurring repetitive movements described by his mother and grandmother as brief "shudders" that continued to increase in frequency and severity. The treating physician did not see these incidents, dismissing them as probably "chills" due to low grade fever, and when they did not stop, the doctor characterized the incidents as a "habit" the infant had developed. As stated earlier, when another doctor finally observed the incidents, he diagnosed them as seizure activity.[6] Within a few weeks other neurological signs became apparent. The medical records document "drifting of the right eye" and "mildly delayed gross motor functioning." Dr. Richard Marek provided a letter, in preparation for hearing, confirming that Lori Barton did in fact communicate her concerns about the pertussis vaccine as the possible cause of seizure activity, and that he agreed to eliminate the pertussis component of the DPT shot in subsequent vaccinations. Letter of Dr. Marek of September 10, 1991.

September 28-29, 1993 Bench Ruling

Following the September 28-29 hearing, the court placed on the record its bench ruling finding that Dustin had sustained an on-Table injury and that onset had occurred within the statutory time frame. Because the medical records did not record certain events surrounding the onset of symptoms, the court set forth its reasoning in the bench ruling that included a comprehensive discussion of credibility issues. The court reaffirms its bench ruling found on pages 461 through 471 of the Transcript of proceedings of September 28-29, 1993, and hereby adopts that ruling in its entirety. The following paragraphs may be somewhat duplicative, but will summarize the court's findings.

The court found the eyewitness testimony to be not only credible, but also compelling. Other eyewitnesses were called to testify who corroborated the factual claims. Minor failures of recall were apparent but only as to a few non-essential details. The

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[6]Two and one-half years later, supporting documentation of the on-Table onset of seizures appears in a medical report of an evaluation by Dr. Jon Aase: "First seizure ('shuddering') at 6 months." P.Ex. I at 1. Respondent argues that one cannot characterize "shudders" as "seizures" because the original treating physician did not identify them as such. Petitioner's expert argues, to the contrary, that one can assume the diagnosis of seizure activity to be accurate based on their persistence. The seizure activity did not abate, but continued to occur and worsened. Respondent counters that even if they were seizures, they were probably related to the PVL rather than the DPT. A preponderance of evidence leads the court to find that the initial shudders, mis-diagnosed by the treating physician as "chills" or merely "a habit," in fact constituted seizures.

discrepancies were minor and did not impeach the reliability of the basic narration of relevant facts. [7]

PVL

Following the third DPT shot, on July 13, 1989 and again on December 14, 1989 respectively, Dustin was admitted for MRI tests during which it was discovered that he displayed the typical findings of periventricular leukomalacia. Dr. Roy Strand, a neuroradiologist, explains that PVL is frequently found in subjects who were born as premature infants, and represents injury to the developing brain that results in loss of white matter volume and is associated with thinning of the posterior half of the corpus callosum.[8] Dr. Strand's Expert Report of June 10, 1996. Dr. Kinsbourne testified that it is

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[7] It is the prerogative of the court to assess credibility. In relevant part, the oral testimony was consistent and altogether credible. Respondent placed unwarranted significance in the fact that certain details were incorrectly stated in Petitioner's initial affidavit. It is not unusual for an affidavit, prepared in haste as was necessary in this case in order to meet the deadline for filing, to be corrected and clarified by sworn oral testimony. The discrepancies were satisfactorily explained, and the oral testimony was forthright and well supported.

The testimony of an office associate, Mr. Smith, carried considerable weight. Mr. Smith testified that he overheard telephone conversations that corroborate Mrs. Barton's testimony. He recalls also his own discussions with Mrs. Barton, and was fully aware of the severe problems the infant was experiencing during the times when the medical records themselves remained silent. He stated that Mrs. Barton had a reputation for honesty and had an excellent memory. She was known as "a walking dictionary." She had memorized telephone numbers and departmental codes, a factor that was considered a useful tool to her office-mates.

Mrs. Schindwulf, a neighbor, was another fully credible witness as to facts. Mrs. Schindwulf conducted her testimony in an admirable manner in the face of grueling (and perhaps excessive) cross examination. She refused to deviate from what she claimed that she had vividly and clearly observed.

[8] The corpus callosum is described as an arched mass of white matter of the brain composed of transverse fibers connecting the cerebral hemispheres. Dorland's Pocket Medical Dictionary, 24th ed., at 145. Neither party considers the finding of a thinned corpus collosum as a cause of the child's condition. According to a learned textbook, "The extent of malformation of the corpus collosum varies from partial to complete agenesis. .

(continued...)

in the nature of PVL that it takes origin usually before birth, sometimes during birth, and occasionally soon after birth. Transcript of Proceedings of August 7, 1997 (hereinafter, Tr. II at) at 19. Dustin's PVL had remained subclinical, that is, without manifestations, until it was discovered by the MRI tests. An ophthalmologic examination revealed also "hypoplasia" (under development) of the optic nerve. A single notation in the medical records suggested that the problem may have been optic nerve "atrophy." A majority of the evidence, however suggests that hypoplasia is the more accurate diagnosis. The distinctions between "hypoplasia" and "atrophy" are of interest in this case because their processes or etiologies differ. Hypoplasia indicates a failure of the brain to develop, whereas atrophy is a wasting away.[9] In other words, one is more likely the result of a congenital failure to develop adequately; the other is the result of an acquired insult. Hypoplasia is consistent with the PVL findings.

THE ISSUES

Both experts agree that Dustin had a neurological condition prior to his third DPT shot. The diagnosis of periventricular leukomalacia, or PVL, was not discovered until MRI testing was undertaken several weeks after the January 18, 1991 DPT shot. According to the experts, we know what it is, but we cannot know for certain what caused it. It is believed that in most cases, PVL is probably congenital, [10] and frequently is observed in subjects born prematurely. The most common lasting effect is spastic diplegia, a motor dysfunction of the lower extremities. Dustin's condition, indeed, affected his lower limbs. If the PVL is severe or extensive, the spasticity may affect the upper extremities as well. Dustin did not have spastic upper limbs. Tr. II at 60.

After the third DPT shot, Dustin sustained the onset of a seizure disorder and other

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[8](...continued)
. . Absence of the corpus callosum alone may be accompanied by very mild or subtle clinical manifestations. [Citation omitted]. Normal intelligence is not unusual. It can occur in about 1 to 3 infants per 1000 births." Swainman, Kenneth, Pediatric Neurology: Principles and Practice, 2nd ed. at 440, 441 (1994).

[9]The two descriptions, optical "hypoplasia" as opposed to optical "atrophy" suggest differing processes. The difference is subtle; atrophy involves a wasting away, and hypoplasia is incomplete development of an organ or tissue. Dorland's Pocket Medical Dictionary, 24th ed., at 67, 295.

[10]Dr. Kinsbourne adds: "To be totally accurate, I should say that in a premature child the mechanism of PVL probably includes the first few days of newborn life. So it's during delivery and the early neonatal period." Tr. II at 41.

neurological dysfunctions including motor deficits (cerebral palsy) as discussed heretofore, and other dysfunctions that, according to Petitioner's expert, would not be attributable to the PVL, namely, mental retardation and severe seizures. He was also declared legally blind whereas he had been seeing prior to the vaccination. Petitioner maintains that these conditions were due to additional injuries caused by the third DPT shot. In response to counsel's questioning, Respondent's expert, Dr. Lee, agreed that a child having PVL would not be immune to injury from DPT. Tr. II at 152. Respondent argues conversely, that all injuries could be attributed to the preexisting PVL.

ANALYSIS OF RESPONDENT'S EVIDENCE

Testimony of Dr. Rita Lee:

Dr. Lee, for Respondent, presented a thorough and rational argument that Dustin's present condition could be fully explained by the existence of PVL. Because PVL is frequently found in cases of prematurity, it is her opinion that Dustin had a high risk for suffering the same deficits even without the administration of the DPT vaccine. She acknowledges, however, that the outcome of PVL varies and is not the same in every PVL case. Tr. II at 116. Dr. Lee's opinion in Dustin's case, according to her testimony, relies in part upon a theory of statistical probabilities. Dr. Lee believes that the risk of a PVL etiology is much greater than the relative statistical risk of a vaccine-related etiology which is far more rare. Tr. II at 167. This argument has been offered in a number of vaccine cases and has been rejected by the courts as insufficient to establish a factor unrelated. Knudsen v. Secretary of HHS, 35 F.3d 543 (Fed. Cir. 1994)(In considering "factor unrelated" proof, the trier of fact erred in relying upon statistical evidence that virally-caused encephalopathies are more common than DPT related encephalopathies). Dr. Lee invokes the so-called "unity" theory that it is obviously more economical to implicate a common, expected cause [PVL], than a rare and exceedingly unlikely one [a vaccine injury]. The Knudsen court rejected this theory of proof as well; (in considering "factor unrelated" proof, the special master erred in relying upon the "unity theory" of diagnosis -- i.e., the theory that one should lean toward the diagnosis that takes into account all symptoms). Dr. Lee acknowledges that one simply cannot be sure one way or the other [which is the more likely cause]-- PVL or vaccine reaction.

Opinion statement of Drs. Marcus Nashelsky and Mario Kornfeld:

As discussed earlier, Dr. Nashelsky, Assistant Professor of Pathology / Medical Investigator, and Dr. Kornfeld, Professor of Pathology at the University of New Mexico Office of the Medical Investigator in Albuquerque, New Mexico, provided a joint letter of opinion based on Dustin's autopsy findings. The neuropathology examination, performed by Dr. Kornfeld, confirmed the diagnosis of PVL, a manifestation of a perinatal injury

"such as hypoxia." Respondent's Ex. P. The remainder of the autopsy, performed by Dr. Nashelsky, was essentially unremarkable. Drs. Nashelsky and Kornfeld stated that they could not exclude the possibility that the DPT immunization caused or contributed to the development of the seizure disorder, but they felt that the seizure disorder was most likely the result of PVL. Id. They did not elaborate.

Opinion statements of Lucy B. Rorke, M.D. :

Dr. Lucy Rorke is board certified in Anatomic Pathology and Neuropathology. Dr. Rorke concurs with a diagnosis of PVL and states that the seizure disorder could have been caused by the white matter injury as could also the degeneration of the optic nerves. She considers the possibility of a DPT reaction "patently absurd." Respondent's Ex. L at 4. She insists that "the literature contains no specific central nervous system lesion that bears a cause and effect relationship to DPT." Id. It is not clear whether Dr. Rorke is addressing her view of the potential reactogenic properties of the DPT vaccine, or whether she is arguing that the DPT reaction cannot be attributed to the PVL signs and symptoms. The import of her statement is unclear. If the latter is her intent, the experts do not disagree. Petitioner does not claim that the DPT caused the PVL. Petitioner argues that the DPT superimposed other injuries in addition to the spastic diplegia the parties agree that Dustin's spastic dyplegia is attributable to the PVL). Because seizures have been documented in children with the type of white matter damage found in Dustin's brain, Dr. Rorke believes that the PVL could be responsible for Dustin's seizures. Her opinion takes a further leap:

> Therefore, it can be stated with certainty that the DPT vaccine administered to this child at 6 months of age played absolutely no role in causing either one of these morphological abnormalities of the seizure disorder. . . . [and] no evidence to support the conclusion that the presumed terminal seizure had a cause and effect relationship with administration of DPT on 1/18/89.

Supplemental Report of Dr. Rorke filed May 20, 1999.

Unlike Drs. Nashelsky and Kornfeld, the other experts upon whom Respondent relies, Dr. Rorke is unwilling to consider even the plausibility of a vaccine-related event in her zeal to propound its "absurdity." Nor does she address the abrupt onset of a new set of symptoms following the administration of the vaccine but dismisses them out of hand. This court finds her conclusions poorly supported, tenuous, and speculative. Her discussion of lesions does not explain their effects or their etiologies. In part, Dr. Rorke challenges improperly the credibility of the fact witnesses. That responsibility, of course, remains within the prerogative of the court who is in a better position to address credibility. I have carefully considered her arguments and find them incomplete, unclear,

and less persuasive. Her testimony, at best, suggests only that a PVL causation is theoretically possible, not probable.

ANALYSIS OF PETITIONER'S EVIDENCE

Testimony of Dr. Marcel Kinsbourne:

Dr. Kinsbourne, testifying for Petitioner, argues that Dustin clearly sustained an encephalopathic injury as a result of the third DPT shot that significantly aggravated his preexisting condition. He does not believe that the Table injury aggravated the PVL but argues that the Table injury added additional neurological impairment. Tr. II at 31. He bases his opinion, first, on the following clinical observations: The infant was developing and making progress in spite of notable adverse reactions to the first two DPT shots. However, immediately following the third shot, an abrupt change was observed in the infant's condition and behavior; he would lie immobile in his crib, legs rigid, he lost head control, demonstrated reduced levels of responsiveness, failed to react to his toys, was no longer seeing, and suffered the onset of seizure activity, the first ever. All of these symptoms occurred within hours of the shot, and the child was never again the same. His seizure disorder did not resolve, but became intractable. These factors, Dr. Kinsbourne argues, are not typical of sudden manifestations of PVL, but constitute evidence of an additional injury, an acute encephalopathic event with permanent neurological sequelae.

Dr. Kinsbourne states further, that no conclusive evidence can be identified to suggest that the infant's development was slow prior to the third vaccination. A slowing, however, even if one could so interpret the medical records, would not be surprising in a premature infant. The fact is, however, that Dustin sustained a sudden and abrupt change for the worse immediately after the shot. The sudden onset of his seizure disorder resulted also in a significant worsening of cognitive powers.[11] Dr. Kinsbourne insists that PVL does not cause an abrupt change suddenly at six months. Moreover, Dustin's mental retardation was significantly worse after the encephalopathic event whereas one usually expects only mild retardation in PVL cases.

Although he had been seeing prior to the January 18, 1989 vaccination, it is not clear whether the child had normal vision at that time. But a loss of eye contact and failure to track and follow -- palpable changes for the worst -- were observed immediately after the event; he no longer looked at his parents, nor looked at the revolving ceiling fan, nor laughed at his toy. These factors confirm the loss of discernable visual function and must

[11] Respondent's expert, Dr. Lee, argues that if damage of a PVL nature is very extensive, seizures might occur. Tr. II at 199. Dr. Kinsbourne, points out, however, that no evidence exists to establish that the child's PVL was extensive. Tr.II at 23,26.

be attributed to the encephalopathy, not because of damage to the eyeball, according to Dr. Kinsbourne, but because the encephalopathy damaged the brain centers that process the information being transferred to the brain through the nerve tract, affecting the visual evoked response. Dr. Kinsbourne explains that communication between the eyeball and the brain was apparently open, but the brain's ability to process the information, the brain's receiving areas, were damaged by the vaccine. In other words, although optic nerve hypoplasia was probably present before the third DPT shot, he nonetheless had demonstrated discernable visual function in terms of following people and objects around in space. That ability was lost apparently as part of the vaccine injury. "So it is my opinion," states Dr. Kinsbourne, "that the visual functioning became abruptly worse in table time." Tr. II at 27-28.

One may speculate that Dustin's PVL could have caused certain aspects of his dysfunctions, most notably, his spastic diplegia which is typical of the kind of signs or symptoms seen in PVL in premature children; but not all of his symptoms were typical of PVL. For example, Dr. Kinsbourne points out: "In the typical PVL case, there will be no mental retardation, or only borderline problems in intellect." Tr. II at 75. "In the majority of cases of PVL, seizures are not a feature." Tr. II at 24-25.[12] It is his opinion that the severity of Dustin's retardation is attributable to the table injury. To repeat: "We would not normally expect a child with PVL to be severely mentally retarded. " Id. at 30. Moreover, no evidence of seizures was observed until after the vaccination. So with respect to seizures, "this is a new event." Id. With respect to his general neurological condition, this child's condition was truly aggravated, and he was significantly worse off than he had been before the event. Id.

Testimony of Dr. Roy Strand :

Dr. Roy Strand's evidence is confined primarily to a confirmation of the diagnosis of a preexisting PVL. His testimony supports Dr. Kinsbourne's opinion. Dr. Strand, a pediatric neuroradiologist, presented a written report and was thereafter called upon to testify in person for the purpose of cross examination. Dr. Strand's report was dated April 5, 1996 and, by letter to Petitioner's counsel states: "This testimony is intended to supplement the report of [Dr.] Marcel Kinsbourne of December 3, 1995." Tr. II at 87. Dr. Strand testified that the symptoms of PVL were compatible with a single prenatal or perinatal injury, explaining that such injury "was not a single incident like something that's happened in a minute or so, but a . . . continuous event that has a long duration rather than a traumatic event." Tr. II at 85. During cross examination, Dr. Strand stated that after reviewing Dr. Kinsbourne's opinion, there was nothing in his own findings that in any way

[12]Respondent's expert, Dr. Lee, acknowledged that fewer than one-third of PVL patients develop epilepsy. Tr. II at 122.

would cast doubt on Dr. Kinsbourne's opinion. Id. at 89. Dr. Strand stated that Dr. Kinsbourne's argument that further injury was sustained following the DPT shot includes a clinical opinion that goes beyond what the neuroradiologist can tell from MRI imaging but that he has no findings that would contradict that opinion. Id. at 90.

Dr. Marcel Kinsbourne's Supplementary Report:

Dr. Kinsbourne's initial opinion statement took into consideration the Coroner's findings on Dustin Barton. As discussed earlier, the court requested Dr. Kinsbourne's comments on the additional findings cited by Dr. Rorke as they they apply to the question of PVL as a probable cause of seizures and Dustin's death. Dr. Kinsbourne concluded that nothing material was presented that had not been available and addressed at the evidentiary hearing. Three findings, according to Dr. Kinsbourne, should be addressed specifically. He states: Neither the "early thalamic damage," cited as significant by Dr. Rorke, nor "the caudate lesion," nor the "optic chiasm abnormality," add anything material to the issues. These findings simply do not help to explain the abrupt cognitive worsening of Dustin's condition, or clarify the clinical picture, or explain the worsening of his vision in Table time. In other words, the abnormalities listed in Dr. Rorke's report, he argues, provide no explanation or alternative causation factors for the onset of the residual seizure disorder. He insists again, that the white matter injury is not a recognized cause of seizures. He acknowledges that the abnormality in the parietal cortex can be a risk factor for seizures, but "does not guarantee a seizure disorder, and [more importantly] it cannot address the timing of Dustin's Table injury."

CONCLUSIONS

Respondent has been able to suggest the possibility that PVL "could" have caused or contributed to the child's injury, but the evidence falls far short of establishing, by the required standard of proof, that it did in fact do so. On the contrary, a preponderance of evidence indicates that the level of severity of Dustin's preexisting condition was not extensive enough to cause the additional neurological damage that had its onset within hours of the DPT vaccination. Dustin's spastic diplegia, addmittedly is probably attributed to the PVL.

A preponderance of evidence leads the court to conclude that the onset of post-vaccinal seizures within Table time, the explosive nature of the injury, and the deficits that followed, constitute clear evidence of a vaccine-related encephalopathic event that led, ultimately to Dustin's death. Respondent's evidence of a PVL related cause of death is speculative and inconsistent with the facts and clinical course of this particular case. Dr. Kinsbourne's theory of causation offers a more likely explanation. Dustin's condition immediately following the third DPT shot was considerably worse than his pre-vaccination

condition, and never improved. Respondent's allegation that PVL explains the entire clinical course, including death, although hypothetically possible, is inadequately supported by the evidence. Unfortunately, as is well known, a DPT injury leaves no footprints, a factor that is one of the major difficulties in prosecuting vaccine injury cases and, a DPT reaction is generally diagnosed by its clinical course, as in this case. That brain dysfunction often cannot be identified by MRI, is acknowledged as well. Dr. Lee confirms: "a child can have terrible functional problems and not see it on MRI." Tr. II at 78. Dr. Kinsbourne stated similarly, "Many severely damaged encephalopathic children have normal MRIs." Id. at 80.

Irrespective of the fact that Dustin had a preexisting condition identified as PVL, due probably to immaturity, the court finds that it was the vaccination administered on January 18, 1989, that caused or triggered his seizure disorder and significantly aggravated his neurological condition. (This court finds no rational distinction between "caused" and "triggered.") As Dr. Lee admits, a child with PVL is not immune to injury from DPT. Tr. II at 152. Respondent has failed to establish a factor unrelated that meets the statutory guidelines set forth in §13(a)(2). On the other hand, Petitioner has demonstrated that the event fits the classic picture of a DPT reaction, and the Death Certificate rightly ascribes the "immediate cause (final condition or disease resulting in death)" to a seizure disorder. The court ascribes the death of Dustin Bartin to the vaccine-related injury.[13]

Having so concluded, the court finds that Petitioner is entitled to the statutory amount provided by law to compensate for Dustin's tragic injury and death in the amount of $250,000.[14]

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[13] A recent decision addressed similar issues with a different outcome. In Tersen v. Secretary of HHS, No. 99-341V, (CFC Spec. Mstr. Apr. 27,2000)the Special Master found that petitioners had failed to establish an on-Table significant aggravation of a preexisting condition that included PVL among a number of other severe problems. The instant case is distinguishable. The evidence in Tersen, unlike the case of Dustin Barton, established the presence of severe prematurity and a newborn with considerable evidence of neurological symptoms prior to vaccination including the existence of significantly severe and extensive PVL. The undersigned does not disagree with the Tersen court's findings or conclusions. In contrast, the infant in Barton was only minimally premature, demonstrated a mild and relatively benign level of PVL with no manifestations of neurological problems during the first two months of life,and merits this court's conclusion that his vaccine injuries caused additional permanent harm to his brain and that death could not be attributed primarily to his PVL.

[14] In the event that a reviewing Judge would disagree with the court's findings and

(continued...)

Absent a Motion for Review filed pursuant to CFC Appendix J, The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

E. LaVon French
Special Master

[14](...continued)
conclusions, it is my opinion that Petitioner would still prevail under an alternative theory of causation set forth in Shyface v. Secretary of HHS. The Shyface court held that in a case in which it is not clear which of two causes was the primary cause of injury or death, or if concurrent causes of injury or death exist, the requirements of the Vaccine Act are met prima facie upon a showing that the DPT vaccine "was both a but-for cause of and a substantial factor" in the death of the injured individual. The undersigned is convinced that the evidence is sufficient to satisfy the Shyface criteria and that Petitioners would still prevail. Shyface v. Secretary of HHS, 165 F.3d 1344 (Fed Cir. 1999).