OFFICE OF SPECIAL MASTERS

No. 02-1766V

(Filed: Date November 26, 2003)

SCOTT and JENNIFER KINCAID, on behalf of their minor daughter, LAUREN KINCAID,	*	
Petitioner(s),	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Stephen E. Haynes, Dallas, TX, for petitioners.
David L. Terzian, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Petitioners filed a petition on December 2, 2002 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that their daughter Lauren Kincaid (hereinafter, "Lauren") suffered an on-Table encephalopathy after receiving acellular DPT vaccine. At the hearing on October 21, 2003, petitioners added the allegation of causation-in-fact encephalopathy.

Testifying for petitioners were Lauren's parents, Jennifer and Scott Kincaid, Dr. John D. Dunn, and Dr. Steven Bauserman. Testifying for respondent were Dr. John MacDonald and Dr. Lucy B. Rorke.

FACTS

Lauren was born on September 5, 1999. The nuchal cord had been wrapped around her twice. Med. recs. at 2. She had cerebral anoxia at birth and, after MMR vaccine on September 5, 2000, she had a febrile seizure six days later. Med. recs. at 1, 8, 70, 92. Mr. Kincaid had epilepsy as a child, but was not placed on medication and had not had seizures since childhood. Med. recs. at 12. Lauren's temperature after MMR had reached 104° and she was hospitalized for fever and lethargy on September 11, 2000. Med. recs. at 92, 109.

At her 15th month check-up on December 5, 2000, Lauren received hepatitis B, DPaT, and HiB vaccines. Med. recs. at 79. She was prescribed Motrin and Tylenol for teething and it was noted that she did not say a lot of words. Id. She had a three- to six-word vocabulary, spoke jargon, walked alone, climbed, used a spoon, found hidden objects, held and drank from a cup, fed herself with her fingers, followed simple commands, and scribbled spontaneously. Id. Her head circumference was 49.5 cm., which put her in the 95th percentile. Her weight was 23 pounds, 8.8 ounces, which put her in the 65th percentile. Her height was 32 inches, which put her in the 88th percentile. Id. The record noted that Lauren looked great. Id.

Lauren appeared normal during the evening of December 5, 2000 and the day of December 6, 2000. On December 6, 2000, she was put to bed at 7:00 p.m., but awakened with a whining cry at 11:00 p.m. Her parents gave her Motrin for teething. When they returned to Lauren's crib at 8:00 a.m. on December 7, 2000, they found her blue and unresponsive. Med. recs. at 62. Paramedics pronounced her dead at the scene. Id.

Dr. Nizam S. Peerwani performed the autopsy on December 7, 2000, at 12:45 p.m. Med. recs. at 70. He wrote she had a sudden death with acute, global, severe bilateral pulmonary vascular congestion, with acute cerebral edema. Id. Her brain weighed 1268 grams presenting severe congestion of the leptomeninges. The cerebral hemispheres revealed a normal gyral pattern with moderate to severe global edema. The brainstem and cerebelli showed similar changes with moderate, bilateral tonsillar notching. Med. recs. at 73. One section each of the cerebral cortex, brainstem, and cerebellum revealed prominent congestion. Med. recs. at 75.

Other Submissions

Because respondent asserted that Lauren had suffocated, the undersigned issued an Order dated October 2, 2003 for Dr. Peerwani, the pathologist, to answer whether, during his examination of Lauren during the autopsy, he had checked to see if she had suffocated and, if so, what was his conclusion. On October 14, 2003, petitioners filed Exhibit 15, a letter dated October 7, 2003 from Dr. Peerwani. He stated:

> Suffocation produces death by asphyxia. Etymologically, the word "asphyxia" means "absence of pulsation," although in common usage it implies "lack of oxygen." Suffocation may be produced by smothering, where the facial orifices including the mouth and nostrils are closed by a mattress or pillow by a steady force. The objective findings in such a death may be florid or sparse depending upon the resistance offered by the victim, and may include contusions or abrasions of protruding facial structures including the forehead, nose, etc. accompanied by injuries of mucosal surfaces of the mouth due to compression of these surfaces on teeth. There may also be facial congestion and cyanosis, petechial (pinpoint) hemorrhage of face, surfaces of the eyes and eyelids (bulbar and palpebral conjunctivae). Smothering may also be produced by applying a plastic bag over the head, in which case, there are no significant anatomical findings. Hence absence of anatomic findings cannot rule out the possibility of smothering. Suffocation on the other hand may be produced by bedding items occluding external airways, including nostril and mouth. Large number of infants and children sleep face down and although this is considered a risk factor in Sudden Infant

> Death Syndrome, for infant[s] one month to 12 months of age, it is not so for older children.
> In summary, there are no objective forensic findings to suggest that the death of Laurens [sic] M. Kincaid is due to suffocation.

Initially, the reports of medical investigators stated that Lauren had died from a seizure and also suffocated under her crib bumper pads, depending on which report one read. P. Ex. 11, pp. 1, 5, 8, 12. Presumably, medical investigator John W. Looper with the Tarrant County Medical Examiner's Office was the source of the information that death was due to accidental suffocation from the crib bumper pads. P. Ex. 11, pp. 8, 11.

Petitioners filed an affidavit from John Looper, dated October 6, 2003, that he saw Lauren lying face up on the floor inside the front door of her residence, and not in her crib when he arrived at the scene and that he does not recall ever telling anyone that Lauren had crawled under her crib bumper pad and suffocated. He states he does not know what the cause of Lauren's death is and he does not know if she was up against her bumper pad nor does he recall anyone telling him this. His own report does not indicate she was found against the bumper pads in her crib. He states that in 38 years of experience investigating deaths, he does not ever recall investigating a death where it was ultimately determined that a child of Lauren's age and size suffocated against a bumper pad of a crib. P. Ex. 19, pp. 1 and 2.

In his Investigators Report attached to his affidavit, John Looper writes that Mrs. Kincaid discovered Lauren at 8:00 that morning lying face down on the bed with her face against the left-hand corner of the bed. Mrs. Kincaid removed Lauren from the bed and took her into the living room where she was when investigator Looper arrived. P. Ex. 19, p. 4.

On October 20, 2003, respondent filed Exhibit J, an excerpt from Adverse Effects of Pertussis and Rubella Vaccines, Institute of Medicine (IOM) (1991), pp. 88-91, which includes the following statements, at 88, 89:

> The clinical presentation, natural course, and pathology of encephalopathy following the natural occurrence of pertussis are relevant to the discussion of encephalopathy following pertussis immunization. ...
> Findings are generally nonspecific and include brain edema.... "Toxic effects and anoxemia due to circulatory stasis can account for most of the anatomical findings.... " [citing an author who wrote the most comprehensive review in the English-language literature.]

Because respondent's expert pediatric neurologist Dr. MacDonald raised for the first time at the hearing the issue of whether Lauren had cerebral edema because her head was macrocephalic, the undersigned gave petitioners the opportunity to supplement the record after the hearing from either or both their expert witnesses. Petitioners submitted Exhibit 20, the affidavit of Dr. Bauserman, dated October 22, 2003.

Dr. Bauserman states that the fact that Lauren was macrocephalic with a head circumference of 49.5 centimeters at 15 months of age cannot explain her brain weight at death of 1268 grams. He believes her brain weight at death was greater than 20% above normal because her expected brain weight would be in the upper range of 1,000 grams. "There is significant variation in skull thicknesses and configurations which render the head circumference unreliable in predicting brain weight...." Paragraph 2 of Affidavit. In addition, Dr. Bauserman states that macrocephaly does not necessarily mean a large brain since thick skull bones alone may explain a larger circumference.

Referring to Dr. Rorke's testimony that in order for someone to die of cerebral edema, he or she must have brainstem edema or herniation, Dr. Bauserman disagreed in part. He has personally

seen deaths apparently resulting from cerebral edema without grossly significant brainstem edema or documented evidence of herniation.

Respondent requested and received permission to respond to Dr. Bauserman's affidavit. On October 24, 2003, respondent filed Exhibits K, L, and M. Exhibit K is Dr. Rorke's response to Dr. Bauserman's affidavit. She states that a table of organ weights that she uses gives a mean brain weight of 1064 grams for a child with a head circumference of 49 cm. She finds skull thickness irrelevant. In cases involving cerebral edema which is not the cause of death, there would not necessarily be evidence of herniation.

Respondent's Exhibit L is Dr. MacDonald's response to Dr. Bauserman's affidavit. He states that Lauren's head size at death at the age of 15 months was the same as the average head size for a four-year-old girl. Because she was macrocephalic, her brain weight would be expected to be 1243 gms, and, therefore, her actual brain weight at death of 1268 gms is within the normal range.

Respondent's Exhibit M is an excerpt referred to during the hearing from The Diagnosis of Stupor and Coma by F. Plum and J.B. Posner at page 48 referring to tonsillar herniation: "Variations in the normal degree of grooving make it difficult to interpret cerebellar impaction of tonsillar herniation at the autopsy table unless changes are extensive."

TESTIMONY

Scott Kincaid, Lauren's father, testified first. Tr. at 13. He stated that Lauren seemed fussy and irritable at around the time of her DPT vaccination, but she had four teeth coming in and he and his wife assumed her symptoms were due to teething. Tr. at 17. He and his wife went to Lauren's room when they heard her crying at 11:00 p.m. Tr. at 18. It was unusual for Lauren not to sleep through the

night. Id. They felt her to be warm and gave her Motrin. Tr. at 19. Lauren seemed lethargic to him, which he ascribed to her being tired. Tr. at 20. She did not sit up or stand up in her crib when they entered, as she ordinarily would have, and they kept the light off in her room in the hope of her returning to sleep. Tr. at 19.

On December 7, 2000, Mr. Kincaid was eating breakfast at 7:30 a.m. and Lauren still had not risen, which was unusual for her. Tr. at 20. Mrs. Kincaid slept until 8:00 a.m. and went into the kitchen to yell at her husband for letting her sleep late when they had an appointment to go to the Gymboree. Tr. at 21. They thought it odd that Lauren had not stirred, went to her crib, and found her dead. Mr. Kincaid said that Lauren's forehead and nose were down on the mattress, her behind was up, and she was on her knees. Id. This was a position he had seen her in before. Tr. at 30. He testified that Lauren's mouth was not on the mattress. The angle of her back prevented her mouth from completely touching the mattress. Tr. at 313. The mattress did not seal all of Lauren's air passages. Id.

When Mrs. Kincaid, who was pregnant with twins, lifted Lauren out of the crib, they saw that Lauren had a purple spot in the middle of her forehead and her fingers were blue. Tr. at 23. She was wearing Carter's pajamas, but without any attachment for the feet. Tr. at 28. There was no pillow or toy in the bed and the blanket was underneath and beside Lauren. Tr. at 21. She was not under her bumper pad, and she was not wedged into any corner of the mattress. Tr. at 23, 24. Mr. Kincaid stated, in answer to a later question about macrocephaly or large head size, that he, his father, and his brother all have large heads. Tr. at 181.

Mrs. Jennifer Kincaid testified next. Tr. at 36. Her testimony was consistent with her husband's. Nothing was obstructing Lauren's face or mouth when she picked her up. Tr. at 47.

Dr. John D. Dunn, board-certified in family practice and emergency medicine, testified next for petitioners. Tr. at 52. He is the medical director of the emergency department at Brownwood Regional Center and the local health director of the Brownwood Health Department. He is also an emergency physician at Darnall Army Community Hospital. Id. He is in charge of vaccinations for the county. Tr. at 82.

He stated that an acute encephalopathy can lead to death and is invariably the final mechanism for death. Tr. at 55. Usually tonsillar notching is a preterminal event. Tr. at 56. Someone with tonsillar notching and cerebral edema will have an increased intracranial pressure. Tr. at 57. The amount of cerebral edema in this case was severe. Id. If someone has severe cerebral edema and tonsillar notching, he or she would also have a significantly decreased level of consciousness. Tr. at 58. A patient with cerebellar notching is severely obtunded and preterminal in almost all clinical situations. Tr. at 59. If one did not try to arouse the patient, only someone well-versed in medical science would know the difference between someone with a significantly decreased level of consciousness and someone who was asleep. Id. Someone who had tonsillar notching and severe cerebral edema would gradually lose the ability to breathe, experience hypoxia, and eventually anoxia. Tr. at 60.

Lauren's cerebral edema is irrefutable evidence that she had an encephalopathy. Tr. at 63. The encephalopathy caused her death. Tr. at 64. A toxic immune process created swelling of her brain cells and tissue, increasing the intracranial pressure and ultimately causing enough pressure on her vital brainstem centers to cause them to malfunction so that she stopped breathing. Tr. at 65. Cerebral

edema is not characteristic of death by suffocation unless the patient has suffered a sub- or pre-lethal asphyxiation and then is revived for a period of time long enough for cerebral edema to develop. Tr. at 68. The hypoxia here occurred as a result of the encephalopathy rather than as a cause of it. Tr. at 69. You would have to have an absolute seal of the nose and mouth to cause suffocation, and a blanket or bumper pad will not suffice. Tr. at 71-72. A person's unconscious reflexes keep him or her breathing when he or she is asleep. Tr. at 71, 77.

Dr. Dunn's opinion is that Lauren did not die from suffocation because a child even at the age of two months can move her face if her airways are blocked. Tr. at 72. Lauren died because her brain swelled to the point where she did not have the reflexes to keep breathing. Tr. at 73, 77-78. An increase in intracranial pressure causes tonsillar notching so that the brain is starting to herniate through the foramen magnum, which is the hole in the skull at the bottom where the brain has to go when the pressure increases too much inside the skull. Tr. at 95-96.

He opined that Lauren had an encephalopathy which affected her ability to respond normally and resulted in a significantly decreased level of consciousness, such that she did not move her head to be able to breathe. Tr. at 73. First came the encephalopathy and then the hypoxia. Tr. at 69. Concomitant with tonsillar notching and cerebral edema is increased intracranial pressure resulting in her death. Tr. at 95. Dr. Dunn charged nothing for his testimony, and believes that this is the type of case Congress intended to be compensated under the Vaccine Program. Tr. at 86.

Dr. Steven Bauserman, board-certified in neuropathology and anatomic and clinical pathology, testified next for petitioners. Tr. at 103, 104. He practices anatomic clinical pathology and neuropathology. Tr. at 104. He has about 30 years experience as a neuropathologist. Id. He has

done 10,000 autopsies. Tr. at 122. He opined that Lauren had an encephalopathy which affected her ability to move her head and breathe normally, resulting in a significantly decreased level of consciousness. Tr. at 116, 122, 125, 136. Lauren's brain was swollen 20 percent above normal. Tr. at 118, 123. Her cerebral edema and tonsillar notching must have been accompanied by an increase in intracranial pressure which resulted in her death. Tr. at 106, 107, 108, 113, 114, 115, 128. Lauren was not mechanically obstructed in her airways that her environment would have promoted hypoxemia and she did not have physical signs of suffocation such as petechiae in the eyes and on the membranes of the lungs and heart. Tr. at 109, 125. Her degree of brain swelling, which he considers very significant, was quite compatible with causing death. Tr. at 121, 122, 129. He has seen many cases in which there is cerebellar swelling but no brainstem swelling, yet the patient dies an encephalopathic type of death. Tr. at 129.

Testifying first for respondent was Dr. John MacDonald, a board-certified pediatric neurologist. Tr. at 139. He has testified for respondent for 11 years, and including vaccine and other cases, has been involved in 200 cases. Tr. at 164-66. Ten percent of his income is derived from his participating as an expert witness. Tr. at 166. Dr. MacDonald testified that there was not a clinically-diagnosable acute encephalopathy in this case because the records do not note any clinical signs. Tr. at 142, 151, 167. He said that acute encephalopathy is a clinical diagnosis, and because nothing in the records he reviewed showed symptoms such as an altered mental state, he does not think Lauren had acute encephalopathy. Tr. at 143.

He opined that Lauren died from SIDS or a SIDS-like illness (SIDS-like because SIDS generally occurs to children six months and younger). Tr. at 153, 155, 159, 160. He also thought she

did not have cerebral edema (and thus no increased intracranial pressure) because her head size was macrocephalic. Tr. at 147-48. He thought her tonsillar notching could be a normal variant. Tr. at 149-50, 151.

Dr. MacDonald on cross-examination stated he does not dispute Dr. Peerwani's pathological findings of cerebral edema and tonsillar notching. Tr. at 169, 196. There is not a whole lot of room in any of our brains for much brain swelling. Tr. at 174. There probably was some edema here. Tr. at 182. He agreed that if Lauren had tonsillar notching due to cerebral edema, she would also have increased intracranial pressure. Tr. at 184. He denied that increased intracranial pressure was a clinical sign even though the Vaccine Act states that it is. Tr. at 185, 186, 187, 189. But, when the statute was read to him, he stated that one would have to measure the intracranial pressure with monitors in order to make it a clinical sign. Tr. at 191-92. Even if someone were monitored and did have increased intracranial pressure, he would not conclude there was an encephalopathy without clinical signs. Tr. at 195.

Dr. MacDonald concluded that he did not know why Lauren died. Tr. at 204. He cannot say that it is more likely than not that she died from suffocation. Tr. at 206. He would expect ordinarily that a 15-month-old would move if she were in a situation where her breathing was compromised. Id. If she had an abnormal level of consciousness, she might be limited in her ability to extricate herself, and if there were a significant encephalopathy, Dr. MacDonald would expect she would be limited in protecting her airway and would not be able to move around successfully. Tr. at 206-07. He thinks Lauren had hypoxia first but for some unknown reason, and then encephalopathy secondary to it. Tr. at 207-09. He put the encephalopathy second and not first because the medical and other notes do not

record clinical signs. Tr. at 210. You would suspect that a child is not normal if a 15-month-old did not turn her head or move if she had a problem breathing while lying on a mattress. Tr. at 212. He would suspect something most likely was abnormal in her brain. Tr. at 213. SIDS is not a typical diagnosis for a child over the age of one year. Tr. at 214. He agreed that at Lauren's terminal event, she would have had a significantly decreased level of consciousness. Tr. at 157.

Dr. Lucy B. Rorke, a neuropathologist, testified next for respondent. Tr. at 218. She is board-certified in anatomical pathology and neuropathology. Tr. at 218-19. She is senior neuropathologist at Children's Hospital and the neuropathologist for the Philadelphia Office of thte Medical Examiner. Tr. at 219. She has been practicing pediatric neuropathology since 1962. Tr. at 220. She does not believe that either whole-cell or acellular pertussis vaccine causes encephalopathy. Tr. at 269-70. In her 45 years of experience, she has never seen a child whose death resulted from vaccination. Tr. at 271. She has never seen a morphological counterpart to vaccine encephalopathy. Tr. at 276.

Dr. Rorke's opinion is that Lauren suffocated because of the position in which the Kincaids found her in her crib. The purple spot on her forehead indicates she had been in the face-down position for a considerable period of time, at least a half-hour or an hour. Tr. at 222-23. Her lungs together weighed 235 grams but should have weighed only 130 grams, indicating a marked increase. Lauren died with acute severe pulmonary edema, meaning a significant compromise of her cardiac function, impeding the circulation in her body and indicating a failing heart. Tr. at 224. Her spleen and liver were significantly congested. Her brain weighed 1268 grams, whereas normal should have been 1000 to 1100 grams. She had severe congestion of the leptomeninges, meaning that her blood vessels

in the subarachnoid space were markedly congested due to interference, similar to the problems in the lungs and other organs. Tr. at 225-26.

She faults Dr. Peerwani for not completing his description of Lauren's brain to include the size of the gyri, the sulci, and the unci on the undersurface of the brain, and the appearance of the perihippocampal gyrus. Tr. at 226-28. He does not describe the size of the ventricular system. Tr. at 228. That Dr. Peerwani describes the ventricular system as symmetrical and containing clear cerebral spinal fluid suggests to Dr. Rorke that the cerebral edema did not compromise it and was not clinically significant. Tr. at 228-29.

Dr. Rorke stated that Lauren's cerebral edema was not significant enough to have caused her death. Tr. at 230. She rejects that Lauren had an increase in intracranial pressure. Tr. at 231. There is no evidence of a severe cerebellar pressure cone from herniation due to intracranial pressure. There is no brain swelling. Id. Lauren died because she did not get enough oxygen to her heart and brain, her heart failed, and her circulation slowed, leading to severe congestion and mild cerebral edema and moderate tonsillar notching. Tr. at 232.

Dr. Rorke does not use the word "encephalopathy" as a neuropathologist. Tr. at 233. She always uses a descriptive adjective before saying encephalopathy, e.g., anoxic encephalopathy. Id. Lauren had a moderate cerebellar pressure cone and meningeal congestion. Tr. at 235. Dr. Rorke attributes Lauren's suffocation to positional asyphyxia. She thinks the mattress sealed her nose and her mouth. Tr. at 238, 239. She thinks the cyanosis developed in ten to fifteen minutes, but that the dying process lasted a few hours because of severe congestion to the vital organs. Tr. at 241. Dr. Rorke thinks that Lauren could have had a hypoxic condition or a partial asphyxia which caused coma, but she

may have been getting some oxygen because her air passages were not completely obstructed. Tr. at 242.

She considers SIDS to be a diagnosis of the desperate. Tr. at 248. No pathologist would ever diagnose Lauren with SIDS because she has too much pathology–severe visceral congestion, severe cyanosis. Tr. at 248. In no way would Lauren fit into the category of SIDS. Tr. at 249. She neither accepts nor denies that Lauren had cerebral edema because Dr. Peerwani's description was insufficient. Tr. at 252. Her opinion then is that the hypoxia caused Lauren's brain and heart to fail, leading to her death. Tr. at 254.

Dr. Rorke admitted on cross-examination that Lauren might not have waked up if her brain was not functioning properly. Tr. at 265. We do not know why Lauren did not extricate herself from her sleeping position. Tr. at 266. She does not diagnose encephalopathy because it is a clinical diagnosis. Tr. at 272. Lauren may have had some mild cerebral edema. Tr. at 279. She died from respiratory failure. Tr. at 284.

DISCUSSION

Petitioners have the burden of proving an on-Table encephalopathy.[1] Petitioners allege that Lauren had the Table injury of acute encephalopathy within Table time (72 hours) of receiving acellular

[1] The undersigned finds that the evidence of a causation-in-fact encephalopathy is too weak in this case to satisfy petitioners' burden. The symptoms of fussiness, low temperature, and lethargy are so generic as to be equally attributable to the vaccination as to teething. The undersigned has previously held, inter alia, that acellular DPT caused encephalopathy leading to death. Williams v. Secretary of HHS, No. 00-123V, 2002 WL 1488750, *12-13 (Fed. Cl. Spec. Mstr. June 20, 2002).

pertussis vaccine. If their allegation is successful, they benefit from the statutory presumption of causation. 42 U.S.C. § 300aa-14, as modified by 42 CFR § 100.3(b)(2)(i)(A), states:

> For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. ....

Section 100.3(b)(2)(i)(C) states:

> Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

Section 100.3(b)(2)(i)(D) states:

> A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater....:
>
> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
> (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
> (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

One must note that the Federal Circuit in Jay v. Secretary of HHS, 998 F.2d 979, 983 (Fed. Cir. 1993), held, "We can find nothing in the Vaccine Act which precludes death from being used as evidence of a table injury, here encephalopathy." The Federal Circuit then cites 42 U.S.C. § 300aa-14(b)(3)(A) (referring to a change in consciousness over the requisite period of hours [then six, but now twenty-four]), stating, "There is no more profound and permanent change in level of consciousness than death." Id. at 983 n.6. However, there were more signs and symptoms than death in Jay: inconsolability, prolonged screaming for six hours, limpness, difficulty arousing, and blueness about the lips. Id. at 980. The child's death was attributed at autopsy to SIDS. Relying on the statutory denigration of unusual crying, anorexia, and limpness as symptoms of acute encephalopathy, the special

master dismissed on a summary judgment motion. After remand, the dismissal was upheld until the Federal Circuit reversed and held for the petitioners, stating "The special master, losing sight of the forest for the trees, ignored entirely the fact of [the child's] death." Id. at 983.

Thus, according to the Federal Circuit, the special master must consider the fact of death together with the other evidence in an on-Table encephalopathy case. In the instant action, there is not only the death, but the significantly decreased level of consciousness which preceded Lauren's failure to move her head from the mattress. There is also the intracranial pressure which Drs. Dunn and Bauserman testified is concomitant with moderate to severe cerebral edema and tonsillar herniation.

Obviously, no one saw Lauren have a significantly decreased level of consciousness because she died in the middle of the night. But this does not prevent a holding in favor of petitioners because there is evidence that, had she been observed by appropriately knowledgeable observers, she would have been discovered to have a significantly decreased level of consciousness. Anyone who is honest would recognize that Lauren was going through a condition that attacked her brain as well as her other vital organs. The testimony of Drs. Dunn and Bauserman that together with her severe brain edema and tonsillar notching was increased intracranial pressure, all of which would have produced a significantly decreased level of consciousness, is persuasive to the undersigned. Dr. Dunn's vast experience in the practical field of dealing with children in both vaccination and emergency situations plus his forthright manner were especially convincing, and Dr. Bauserman's contribution that a large head does not negate cerebral edema, and that brainstem herniation or edema are not essential for cerebral edema to lead to death is also very helpful.

In Williams v. Secretary of HHS, No. 00123V, 2002 WL 1488750 (Fed. Cl. Spec. Mstr. June 20, 2002), the undersigned ruled in another encephalopathy-death case, in which the only clinical sign was fever, that the fact that the child died in the middle of the night did not preclude a finding that he had, inter alia, an on-Table encephalopathy. The undersigned stated, at *12:

> Surely, when Congress enacted the Vaccine Act and the Secretary of the Department of Health and Human Services promulgated the recent regulations, the intent behind the descriptions of a Table encephalopathy w[as] of an awake vaccinee whom others observed. It would be ludicrous to assume that Congress (and the Secretary) envisioned compensation only for encephalopathies in those fortunate enough to survive them, whom others observed, but not for those who succumbed to them at night when they were not observed

The undersigned assumes that no one would be absurd enough to suggest that if a vaccinee has a Table encephalopathy, but dies before the 24 hours required under the new regulations, that therefore petitioners should not prevail. Previously, in Williams, supra, and in Sword v. Secretary of HHS, No. 90-1491, 1998 WL 957201 (Fed. Cl. Spec. Mstr. Dec. 29, 1998), aff'd, 44 Fed. Cl. 183 (1999), both cases in which the babies died before the statutory time requirements of 24 hours and 6 hours, respectively, the undersigned held that petitioners had prevailed in proving on-Table encephalopathies.

The undersigned rules that petitioners have satisfied the requirements for proving an on-Table encephalopathy occurring within 72 hours of Lauren's acellular DPT vaccination because of the following: (1) moderate to severe edema; (2) tonsillar notching; (3) credible testimony that the first two factors were connected to an increase in intracranial pressure; (4) hypoxia leading to death as a result of her encephalopathy.

Under the Federal Circuit's decision in Whitecotton v. Shalala, 81 F.3d 1099, 1107 (Fed. Cir. 1996), the burden now shifts to respondent to show by a causation-in-fact standard of proof that a

known factor unrelated to vaccination caused Lauren's encephalopathy. Respondent must provide "proof of a logical sequence of cause and effect" showing that a known factor unrelated was the cause in fact of Lauren's encephalopathy. Cf. Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Respondent's known factor is that Lauren's mattress suffocated her because of her position on it.

Respondent's expert Dr. Rorke testified that Lauren's encephalopathy and death were due to suffocation because her forehead and nose were down on her mattress, she had a purple spot in the middle of her forehead, and her fingers were blue, indicating she had been in that position a long time. The undersigned finds implausible that suffocation is the primary cause of Lauren's encephalopathy for two reasons. First, the undersigned asked Mr. Kincaid if, when he found Lauren, her mouth was covered by the mattress. He answered no. Secondly, it seems physically impossible for the mattress to cover both Lauren's nose and mouth. Dr. Dunn testified for petitioners that the only way to suffocate someone is to seal completely the airway passages. Moreover, if her brain had been working properly, Lauren would have moved her head if she were having trouble breathing. That she did not move her head means that something was already wrong with her brain, the opinion not only of Dr. Dunn, but also of Dr. Bauserman and Dr. MacDonald (respondent's expert pediatric neurologist). Except for Dr. Rorke, who most definitely is biased against finding any encephalopathic death due to DPT vaccine because she does not believe it happens, all the experts were unanimous that Lauren should have been able to move her head if her brain were working properly. This establishes, most notably in Dr. Dunn's testimony, that Lauren's encephalopathy preceded any hypoxia she experienced, rather than the other way around–that a lack of oxygen caused her encephalopathy.

As for Dr. MacDonald's opining at the hearing (but not before) that he did not think Lauren had much cerebral edema, if any, because she was macrocephalic, her brain weight of 1268 grams at autopsy was, according to Dr. Bauserman, 20% above normal and Dr. Rorke agreed that she did have cerebral edema (although she waffled on the issue) and that her large brain was familial in origin since her father, grandfather, and uncle all have large brains. Her pediatrician put her head size in the 95th percentile. The undersigned sees no reason to accept Dr. MacDonald's theory that she really did not have cerebral edema.

Dr. MacDonald's report to the court dated August 5, 2003 (before the hearing) describes Lauren's significantly decreased level of consciousness neatly in these sentences (although, at trial, Dr. MacDonald insisted that unless someone sees encephalopathic signs, no one can diagnose an acute encephalopathy):

> ... I think a child of this age would ordinarily be able to extricate herself from being trapped at the edge of the bed such that suffocation would not occur unless the child was in an altered mental state that impaired the motor abilities, ...

Respondent filed Exhibit J, an excerpt from the Institute of Medicine's discussion of whooping cough (pertussis) encephalopathy in Adverse Effects of Pertussis and Rubella Vaccines (1991), at 89:

> Findings are generally nonspecific and include brain edema.... Certainly the effects of anoxemia (used synonymously with asphyxia or hypoxia or hypoxic-ischemic encephalopathy) have been well described in both preclinical and human investigations.

The IOM states that the clinical presentation, natural course, and pathology of encephalopathy following wild pertussis are relevant in the discussion of encephalopathy following pertussis vaccination.

They also say that nonspecific findings on pathology include brain edema. Moreover, citing the most comprehensive review in English-language literature, the IOM notes that toxic effects and anoxemia (reduction of oxygen content of the blood below physiologic levels)[2] due to circulatory stasis can account for most of the anatomical findings. That dovetails quite well with what happened to Lauren. Thus, respondent's own evidence shows that Lauren fits into the pathologic description of a pertussis-vaccine encephalopathy which includes brain edema, hypoxia, and circulatory stasis.

This is the situation that tragically we find here. Lauren received her acellular DPT and, within 72 hours, had a moderate to severe cerebral edema, bilateral tonsillar notching, hypoxia, and congestion of her brain and visceral organs, leading to death. As she was kneeling on her mattress, a position she had had numerous times before without ill effect, she experienced a significantly decreased level of consciousness, and died in that position, producing the purple spot on her forehead, and cyanosis in her fingers. Dr. Dunn testified that this is the kind of case Congress envisioned when it passed the Vaccine Act. The undersigned agrees.

The undersigned must commend Mr. and Mrs. Kincaid for their forthright testimony about their terrible ordeal, Dr. Dunn's open manner and candid opinion, and Dr. Bauserman's contribution to the undersigned's understanding of this case. Even respondent's Dr. MacDonald recognized before the hearing in his report discussed supra that something had to have been wrong with Lauren's brain (an "altered mental state") for her not to move from her position on the mattress although at trial he retreated from his report because no one had seen her in an altered mental state.

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[2] Dorland's Illustrated Medical Dictionary, 27th ed.(1988) at 94.

The undersigned holds that when someone dies in the middle of the night, and there is sufficient evidence to show that the person had an acute encephalopathy (e.g., credible medical interpretation of pathologic findings and the failure to move in order to breathe, showing an altered mental state), the mere fact that the contemporary records do not show clinical symptoms of a significantly decreased level of consciousness does not defeat petitioners' case.

The Vaccine Act states, "Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group." Petitioners' doctors stated that Lauren's cerebral edema and tonsillar notching were accompanied by increased intracranial pressure, and respondent's Dr. MacDonald agreed this would be consistent, although he read into the statutory language the requirement that there be a pressure monitor showing increased intracranial pressure. The undersigned does not agree. Where credible testimony such as Dr. Dunn's and Dr. Bauserman's links cerebral edema and tonsillar notching to increased intracranial pressure, that is sufficient to persuade the undersigned even without a pressure monitor.

Moreover, even if the undersigned agreed with respondent's Dr. MacDonald that hypoxia came first and then encephalopathy, and with respondent's Dr. Rorke that hypoxia led to cerebral edema as well as heart failure, the undersigned still does not accept Dr. Rorke's hypothesis that the suffocation came from Lauren's mattress. The undersigned finds Dr. Dunn's testimony more credible that in order for Lauren to have suffocated, her nose and mouth must have been sealed, and the mattress could not do that. In addition, she had the ability to move around, if her reflexes had been working properly. Respondent's burden is to show that a known factor unrelated caused her Table injury and death and, as Dr. MacDonald testified, he does not know what caused her hypoxia. But

assuming, arguendo, that Dr. MacDonald were correct that Lauren had hypoxia first for some unknown reason, respondent would not be able to satisfy his burden of showing that a known factor unrelated to the vaccine caused Lauren's encephalopathy and death. 42 C.F.R. § 100.3(b)(2)(iii) states:

> If ... it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

Thus, even assuming, arguendo, that respondent's experts are correct that hypoxia preceded encephalopathy (instead of the other way around, as the undersigned has found), petitioners would still prevail because the undersigned would agree with Dr. MacDonald that the cause of the lack of oxygen is unknown and the lack of oxygen was integral to the acute encephalopathy (Dr. MacDonald described it as a vicious circle, inextricably linked). The undersigned would not agree with Dr. Rorke that the mattress suffocated Lauren. Respondent would thus fail to satisfy his burden of showing that a known factor unrelated to the vaccine caused Lauren's Table encephalopathy. As for SIDS, beyond Dr. Rorke's pithy observation that it is a diagnosis of the desperate, legally, it is not a known factor unrelated to the vaccine,[3] and, moreover, Dr. Rorke's testimony that Lauren's pathological picture does not justify a diagnosis of SIDS is more credible than Dr. MacDonald's opinion on the matter.

Dr. Rorke went to great lengths to denigrate the pathological examination Dr. Peerwani did, but the fact is he was there at the autopsy, he did look for suffocation and, as he explained in his report dated October 7, 2003, he did not find any "objective forensic findings to suggest" that Lauren's death was due to suffocation. His analysis, Dr. Dunn's and Dr. Bauserman's testimony, and the testimony of

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[3] Hess v. Secretary of HHS, No. 90-760V, 1991 WL 123577 (Ct. Cl. Spec. Mstr. June 17, 1991).

the Kincaids persuade the undersigned that Lauren did not suffocate, that her hypoxia was part of her Table encephalopathy which also encompassed cerebral edema, tonsillar notching, and circulatory stasis, severely congesting her vital organs, leading to death.

Petitioners have satisfied their burden of proving an on-Table encephalopathy which led to Lauren's death. Respondent has not satisfied his burden of proving under a causation in fact standard that a known factor unrelated to Lauren's vaccination caused in fact her encephalopathy and death. The undersigned ORDERS that petitioners be compensated for Lauren's death in the amount of $250,000.00.

CONCLUSION

Petitioners have prevailed and are entitled to an award of $250,000.00. The clerk shall enter judgment for petitioners and shall direct that an award be in the form of a check made jointly payable to petitioners and Mr. Stephen E. Haynes in the amount of $250,000.00. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.[4]

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master

[4] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.