OFFICE OF SPECIAL MASTERS

95-0295V

(Filed: August 5, 1997)

* *		
AMANDA K. RIGGS, as Parent and	*	
Legal Representative of the Estate	*	
of GABRIEL LUCAS, deceased,	*	
	*	
Petitioner,	*	
	*	
vs.	*	PUBLISHED
	*	
SECRETARY OF THE DEPARTMENT	*	
OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

David Daulton, Norfolk, Virginia, for petitioner.

Vincent Matanoski, U.S. Department of Justice, Washington, D.C., for respondent.

French, Special Master.

DECISION

This case arises under 42 U.S.C. §300aa-1 et seq., the National Vaccine Injury Compensation Act and is brought on behalf of Gabriel Lucas, a deceased infant. On July 8, 1997, a hearing was held in Norfolk, Virginia. Petitioner presented the testimony of Mrs. Amanda Riggs, mother of the deceased, Mrs. Nena Lucas, maternal grandmother, Mr. Brett Lucas, maternal grandfather, Ms. Linda Petcock, a friend, and Dr. Larry White. The written report of Dr. Robin Geier was also filed on behalf of petitioner in this case. Respondent presented the testimony of Dr. Russell D. Snyder, pediatric neurologist, and Dr. Virginia Anderson, pediatric pathologist. For reasons that follow, the court finds that petitioner has failed to establish her claim.

ISSUES

Petitioner filed her claim on April 18, 1995 alleging that within three days of receiving his first diphtheria-pertussis-tetanus (DPT) vaccination on April 16, 1993, her son, Gabriel Lucas, sustained a

vaccine-related injury and that his death on April 19, 1993, was a sequela of that injury. Respondent defends by arguing that petitioner's claims are not supported by the contemporaneous medical records, that his condition following vaccination does not suggest any injury listed on the Vaccine Injury Table set forth in §14 of the Vaccine Act, and that the infant's unfortunate death was appropriately classified as Sudden Infant Death syndrome (SIDS).

STATUTORY REQUIREMENTS

Petitioners in vaccine cases may establish their claim by either of two methods. First, the table-case method requires petitioners to prove that the injured sustained one of the listed injuries described in the Vaccine Injury Table and that the first manifestation of onset of such injury occurred within the time frame prescribed by the statute. §14(a). Thereafter, petitioners enjoy a presumption of causation unless respondent successfully rebuts the presumption by demonstrating that the injury, more likely than not, was caused by factors unrelated to the vaccine. §13(a)(1). Encephalopathy is listed as a table injury if the first manifestation of the onset of the encephalopathy was observed within three days of vaccination. The statue provides the following explanation regarding the term "factors unrelated:"

[T]he term "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 . . . .

§13(a)(2).

Failure to establish a table case does not preclude an award if sufficient evidence is presented to demonstrate that the vaccine, in fact, caused the injury. This second method of proof is popularly called "causation-in-fact." Once causation has been established, petitioners must establish that any sequela of such injury (in this case the alleged sequela is death), more likely than not, was causally related to the vaccine-injury. §14(a)(I)(E). Petitioner in this case has pursued her claim by the table-case method, alleging that Gabriel sustained an encephalopathy, and that his death ensued as a result of his vaccine-related injury.

FACTS

Gabriel Lucas was two months and three days old when he received his first DPT shot. The shot was administered on the 16th day of April, 1993 in the office of his pediatrician, Dr. Ruth Vogel. Prior to his DPT vaccination, he had been a normal, healthy infant, a good baby, happy, easy to care for, and was eating well. He had been diagnosed with an upper respiratory infection approximately two weeks prior to the April 16, 1993 visit to his doctor. His cold had not bothered him unduly, and he was still eating well. But when he visited Dr. Vogel on that date, he still had nasal congestion and the cold had deepened somewhat. His breathing was more raspy, and his mother described him as "sounding like Darth Vader." Mrs. Riggs testified that she had to wait two hours before the doctor was able to see them, and, based on the nurse's opinion that he might not get his shot that day because of his cold, Gabriel's mother questioned the doctor about the advisability of giving the shots. According to her testimony, Dr. Vogel said "Nonsense -- he's as healthy as a horse." And the shot was given. It was Friday morning.

After crying briefly, the infant fell asleep and did not awaken for about five or six hours although he usually was fed every three hours. He was then breast fed briefly -- taking less than usual-- and fell back asleep. This time he slept through the night without waking, a period of nearly 12 hours, and had to be awakened in the morning, a Saturday, and was taken to the home of his maternal grandmother because

his mother had to work. According to Mrs. Lucas, his grandmother, the baby remained abnormally sleepy. She expected him to waken for his usual three hour feedings, but on this morning, he slept for another six hours without waking. When he awoke, he was very fussy. It was at this time that she observed a pulsating spot in the middle of his fontanelle, something she had not noticed before.

In summary, Gabriel slept for approximately 60 hours of the first 72 hours following his vaccination: On Saturday, the day after his Friday vaccination, he slept through a shopping trip to the local mall, a trip to the supermarket, a visit to friends that evening, and slept through Saturday night. He awoke briefly on Sunday for feeding although he took only four ounces, less than usual, took a lengthy one-half hour to feed, and went back to sleep. His mother and father got up about 11 a.m. and went to MacDonald's for breakfast while the baby slept. His mother went to work about two p.m., leaving the baby in the care of his father until that evening. His father apparently gave the infant a bath, but no other information is available about the baby's condition until early that evening. For about one-half hour before his mother returned home from work that Sunday night, Gabriel was in the care of his mother's friend, Linda Petcock, who was also her roommate. Ms. Petcock played with him for a period of about twenty minutes during which time the baby was quietly awake and lying in her lap. Ms. Petcock testified that the baby smiled at her and she thought it was nice to see him finally awake after so much sleeping.

The testimony is unclear as to whether Ms. Petcock put the baby to bed, or whether it was Mrs. Riggs who put the baby to bed when she returned from work. It appears, however, that the baby was breast fed at some time late that evening and that he went to sleep in his own crib. He awoke the next morning, Monday, without having to be awakened, but he was irritable. He nursed a bit, his mother changed his diaper, and he was put on his tummy, next to his mother in her bed, where they both fell asleep again. His mother was awakened by a phone call about 11:30 a.m. and discovered Gabriel next to her -- unmoving and not breathing. CPR was unsuccessful; he was pronounced dead at the hospital at 1:30 on the afternoon of Monday, April 19, 1993.[(1)]

DISCUSSION

Although respondent argues that contemporaneous medical records do not document the existence of symptoms claimed, the court finds no reason to question the factual accounts. The witnesses were forthright and credible although not all recollections are consistent in every detail. Recollections as to basic essentials, however, are consistent, and the court finds the facts set forth herein, more likely than not, a reliable account of Gabriel's clinical course. The sole issue in this case is whether the symptoms described identify a pre-death encephalopathy, or an evolving encephalopathy, that caused a downhill progression unto death. The clinical presentation described by the fact witnesses indicates that the child was certainly not his normal self, but the question to be resolved is whether his condition meets the legal standard required to establish the existence of an encephalopathy prior to death.

As an initial matter, the fact that Gabriel's death was ascribed to SIDS is irrelevant. SIDS cannot qualify as a factor unrelated to the DPT vaccination because SIDS is a classification for an idiopathic and undocumentable cause of death as defined by §13(a)(2)(A). However, even if a SIDS diagnosis cannot defeat petitioner's claim, petitioner is not released from her affirmative burden of establishing 1) a table injury and a causal link between the injury and death, or 2) in the alternative, establishing causation-in-fact proved by strong medical testimony, documentable empirical evidence, or epidemiological studies that relate the sequela to the DPT vaccine. Death, in and of itself, does not qualify as a table injury even if it occurs within the 72 hour time frame. It is not enough to establish what was not the cause of death, but instead, petitioner must establish what was the cause of death. To repeat, death must be found to be a sequela of a pre-death §14 table injury.

To assist the court in determining the existence of an encephalopathy, §14(b)(3)(A) provides the following qualifications and aids to interpretation:

The term "encephalopathy" means any significant 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 [sic] crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be identified by electroencephalogram.

§14(b)(3)(A)(emphasis added).

On March 10, 1995, amended regulations became effective that added the following new guidelines for interpreting §14 of the statute:

(A) 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. . . .

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater . . . (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).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), . . . [or] bulging fontanelle. . . .

42 CFR §100.3(b)(2)(i)(A),(D,) and (E).

The court finds that the clinical course in this case does not comport with the guidelines for finding an encephalopathy. Petitioner presents a labored construction of the facts in an attempt to fit the statutory and regulatory definitions of an encephalopathy. Petitioner argues four points: First, that excessive somnolence from which Gabriel had to be awakened during most of the first 72 hours is evidence of "a reduced level of consciousness;" second, that the lethargic behavior exhibited when he was awake is evidence of "non-responsiveness to his environment or to external stimuli"; third, that the "pulsating" fontanel was evidence of a "bulging" fontanel, and, therefore fits under §14(b)(3)(A) as compatible with intracranial pressure, and thus, encephalopathy.

Petitioner's characterizations do not fit the facts. First, Gabriel was arousable; the evidence does not suggest that he was unconscious, only asleep. Transcript of Proceedings of July 8, 1997 (hereinafter Tr.) at 65. Sleepiness is specifically disqualified by subparagraph (E) of the amended regulations cited herein. Second, his condition does not meet the definition of decreased or absent response, nor did he fail to recognize familiar people. He responded to his environment, (although his irritability was uncharacteristic for this normally happy baby)(Tr. at 301; he had eye contact (Tr.at 52-53, 59); he smiled at his care givers on occasion (Tr.at 30,33,42,298,300); he took some nourishment (Tr. at 19,21,22,26,28,30,33,35); and he stretched during a diaper change and gave his mother a little smile.

Tr.at 42. He was not his usual self, but his behavior fits neither the statutory nor the regulatory guidelines for an encephalopathy. Finally, petitioners' characterization of the fontanelle as bulging, consistent with intracranial pressure, was persuasively challenged. Respondent notes that the fontanelle is normally pulsative, citing four learned treatises in support.[(2)] The first from Clinical Pediatric Neurology:

The normal fontanelle is clearly demarcated from bone edges, falls below the surface, and pulsates under the examining finger.

Id. Gerald Fenichel (1988) at 91. Respondent's Report of July 17, 1995, Exhibit 1.

The second is a quote from Nelson Textbook of Pediatrics:

The fontanel is normally slightly depressed and pulsatile and is best evaluated when the infant is held upright and asleep or feeding. A bulging fontanel is a reliable indicator of increased intracranial pressure . . . .

Id. 14th ed., 1992, at 1474 (emphasis added).

The third article discusses intracranial pressure and is quoted from Neurosurgery of Infancy and Childhood:

Clinical features of . . . intracranial pressure [includes the following:] . . . The fontanelles . . . are enlarged, distended and tense. When the baby is placed in the upright position, the fontanelle does not become depressed and there is no pulsation visible .

Matson, Donald D., Id.2d ed., 210-11 (1969) at 211. Respondent's Exhibit J (emphasis added).

The last article is a quote from Bedside Pediatrics: "Diagnostic Evaluation of the Child" describing intracranial pressure:

The anterior fontanelle may be bulging, and the normal pulsations are absent.

Ziai, Moshen, ed., Id.(1983) at 119. Respondent's Exhibit K; See also,Respondent's Exhibit L at p. 1474.

Dr. Russell D. Snyder, testifying for respondent adds that a normal fontanel pulsates, and although pulsation may be increased in some situations, this is not in itself a sign of encephalopathy:

Encephalopathy, with increased intracranial pressure, will dampen and eliminate pulsation of the fontanel exactly the opposite of what was found in this case.

Letter of January 23, 1997, Respondent's Exhibit A, filed February 14, 1997.

A preponderance of evidence leads the court to conclude that the pulsating fontanelle observed in this case is insufficient evidence of intracranial pressure.

Petitioner's expert, Dr. Larry E. White, a board certified pediatric neurologist, is of the opinion that the unusually prolonged state of somnolence qualifies as an acute abnormality or impairment of function of

the brain and meets the statutory interpretation of severe or "significant" simply because of its longevity. Dr. Snyder disagrees, arguing that the symptoms described are mainly anticipated responses to DPT found in many children, perhaps exaggerated by this infant's upper respiratory infection.

Dr. White's argument merits consideration. Dr. Snyder's explanation, however, is more in keeping with the new regulations which present a clear mandate that "(b) Qualifications and aids to interpretation shall apply to the Vaccine Injury Table . . .:"

(2) Encephalopathy. For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy . . . .

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

42 CFR §100.3(b)(2)(i).

The court concludes that for cases filed after March 10, 1995, the regulations limit severely the signs that can be considered encephalopathic. See generally, 42 CFR 100.3(b)(2),(i),(A), (C),(D), and (E).

The court's discretion in determining whether clinical symptoms demonstrate an encephalopathic condition have been significantly curtailed by the foregoing regulatory provisions, although, perhaps, not entirely eliminated. CFR 100.3(b) requires that [t]he qualifications and aids to interpretation shall apply to the Vaccine Injury Table . . . :" Applying the changes cited, the court concludes that the facts cannot support a finding that the infant had a significantly decreased level of consciousness, decreased or absent response to environment, decreased or absent eye contact, or inconsistent or absent responses to external stimuli at the level required by law. Dr. White's testimony was insufficient to establish causation-in-fact.

The March 10, 1995 amendments may indeed make it more difficult for petitioners to recover in death cases because the time between vaccination and death may be too brief to discern the signs required, although one might argue that death is the ultimate encephalopathy. Congress may or may not have intended such result, but the imposition of stringent regulatory guidelines cited herein requires such an outcome.[(3)]

CONCLUSIONS

The court cannot conclude that Gabriel's death was due to SIDS, although respondent's experts are convinced that SIDS was the more likely event that intervened between the infant's vaccination and his death three days later. The court concludes merely that petitioner has not been able to meet the legal burden of establishing the required severity by which an encephalopathy must now be measured, nor has she established a causal link between the vaccine and Gabriel's unfortunate death. Petitioner's claim is denied.

Absent a motion for review filed pursuant to RCFC Appendix J, the Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

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E. LaVon French

Special Master

1. The experts believe it unlikely that the baby was smothered by a "lay over," an accident that is occasionally caused by an unusually large mother or parent sleeping in the same bed.
2. "Fontanelle" is spelled frequently as "fontanel." The spellings cited will correspond to those used by the respective authors.
3. The foregoing discussion applies only to proof of a Table injury. Causation-in-fact cases are not constrained by the new regulations.