

OFFICE OF SPECIAL MASTERS

No. 90-1491V

(Filed: December 29, 1998)

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HAROLD and DEBHI SWORD, \*
Individually and as Parents and Legal \*
Representatives of NATALIE NICHOL \*
SWORD, their Infant Daughter, \*

Petitioners, \* TO BE PUBLISHED

v. \*

SECRETARY OF HEALTH AND \*
HUMAN SERVICES, \*

Respondent. \*

\*\*\*\*\*

Ronald C. Homer and Sylvia Chin-Caplan, Boston, MA, for petitioners.

Glenn A. MacLeod, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On September 26, 1990, Harold and Debhi Sword, on behalf of their daughter, Natalie Nichol Sword (hereinafter "Natalie"), filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986(1) (hereinafter the "Vaccine Act" or the "Act"). Petitioners has satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) they have not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, and (2) DPT vaccine was administered to Natalie in the United States.

Petitioners allege that Natalie suffered an on-Table encephalopathy as a result of her DPT which subsequently led to her death four hours after vaccination. 42 U.S.C. §§300aa-11(c)(1)(C)(I); 14(a)(I) (B). Respondent defends by arguing that Natalie did not have encephalopathy, and she died from a lung condition, congenital cystic adenomatoid malformation (CCAM).

The court held a hearing in this case on August 19, 1998. Testifying for petitioners were Debhi Sword, Harold Sword, Dr. Marcel Kinsbourne, and Dr. John J. Shane. Testifying for respondent were Dr. Russell D. Snyder, Dr. Lester S. Adelman, and Dr. Virginia M. Anderson..

## FACTS

Natalie was born on February 13, 1975. Med. recs. at Ex. 1, p. 2. She received her first DPT vaccination on April 8, 1975 when she was two months old. Id. She received her second DPT vaccination on May 13, 1975 when she was three months old. Med. recs. at Ex. 1, p. 6. She died four hours later. Med. recs. at Ex. 6, p. 1.

The medical records for Natalie's visit on May 13, 1975 show that she had a cough. Med. recs. at Ex. 1, p. 6. The doctor (Dr. Bruce P. Meyer) noted that she had a "developing chest" meaning a developing chest problem. Id. Under growth and development, he noted that she followed, laughed, and babbled. Id. He checked her chest and wrote she had a cough. Id. He said to call if the cough worsened or persisted. Id.

In his clinic notes, Dr. Meyer wrote that Natalie had vomiting and diarrhea. Med. recs. at Ex. 1, p. 3. She was off her formula and seemed better. Id. When she resumed her formula, she had vomiting and diarrhea again. Id. She spat up jello and water that day. Id. She started formula again with cereal. Id. There was no increase in temperature. Id. Her stools were firm without diarrhea. Id.

Dr. Meyer was notified later about Natalie's demise and wrote that she did not have any evidence of illness on the way home and had slept on the way home. Med. recs. at Ex. 1, p. 6. In the evening, Mr. Sword called frantically because Natalie was blue and not breathing. Id. The police came and told him that Natalie's body was cold. Id. They intubated her with difficulty. Med. recs. at Ex. 5, p. 2.

Dr. Robert C. Harsh performed an autopsy on May 14, 1975 and wrote SIDS as the cause of death. Med. recs. at Ex. 2, p. 2. He noted petechial hemorrhages of pleural and pericardial surfaces. Id. He wrote, "The lungs are normally aerated, except for the right middle lobe which is greatly hyperdistended." Med. recs. at Ex. 2, p. 3. On microscopic examination, Dr. Harsh wrote, "Sections of lungs show most of the lung to be normally aerated with intervening small slightly collapsed portions. There is minimal cellular infiltrate in the interstitial tissues of one section but no definite pneumonic process noted.... One of the sections shows hyperdistention apparently due to postmortem resuscitation attempt." Med. recs. at Ex. 2, p. 5.

## TESTIMONY

Debhi Sword testified first for petitioners. Tr. at 5. She had two children before Natalie was born, and two children afterwards. Tr. at 7. Natalie was a healthy baby. Id. She was alert, happy, very active, and pretty. Tr. at 8. At her pediatric visits, she was progressing well, gained weight, and was healthy. Id. Mrs. Sword did not remember if Natalie reacted to her first DPT vaccination on April 8, 1975. Tr. at 8-9. She probably had some fussiness. Tr. at 9.

Natalie had a little cough prior to her second DPT vaccination on May 13, 1975. Id. The doctor checked her lungs and said there was nothing unusually alarming. Tr. at 10. She does not remember if Natalie had a cold. Id.

Before she received the second DPT, Natalie would have a bottle every two to three hours. Tr. at 11. She would nap two to three times a day for an hour or two, and woke daily from 6:00 to 8:00 a.m. Id. Natalie

would cry when she was hungry or wanted to be held. Tr. at 13. She would smile and coo. Id. She was starting to hold up her head when on her chest. Id. Natalie was very observant and focused. Tr. at 14. She was responsive and verbalizing. Id. She drank formula. Tr. at 15. In the afternoon, she always napped. Tr. at 18.

The second DPT was given in the morning, at 10:30 to 10:45 a.m. Tr. at 21. Natalie started crying immediately and was very upset. Tr. at 23. Mrs. Sword gave her a bottle to calm her. Id. Natalie drank one-quarter of it. Id. Mrs. Sword dressed her and Natalie was fussy. Id. Natalie became all right while feeding and started to get sleepy. Tr. at 24. Mrs. Sword continued to feed her and Natalie drank one-quarter to one-third of the bottle and fell asleep. Tr. at 25.

It was a forty-five minute trip home from the doctor, but the Swords made two stops. Tr. at 26. First, they stopped at Dairy Queen. Id. Mrs. Sword tried to feed Natalie again but she was still asleep and did not respond. Tr. at 27. She tightened her lips and would not drink. Id. Her husband tried to feed her cold ice cream, but she did not respond. Tr. at 33. The second stop was at a nursery. Tr. at 31. Mrs. Sword stayed in the car while her husband and son went to buy a plant. Id. Natalie was asleep. Id. Their trip home took one hour and ten minutes. Id.

Natalie was still asleep. Tr. at 32. Mrs. Sword set her in the bucket seat on the kitchen counter. Id. Natalie did not have a fever. Id. Mrs. Sword took Natalie's jacket off. Id. Natalie usually did not like having it taken off, but she did not awaken. Id. She kept her mouth closed and would not take her bottle. Tr. at 33. Mrs. Sword put her in her bed for a nap. Id.

Mrs. Sword fixed a casserole for dinner and refrigerated it. Id. Her husband and son planted the new plant. Id. Since her husband had to go to work at 3:30 p.m., they all decided to nap at 2:30 p.m., although Mrs. Sword did not sleep. Tr. at 34. Natalie was in the bassinet on her stomach next to Mrs. Sword. Tr. at 35. Natalie almost always slept on her stomach. Tr. at 38. Her husband got up and checked on Natalie. Tr. at 35. He tapped her on her backside and she did not respond. Id. Mrs. Sword screamed when she saw Natalie's face. Id. Her husband had her call the doctor's office while he performed CPR on Natalie. Tr. at 35-36. Natalie was limp when Mrs. Sword saw her. Tr. at 36. She had a blue-gray color. Id. Two sheriffs came and took Natalie to the hospital. Tr. at 37.

Before the second DPT, there was nothing unusual about Natalie's breathing. Tr. at 49. It was not rapid or noisy. Id. After the second DPT, Natalie's breathing was normal after she stopped crying. Tr. at 49-50.

Natalie did not nap the morning of her second DPT vaccination. Tr. at 54-55. However, she slept all the way to the doctor's office (forty-five minutes). Tr. at 55.

Harold Sword testified next for petitioners. Tr. at 66. He had a daughter before Natalie. Tr. at 67. He is a printer and worked a shift from 3:30 p.m. to 11:00 p.m. Tr. at 68. He also went to school at the time Natalie received her second DPT. Tr. at 68-69. Natalie was bright, responsive, with dancing eyes. Tr. at 71. She seemed ahead of her siblings. Id. On May 13, 1975, he got up and intended to go to 10:00 a.m. class, but decided to go to the doctor's office instead. Tr. at 71-72. Natalie slept in the car on the way. Tr. at 72. Her breathing was fine. Tr. at 73. She had had an occasional cough for one to two days. Id.

After the second DPT, Natalie was almost hysterical. Tr. at 77-78. She was crying, looked angry, and scowled. Tr. at 78. In the car, she was not happy. Id. Within five minutes, Natalie fell asleep. Id. At the Dairy Queen, he got ice cream for his wife and himself and a cone for his son. Tr. at 79. He took some of his ice cream and put a spoon of it in Natalie's mouth. Tr. at 80. Natalie did not respond at all. Id. It

ran down her mouth. Id.

Dr. Marcel Kinsbourne testified next for petitioner. Tr. at 103. He is a pediatric neurologist. Tr. at 105. His opinion is that Natalie had on-Table encephalopathy after her second DPT which led to her death. Tr. at 105-06. The basis of his opinion is that within a short period of time, she fell asleep to a depth of non-responsivity that was unusual. Tr. at 106. She had not had much to drink and did not respond to manipulations. Id. The majority of DPT injuries occur soon after vaccination. Tr. at 106-07. The autopsy concluded SIDS because there was no apparent cause of death. Tr. at 108. There was nothing significantly wrong with Natalie's lungs. Id. There was no collapse or compression in the lungs and no signs of tension in the thorax. Id. The prosecutor thought Natalie was normal until her death. Tr. at 109.

Respondent's expert Dr. Adelman thinks that Natalie died of a bacterial lung infection, but Dr. Kinsbourne testified that Natalie's breathing was not obstructed. Tr. At 109-10. She was not in respiratory distress. Tr. at 110. There was no intercostal retraction or she would have been sucking air. Id. An acute respiratory event would not have gone unnoticed. Id. Natalie did not have any cyanosis or pallor. Id. If she had a bacterial infection of the lungs, she would have had a fever. Tr. at 111.

Respondent's expert Dr. Anderson thinks that Natalie had CCAM, but Dr. Kinsbourne testified that children usually do not die of CCAM. Id. Cystic changes in parts of the lung expand in the lung. Tr. at 112. This would cause enormous pressure in the thorax. Id. One can die if pneumothorax occurs: if the cyst bursts, this puts air in the cavity between the lung and chest wall. Tr. at 112-13. This considerable pressure is an acute emergency and the person would be struggling for breath. Tr. at 113.

Regarding Natalie's cough, Dr. Kinsbourne testified that it is common in babies. Id. Natalie's pediatrician focused on her chest. He examined her and wrote that her chest was clear. Tr. at 113-14. Thus Dr. Adelman's opinion of lung infection is wrong. Tr. at 114.

In explaining how Natalie died from encephalopathy, Dr. Kinsbourne said that acute encephalopathies do cause death in babies. Tr. at 115. The energy metabolism of neurons is inactivated. Tr. at 116. Part of the brainstem deals with vital organs. Id. Experiments in the laboratory show that pertussis vaccine has affinity for G proteins which have to do with intercellular and intracellular sequencing. Tr. at 117. The G proteins mediate inhibitory levels of neurons. Id. When pertussis inhibits the G protein, this causes excessive firing. Id. Exhaustion of neurons leads to death of neurons. Id.

To Dr. Kinsbourne, a lowered level of consciousness goes to the heart of encephalopathy. Tr. at 122. If Natalie had not died but instead recovered, Dr. Kinsbourne said he would not have diagnosed encephalopathy. Tr. at 126. Most acute encephalopathies are not fatal and are usually transient. Tr. at 127. Dr. Kinsbourne said there is no dispute that Natalie had CCAM. Tr. at 133. However, Natalie did not have carbon dioxide narcosis. Id. When carbon dioxide levels mount in the blood, the reflexes increase to stimulate ventilation to blow off the carbon dioxide. Id. Natalie's respiration did not increase. Id. No literature relates CCAM to carbon dioxide narcosis. Tr. at 134. Narcosis is like anesthesia with decreased responsiveness and dulled senses. Tr. at 135.

CCAM can cause death in children and is unrelated to DPT. Id. Natalie did not have an infection in her lungs to cause her death. Id. Her doctor thought she was developing something because he wrote "developing chest." Tr. at 136. Today, Natalie would not have been diagnosed as dying of SIDS because her autopsy was not normal; she had CCAM. Tr. at 137. Drowsiness and napping can be a minor symptom of DPT. Tr. at 138-39. Natalie was responsive only for the first fifteen minutes after the vaccination. Tr. at 139. The gathering poison in her brain lowered her level of consciousness. Id. Natalie slept when her parents expected her to be awake. Tr. at 149-50. She did not react to the bottle offered to

her, the ice cream put in her mouth, or her jacket being removed. Tr. at 150.

Natalie's CCAM existed before she was born, but it was static, not developing. Tr. at 154. If her CCAM had compressed both her lungs, this would cause death and his opinion would change. Tr. at 155. In Dr. Kinsbourne's opinion, the onset of Natalie's encephalopathy was one hour after vaccination. Tr. at 159.

Dr. John J. Shane, a forensic neuropathologist, testified next for petitioners. Tr. at 162. Natalie had changes leading to somnolence related to DPT-encephalopathy. Tr. at 167. Clinically, she had encephalopathy, but nothing showed up pathologically because it was too soon. Tr. at 168. Dr. Cox, the pathologist who preceded him in this case, described early changes in Natalie's brain: mononuclear infiltrate, vascular necrosis, petechial hemorrhages. Tr. at 169. This is a classic description of DPT-encephalopathy. Tr. at 171. Natalie did not die from CCAM. Tr. at 173. This lung condition caused no symptomatology whatsoever. Id. Her pediatrician described her lungs as clear four hours before her death. Id. She had cystic changes limited to the right lower lobe. <sup>(2)</sup> Id. The remainder of her lung tissue was normally irritated due to the vigorous resuscitation efforts. Id.

Natalie did not have pneumothorax. Id. She would have had compression or atelectasis (absence of aeration). Tr. at 173-74. Most CCAM's that are clinically significant occur in neonates. Tr. at 174-75. CCAM is usually associated with other congenital abnormalities, but Natalie did not have any other congenital abnormalities. Tr. at 175. Natalie had mild pectus excavatum, which Dr. Kinsbourne testified was not normal, but a structural variation, a mild congenital anomaly, not associated with any other disease. Tr. at 178-81. Natalie's entire left lung was normal. Tr. at 175.

Natalie did not have carbon dioxide narcosis. Id. There was no profound cerebral edema which would have been associated with narcosis and no tachypnea (rapid breathing). Id. She did not die an anoxic death. Tr. at 176. Most CCAM's are associated with male children. Id. In females, CCAM is less serious. Id.

Dr. Shane testified that the causes of death in CCAM are other anomalies like renal agenesis. Tr. at 182. Another cause of death is extensive CCAM. Tr. at 183. In pneumothorax, one would have a ruptured cyst. Tr. at 184. Air is expelled into the pleural space producing atelectasis. Tr. at 185. The lung would look solid and not aerated. Tr. at 186. Dr. Shane agreed that Natalie had CCAM in her middle lobe, but it was not a factor in her death. Tr. at 188. There was no inflammatory infiltrate and no pneumonia. Tr. at 189.

Dr. Shane opined that DPT caused Natalie's death because she was normal before the vaccination and died four hours later. Tr. at 190. She did not have a catastrophic event pathologically. Id. In looking at slide number 2, Dr. Shane stated that the lung tissue showed atelectasis but only in the middle lobe. Tr. at 194. The remaining 85 percent of the right lung was aerated. Tr. at 195. The upper and lower lobes were normally aerated. Id. There was no atelectasis in the entire left lung. Tr. at 196. Natalie had a mild pectus excavatum. Tr. at 209. If it had restricted her, she would not have had normal aeration. Id.

Natalie had either Type 1 or Type 2 CCAM. Id. Type 2 has a 56 percent survival rate. Tr. at 211. Anomalies occur in 15 to 20 percent of CCAM. Id. Death occurs, but it is extremely rare. Id. CCAM is unilateral in 95 percent of the cases. Tr. at 213. A single lobe is affected in 90 percent of the cases. Tr. at 213-14.

Dr. Russell D. Snyder, a pediatric neurologist, testified first for respondent. Tr. at 217. He is on the faculty of the University of New Mexico and works clinically part-time, seeing eight patients a week. Tr. at 218. His opinion is that Natalie did not have an acute encephalopathy after her second DPT

vaccination. Tr. at 219. His basis is that being sleepy is not sufficient for an encephalopathy that leads to death. Id. Being able to drink part of a bottle is not sufficient for an encephalopathy that leads to death. Id. Usually other symptoms besides drowsiness comprise encephalopathy. Id. Natalie's cause of death was pulmonary difficulty. Id. That Natalie had some symptoms before she saw her pediatrician might mean that there was a process ongoing that began earlier. Id.

In 1,553 doses of DPT administered, as described in a medical article (R. Ex. M), uncharacteristic drowsiness or napping occurred in 58.2 percent (but 42.9 percent if under six months of age). Tr. at 220. It occurred in 39.8 percent in the first six hours (but 22.3 percent if under six months of age). Id. Dr. Snyder had never heard of CCAM before this case. Tr. at 227. He would not conclude that Natalie died from pulmonary difficulties without Dr. Anderson's report. Tr. at 229.

Dr. Snyder testified that someone with encephalopathy sufficient to cause death is very ill. Tr. at 231. That Natalie drank a third of a bottle of formula means that she was not ill to that degree. Id. He admitted it was possible she was encephalopathic after she drank the bottle when her jacket was being removed at home. Id. She did not have anaphylaxis or HHE. Tr. at 232.

Dr. Snyder said that a child with acute encephalopathy does not have normal breathing. Tr. at 232-33. The breathing of an encephalopathic child can be rapid, slow, or irregular (noisy). Tr. at 233. Dr. Kinsbourne said this was often, but not always, the case. Id. Often, we intubate encephalopathic children and put them on oxygen. Tr. at 233-34. This occurs in drowning, meningitis, head trauma, and some strokes. Tr. at 234.

Dr. Snyder had not seen or read about a case like this. Id. He would expect profound changes in tone, abnormal pupillary activities, and full fontanelle if Natalie were encephalopathic. Tr. at 235. Dr. Cox, petitioners' prior pathological expert, stated it was hard to separate unusual from regular drowsiness. Tr. at 236.

Dr. Snyder's explanation for Natalie's failure to respond to ice cream in her mouth is that she was asleep, but he did not know what the response should be. Tr. at 237-38. If the only symptom of Natalie's encephalopathy were sleepiness, Dr. Snyder said we do not know when it began. Tr. at 241. Dr. Snyder stated he did not know what caused Natalie's death. Tr. at 253.

Dr. Lester S. Adelman, a neuropathologist for thirty years, testified next for respondent. Tr. at 257. He has done several thousand autopsies in his career. Tr. at 258. He reviewed the slides of Natalie's autopsy. Id. In his opinion, there is no anatomic evidence of DPT causing Natalie's death. Tr. at 259. His basis is that the medical examiner's report is entirely inadequate. Id. The prosecutor did not even weigh Natalie's brain or any other organ. Id. He is missing normal descriptions, for instance, of the meninges (coverings). Tr. at 260. There are no data in the autopsy report, just conclusions. Id. The report is not useful for a review of Natalie's brain. Tr. at 261.

Dr. Adelman found few inflammatory cells in the meninges of Natalie's brain. Id. She did not have encephalitis. Tr. at 262. There was nothing of pathological or clinical significance. Id. He found the same as Dr. Cox did. Id. In the lungs, he saw inflammation, as did Dr. Cox. Tr. at 263. He saw some colonies of bacteria, but there was a delay in the autopsy although she had been embalmed before it. Tr. at 263-64. Dr. Adelman admitted that one might not find much pathologically if a person died within a few hours of the onset of encephalopathy. Tr. at 264.

Natalie's lung was peculiar-looking. Id. She had significant changes in her lung, but he does not know if it is CCAM and relies on Dr. Anderson for that diagnosis. Tr. at 264-65. He cannot quantify the

infection and does not know if it caused Natalie's death, although his report said it did. Tr. at 266. Dr. Adelman described himself as a brain, muscle, nerve, and pituitary man, not a lung man. Tr. at 270. Dr. Adelman believes Natalie died from pulmonary disease. Tr. at 278.

Dr. Virginia Anderson, a pediatrician and pediatric pathologist, testified last for respondent. Tr. at 279. She first described CCAM in an adolescent in 1971. Id. She has seen approximately six cases of CCAM in children. Tr. at 280. It can be found in fetuses. Id. CCAM can be progressive and last a long time. Id. It is not a common lesion. Tr. at 281. There are four major ways of presentment:

(1) in the neonatal period with acute respiratory distress. Id. Very small infants have poor reserve. Id. This can cause acute rapid deterioration. Id. Most cases present in smaller babies. Id.;

(2) some cough or respiratory symptoms. Tr. at 282. A chest x-ray would show a hyperlucid lung, a big air pocket, a cyst, or a foreign body. Id. It must be excised or it will cause atelectasis or get bigger and become infected, necessitating a thoracotomy. Tr. at 282-83;

(3) chronic pulmonary disease referable to the chest, causing pneumonia or obstruction. Tr. at 283-84;

(4) spontaneous pneumothorax. Tr. at 284. This pops the lung and is a catastrophe. Id. Tiny babies do not have a reserve. Id. It can cause a quick death. Id.

Ten percent of asthmatics die of spontaneous pneumothorax. Tr. at 285. CCAM is a potential for pneumothorax. Id. Dr. Anderson is not sure that Natalie had a pneumothorax. Id. If it is acute, the person will not have atelectasis. Tr. at 286. The younger the baby, the greater the risk for pneumothorax. Id.

Natalie's autopsy was not up to Dr. Anderson's standards, but the pathologist was very clear in describing the right middle lobe, where the CCAM lesion was. Tr. at 286-87. It was a significant lesion because it involved the whole middle lobe, putting pressure on the adjacent lung. Tr. at 287. Cysts enlarge because they entrap air. Tr. at 288. The cyst is full of carbon dioxide and acts as a rebreathing bag. Id. The person is breathing oxygen plus another dose of carbon dioxide. Id. The lesion caused her death. Tr. at 289.

The infection in Natalie's right lung was not enough to kill her. Tr. at 290-91. She had a type 2 CCAM. Tr. at 291-92. The pathologist described the hyperlucidity but not the cyst. Tr. at 292. Type 2 CCAM is associated with other malformations and has a 44 percent mortality rate. Id. The mortality is highest early in life. Id. Most CCAM's are solitary. Tr. at 293. Natalie's lesion started when she was an embryo. Id. The rise in carbon dioxide in the lesion (hypercapnia) opens the blood vessels in the brain, causing sluggishness and sleepiness. Tr. at 295-96. When asked why Natalie experienced this sluggishness and sleepiness right after the DPT vaccination, Dr. Anderson at first said she did not know why although, later, she testified that DPT caused Natalie's somnolence. Tr. at 296, 361. The pathologist did not see open blood vessels in Natalie's brain, but Dr. Adelman said he would have needed an electron microscope to see them. Tr. at 297.

Dr. Anderson's opinion is that Natalie's CCAM caused her death. Tr. at 298. She had atelectasis of the surrounding lung and the other lung. Id. There were focal areas of collapse. Tr. at 299. She had a rupturing cyst, pneumothorax. Tr. at 300-01. The dead space became metabolically significant. Tr. at 301. Even so, she might not have manifested clinical symptoms, although the dead space could have resulted in tachypnea. Tr. at 305. Her lobe was deflated at autopsy. Tr. at 307. A hyperlucent lung always has carbon dioxide in it. Tr. at 309.

Dr. Anderson presented a number of slides she had made. Tr. at 319. Slide 1 showed early bronchitis, but this did not cause Natalie's death. Tr. at 319-20. Slide 2 showed atelectasis or collapsed lung. Tr. at 320. The air spaces are like slits, as a result of CCAM. Id. Dr. Anderson did not know which lung this was but it was a dead lung. Tr. at 321. There were focal areas of collapse through the lung. Id. It could be the right middle lobe. Tr. at 322. It could be a cyst in the upper left corner. Id. Slide 3 showed the lesion. Tr. at 323. It was cystic with huge cysts. Id. We see them collapsed, but, in Natalie, they were full of air. Id. She was breathing carbon dioxide. Id. The lung was not properly communicating with the bronchus, and the bronchus was maldeveloped. Tr. at 324. Slide 4 showed more of the lesion, which was a major, not an incidental, finding. Tr. at 328-29. She had dysplastic epithelium. Id. Slide 5 showed part of cysts. Id. This was a non-functioning lung. Tr. at 330. It compressed the normal lung and had dead space full of carbon dioxide. Id. Some people are asymptomatic. Id. But it can cause spitting up and sleepiness. Id. It is millimeters in size, which is large. Tr. at 330-31. Dr. Shane interposed that it was just fractions of an inch, but Dr. Adelman said that a baby's lung is just a few inches in size.<sup>(3)</sup> Tr. at 331.

Small babies have less reserve of air. Tr. at 335. One would expect shortness of breath if the baby were experiencing lessened reserve. Id. In the literature Dr. Anderson read, she did not focus on clinical signs of respiratory distress, but all the patients did have respiratory distress. Tr. at 336. Natalie did not have evidence of pneumothorax on autopsy, but the pathologist did not look for it. Tr. at 336-37. One would have to open the lungs under water to detect it. Tr. at 337. Five percent of children have pneumothorax. Id. An autopsy is not a proper method to diagnose carbon dioxide narcosis. Tr. at 344.

Dr. Anderson said she did not know if carbon dioxide narcosis is accompanied by cerebral edema (as Dr. Shane stated), but it is accompanied by somnolence. Tr. at 349-50. Natalie should have had symptoms with atelectasis. The literature (R. Ex. J, p. 763) describes a four-month-old baby who had a dry cough and fever with atelectasis. Tr. at 351-52. Natalie did not have a fever, but she had a slight cough and had spat up earlier. Tr. at 353. Later, she was somnolent. Id. Dr. Anderson regarded the DPT as unrelated to her death. Tr. at 354.

If Natalie's CCAM had been known, she would have had surgery to remove the lesion. Tr. at 358. CCAM is a time bomb and can cause increasing respiratory distress. Tr. at 359. Respondent's Exs. H through K show that immediate removal of the lesion is important because CCAM can kill. Id. Dr. Anderson thought Natalie's somnolence was related to her DPT, not to her CCAM. Tr. at 361. She did not think very much could be made of Natalie's failure to respond to ice cream in her mouth because Dr. Anderson has applied cold stethoscopes to sleeping babies without their waking up. Tr. at 361-62. She believes Natalie's cyst was full of carbon dioxide. Tr. at 363. Whether or not the cyst was significant to cause somnolence, she did not know. Id.

## DISCUSSION

The Vaccine Act affords petitioners two theories of recovery, thereby allowing them to prove causation by showing that either: (1) a Table-injury occurred or (2) the vaccine was the cause-in-fact of the injury. The former theory is governed by Section 14(a) of the Act which contains a Vaccine Injury Table. If the injuries described in this Table occur within the statutorily defined time period, petitioners have proven the existence of a "Table-injury," creating a rebuttable presumption of causation. To rebut this presumption, respondent must provide affirmative evidence demonstrating that a known factor unrelated was the cause-in-fact of the vaccinee's condition.<sup>(4)</sup>

In the instant matter, petitioners claim that Natalie suffered an on-Table encephalopathy as a result of her second DPT vaccination which, in turn, led to her death. In support of their claim, petitioners provided the medical expert opinion of Dr. Marcel Kinsbourne. Dr. Kinsbourne opined that Natalie

suffered an on-Table encephalopathy based on her failure to respond to her parents during the four hours between vaccination and her death. All she did was sleep. Even when her father put ice cream in her mouth, she did not awaken. When her mother attempted to feed her a bottle, she did not respond by sucking. She did not awaken when her mother took off her jacket when they came home. Natalie, in the office visit notes for May 13, 1975, the date of her second DPT vaccination, is described as following (with her eyes), laughing, and babbling. After the DPT, she screamed and fell asleep. She never woke up. Dr. Kinsbourne thinks that the onset of the encephalopathy was one hour after vaccination. He gave a somewhat strained interpretation of the effect of pertussis toxin on G proteins, interfering with the firing of neurons, resulting in the neurons' death.

Respondent would have the undersigned believe that Natalie's drowsiness was merely a common reaction to DPT and had nothing to do with her death which CCAM caused by carbon dioxide narcosis. On the other hand, respondent in its Post-Hearing Brief at pages 4-8 states that the special master cannot hold that a Table injury occurred based solely on petitioners' claims, unsubstantiated by medical records or medical opinion, citing 42 U.S.C. §300aa(13)(a)(1). Is the undersigned supposed to hold that Natalie was somnolent for purposes of ascribing little significance to it because drowsiness is common after DPT inoculation, but on the other hand, to hold that petitioners have failed to prove Natalie was somnolent because there are no substantiating medical records?

Firstly, petitioners' claim of Natalie's post-vaccinal sleepiness is substantiated by her pediatrician's note of Mr. Sword's phone call to him the day of her death that she slept on the way home. Although respondent does not contest that Natalie experienced somnolence, what respondent seems to contest is the medical and legal significance of that somnolence culminating in her death.

Secondly, this special master has never held in other cases that details in parents'

testimony that may be additional to those in the medical records are statutorily forbidden if the special master finds the testimony credible and not markedly different from the medical records.

Thirdly, the statutory requirement of medical substantiation is met with the expert medical reports. In Raley v. Secretary, HHS, 1998 WL 681467 (Fed. Cl. Spec. Mstr. August 31, 1998), the same respondent's counsel made the same argument in a one-day death case but to no avail. Respondent moved for summary judgment based on this argument, and Special Master Elizabeth Wright denied respondent's motion, after a thorough analysis of all the case law on this issue. She stated, "It is within the province of the special master to find facts upon which an expert may base his or her testimony." *Id.* at \*6. In addition, Special Master Wright stated, "The plain language of Section 13(a)(1) does not require independent medical record corroboration of the facts supporting a vaccine-related injury. ... There is no requirement in the Vaccine Act that the medical opinion independently corroborate the *facts* of an injury." *Id.* at \*7 (emphasis added). Special Master Wright found that a requirement that a medical expert have independent knowledge of the facts would be an extraordinary, nonsensical, and absurd burden under the Vaccine Act. It would make congressional intent in passing the statute unfathomable because it would require a higher standard of proof than obtains in traditional tort litigation. Because the statute provides in the alternative for substantiation by medical record or expert medical opinion, petitioners have the option of relying upon either. *Id.* at \*7-8. Respondent's argument of independent corroboration from the records is especially egregious in a situation such as the instant case in which death occurs within four hours of vaccination. It is surprising that in the instant action, where a medical record does support the claim of post-vaccinal sleepiness, where respondent accepts that this symptom occurred, and where petitioners have satisfied the statutory requirement of medical opinion corroboration, that respondent still adheres to this particular defense.

#### Causation in Fact

Petitioners have not pleaded causation in fact from the DPT to death, but it seems the most obvious theory of entitlement, as will be discussed infra.<sup>(5)</sup> To satisfy their burden of proving causation in fact, petitioners must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Here, it is respondent that has offered the proof that satisfies petitioners' burden.

"[E]vidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149. In addition, death is not a Table injury. Hodges v. Secretary, HHS, 9 F.3d 958 (Fed. Cir. 1993); Hellebrand v. Secretary, HHS, 999 F.2d 1565 (Fed. Cir. 1993).

The following logical sequence of cause and effect seems most obvious to the undersigned. Natalie had Type 2 CCAM which was beginning to develop clinical signs (her cough) at the time of her second DPT. Her pediatrician, while examining her on that fateful day, noted in the records that she had a developing chest. That meant there was some question of her developing a chest problem. He did examine her lungs in light of her slight cough but found them clear. That means that Dr. Shane, petitioners' pathologist, and Dr. Kinsbourne, petitioners' neurologist, were correct that Natalie's CCAM was in a minor stage at that point.

The scenario that seems most likely to the undersigned is that Natalie experienced drowsiness, a typical response to DPT, and because of her underlying CCAM, she could not recover from her DPT-induced drowsiness because of insufficient reserve of air and died. Respondent's expert Dr. Anderson stated that if Natalie's CCAM had been diagnosed, she would have had the lesion surgically removed. This would have cured her.

Clearly, DPT vaccination caused Natalie's drowsiness, as Dr. Anderson, Dr. Shane, and Dr. Kinsbourne agreed. Before the vaccination, she was bright-eyed, alert, and happy. But she was developing a chest problem and had a slight cough. Had she not received her second DPT which induced somnolence, Natalie would have developed more clinical signs of her CCAM, sending her mother back to the doctor where her CCAM could have been diagnosed and surgically treated. Because the DPT vaccination caused the reaction of somnolence, Natalie was too vulnerable from her underlying condition to recover from the somnolence and died.

It is a standard principle of tort law that defendants take their victim as they find him. If the victim has an eggshell-thin skull, then defendant must pay damages for a blow which might leave a normal person uninjured but which causes a concussion to an eggshell-thin-skulled person. In D'Ambra v. United States, 396 F. Supp. 1180 (D.R.I. 1973), aff'd, 518 F.2d 275 (1st Cir. 1975), the mother of a four-year-old boy killed by a postal truck sued the United States for her consequent psychoneurosis. The court stated:

[W]here the negligent infliction of injury aggravates a pre-existing condition or disease, and no apportionment is possible, it has been held that the defendant is liable for the entire damage, i.e., Newbury v. Vogel, 151 Colo. 520, 379 P.2d 811 (1963) (pre-existing arthritic condition); Kawamoto v. Yasutake, 49 Hawaii 42, 410 P.2d 976 (1966) (possible prior back problems and an arthritic condition); Blaine v. Byers, 429 P.2d 397 (Idaho 1967) (pre-existing arthritic condition); Matsumoto v. Kaku, 484 P.2d 147 (Hawaii 1971) (pre-existing back pain), Wise v. Carter, 119 So.2d 40 (Fla. App. 1960) (prior injury). The justifications for this principle are, however, different from that used in the multi-collision

cases. It is sometimes said that a tortfeasor takes his victim as he finds him. See Blaine v. Byers, supra. Another rationale is that when a prior condition does not cause pain or disability, the injury caused by the tortfeasor is the proximate cause of the pain or disability. Comment. Apportionment of Damages, 49 Denver L.J. 115, 116 (1972) and cases cited therein. See also Newbury v. Vogel, supra.

Id. at 1180.

In Duty v. United States Dep't of Interior, 735 F.2d 1012 (6th Cir. 1984), one of the two plaintiffs in a car accident had had a pre-existing abnormal curvature of the spine at the tailbone (known as spondylolisthesis). However, she had not experienced pain from this condition prior to the accident. After the accident, she experienced substantial pain and suffering. The court held that defendant was liable for all damages proximately resulting from his negligence even though plaintiff's injuries may have resulted from the aggravation of a pre-existing physical impairment. Id. at 1014.

The facts of this case present a logical sequence of cause and effect to explain how Natalie went from uncontestedly DPT-induced somnolence to death. Natalie was born with a congenital condition, CCAM, which was still in a developing stage at the time of her second vaccination. Her only symptoms were a slight cough and a developing chest when she received the second DPT. Unfortunately, a common reaction to DPT is somnolence, and Natalie fell into a deep sleep. Because of her CCAM, she had a lobe in her lung filling with oxygen and carbon dioxide. The more she slept, the less likely she could wake up. Thus, she died.

Had Natalie not experienced the deep somnolence from the vaccine, she would have had the development of her cough, rapid breathing, and other acute symptoms that would have compelled a return to the doctor's office to treat her symptoms, at which point, the doctor would have checked her chest and found evidence of the CCAM. She would have had surgery to remove the lesion and lived.<sup>(6)</sup>

Petitioners have prevailed on a theory of DPT causation in fact somnolence leading to death.

#### On-Table Encephalopathy

To determine whether or not a vaccinee experienced an encephalopathy, the undersigned turns to a section of the Act entitled "Qualifications and aids to interpretation." 42 U.S.C. § 300aa-14(b). Under this section, encephalopathy is defined as:

The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery,<sup>(7)</sup> or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent inconsolable [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 documented by slow wave activity on an electroencephalogram.

The question is whether Natalie's prolonged unresponsiveness was mere post-vaccinal drowsiness or a neurologic illness. Whereas evidence from the respondent's literature supports the conclusion that post-vaccinal drowsiness is common, a lower level of consciousness is not. That Natalie did not awake when her father put ice cream in her mouth was quite significant to Dr. Kinsbourne, petitioners' expert neurologist, because the coldness should have caused her to stir but did not. It was not, however,

meaningful to Dr. Anderson, who, when in her pediatric practice, used to examine sleeping babies with cold stethoscopes without waking them.

Applying the statutory "Qualifications and aids to interpretation" to the instant case establishes that Natalie's clinical presentation meets only one of the criteria if her unresponsiveness for four hours is construed as a change in the level of consciousness. This symptom did not last for at least six hours because she died just four hours after vaccination. But the "Qualifications and aids to interpretation" are not inflexible since they admit the appearance of numerous symptoms and the possibility of someone's having an encephalopathy with or without seizures. When someone does not live long enough to satisfy the interpretive aid of having encephalopathy for at least six hours, the undersigned will not hold that that vaccinee is precluded from prevailing under a theory of on-Table encephalopathy if his or her symptoms justify a finding that the individual had encephalopathy.

The court need not determine whether or not Natalie's stupor was an on-Table encephalopathy in light of its holding that DPT caused her somnolence which led to her death because of her underlying pulmonary vulnerability due to CCAM. However, if respondent chooses to appeal that holding, the undersigned holds in the alternative that she did have an on-Table encephalopathy because the hallmark of encephalopathy is an altered level of consciousness and Natalie never woke up after the second DPT vaccination. She did not eat or respond to any stimulus such as her mother's talking to her and dressing and undressing her, her father's attempt to feed her ice cream, or her regular schedule of eating and napping..

Petitioners' burden to show by a causation in fact analysis how the Table injury led to her death is satisfied by respondent's expert Dr. Anderson's testimony. Dr. Anderson stated that the lesion due to Natalie's CCAM caused her to experience carbon dioxide narcosis from which she died. She attributed the somnolence to the DPT. Thus, the lesion, together with the somnolence that DPT caused (which under this theory of entitlement is an on-Table encephalopathy), led to her death.

Accordingly, proceeding from DPT-somnolence to death through her CCAM-compromised lumbar ability satisfies the standard of "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Grant, supra, at 1148.

The undersigned does not view the CCAM as an intervening or superseding cause so as to remove the causative link between Natalie's vaccine injury (either unusual somnolence or on-Table encephalopathy) and Natalie's death. In Maley v. Secretary, HHS, 1991 WL 80662 (Cl. Ct. 1991), the special master ruled that putative medical malpractice resulting in the vaccinee's death would not "break the chain of causation so as to make this malpractice a factor unrelated to the administration of the vaccine," relying on Restatement (Second) of Torts § 457 (1965). Id. at \*4. The special master awarded full recovery, \$250,000.00, to petitioners in that case.

See also, Allen v. Secretary, HHS, 24 Cl. Ct. 295 (1991), appeal dismissed, No. 92-5028 (Fed. Cir. 1992), in which the Honorable Eric G. Bruggink affirmed a decision that the vaccinee's death was a sequela of HHE, stating, "The result in any given case must depend on whether there is an observable and relatively uninterrupted progression from vaccination, through HHE, to death." Id. at 296. In the instant action, there was an observable and uninterrupted progression from vaccination through unusual somnolence or encephalopathy to death.

Petitioners have prevailed on a theory of on-Table encephalopathy causing death.

#### Significant Aggravation

Petitioners did not allege significant aggravation herein, but it would have been a viable theory for them. Congress defined "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). In order for this court to hold that DPT vaccine significantly aggravated Natalie's CCAM, the undersigned must find that Natalie experienced greater disability, pain, or illness accompanied by a substantial deterioration of health within Table time of the vaccination. The court finds that DPT caused Natalie greater disability by causing somnolence which significantly worsened the effects of her underlying CCAM, causing her breathing ability to deteriorate substantially so that she died.

In, Leary v. Secretary, HHS, 1994 WL 43395 (Fed. Cl. 1994), the special master ruled that DPT caused significant aggravation of a subclinical, i.e., previously undiagnosed, myocarditis, resulting in HHE and death two days post-vaccination. The special master awarded full recovery, \$250,000.00, to petitioners in the case. In Leary, as in the instant action, the vaccine caused a worsening of a condition that until that point had been subclinical.

Petitioners have prevailed on a theory of on-Table significant aggravation causing death.

Petitioners prevail on all three theories: causation in fact (DPT-induced somnolence coupled with CCAM); on-Table encephalopathy with death as a sequela (as in Allen); and significant aggravation of a subclinical disease leading to death (as in Leary).

Petitioners have satisfied their burden and are entitled to an award of \$250,000.00.**CONCLUSION**

The Vaccine Injury Act provides a death benefit of \$250,000.00 to be paid to the decedent's estate. 42 U.S.C. 300aa-15(a)(2). In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

**IT IS SO ORDERED.**

DATE: \_\_\_\_\_

Laura D. Millman

Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §300aa-1 et seq. (West 1991), as amended by Title II of the Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of November 26, 1991 (105 Stat. 1102). For convenience, further references will be to the relevant subsection of 42 U.S.C.A. § 300aa.

2. Although Dr. Shane initially described the cystic changes as limited to the "right lower lobe," the cystic changes were limited to the right middle lobe which he later stated. Tr. at 173.

3. Dr. Adelman stated, "But a baby's lungs are only a few inches wide" although the transcript incorrectly attributes this statement to respondent's counsel, Mr. MacLeod.

4. 42 U.S.C § 13(a)(1)(B).

5. Respondent may object to the undersigned's discussion of causation in fact and significant aggravation, infra, because petitioners did not avail themselves of these alternative theories of recovery. However, the Vaccine Act provides that special masters may adopt practices that are "flexible and informal." 42 U.S.C. §300aa-12(d)(2)(B). Additionally, the legislative history of the Act further provides that the Vaccine Program's purpose is to make awards to "vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. 99-908 (1986) *reprinted in* 1986 U.S.C.C.A.N. 6344.

6. As Dr. Anderson stated during her testimony, "Yes, I wish to God she had a symptom [at the time of shot]...If she had a symptom, we could have cured her." Tr. at 350.

7. One would presume that an encephalopathy which is temporary and results in complete recovery, as described in aforementioned section, would not be compensable pursuant to the Act in contradistinction to an encephalopathy which results in permanent impairment.