In the United States Court of Federal Claims

OFFICE OF THE SPECIAL MASTERS

February 18, 1997

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TROY AND JOY COX, as legal representatives of the estate of RORY COX,

Petitioners,

vs.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

No. 90-1673V
PUBLISHED

Conrad R. Kindsfather, Arvada, CO, for petitioners.
Gabrielle Manganiello, Washington, DC, for respondent.

DECISION

On behalf of Rory Cox (hereinafter, "Rory"), petitioners filed a petition on September 27, 1990 for compensation under the National Childhood Vaccine Injury Act of 1986[1] (hereinafter, the "Vaccine Act" or the "Act"). Petitioners initially alleged that Rory suffered anaphylaxis as a consequence of a DPT vaccination that he received on October 14, 1987, according to the medical records (according to the parents, however, the vaccination was on October 15th), at approximately 8:00 a.m., that led to his death on October 16, 1987 between the hours of 4:30 and 7:30 a.m.

[1] The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-1 et seq. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

Subsequent to amassing evidence in this case, petitioners changed their allegation to on-Table HHE. Later, petitioners alleged an on-Table encephalopathy.

The parents have satisfied the prima facie criteria enunciated in 42 U.S.C.' § 300aa-11(c) of the Act, i.e., that they have not previously collected an award or settlement of a civil action for Rory's death, and that Rory received his DPT vaccination in the United States.

The court heard the evidence in this case initially on July 15, 1994. Testifying for petitioners were Joy Cox, Troy Cox, Dr. T. Edgar Huang, and Dr. Gary L. Trock. Testifying for respondent were Dr. Rita T. Lee and Dr. Virginia Anderson.

Based on that evidence, the court found itself unable to decide this case without further evidence, i.e., on the issue of encephalopathy. The court heard evidence on the issue of encephalopathy on November 26, 1996. Testifying for petitioners were Dr. Mark R. Geier and Dr. Paul Maertens. Testifying for respondent were Dr. Rita T. Lee, Dr. Constance M. Bowe, Dr. Max Wiznitzer, and Dr. Virginia Anderson.

FACTS

The unpaginated medical records show that Rory was born on August 12, 1987. He had right parietal craniotabes (softness of the bone). Med. recs. at Ex. 3.

On September 28, 1987, Mrs. Cox brought him to Dr. Murray Caplan with a complaint of left otitis media. He had been

congested for one week. He had green, thick drainage and coughed night and day. Med. recs. at Ex. 4.

On October 5, 1987, Mrs. Cox telephoned Dr. Caplan to report that Rory had been awake all day and fussy: he had been fussy for two days and seemed really tense. She was concerned that his ears were not healing. The doctor switched him from Amoxicillin to Pediazole. Med. recs. at Ex. 4.

On October 7, 1987, Mrs. Cox telephoned Dr. Caplan to tell him that Rory was vomiting. The doctor decreased the Pediazole dosage by half. Med. recs. at Ex. 4.

On October 14, 1987, Rory returned to the doctor for a recheck of his left otitis media. The doctor noted that his ears were healed and he was eating and sleeping "great." He had finished the Pediazole. The nurse noted that Rory needed to receive his DPT and polio vaccinations. (There are two handwritings on this record, one presumably from the nurse and the other from Dr. Caplan.) When the nurse wrote that Rory needed the DPT and OPV, Dr. Caplan wrote 'Yes. Ears are healed. Go with DPT and OPV and use Tylenol. Back in 2 mos." Then the nurse wrote that she administered DPT intramuscularly in Rory's left gluteus maximus .5 cc. as well as the OPV. Med. recs. at Ex. 4.

The next inscription is dated October 16, 1987. At 8:30 a.m., Dr. Connors from Porter Memorial Hospital Emergency Room contacted Dr. Caplan's office to notify him that Rory was dead. The cause of death was SIDS. The handwriting looks like that of

the nurse. She notified Dr. Caplan and the Children's Hospital SIDS Foundation. Med. recs. at Ex. 4.

Rory had been brought by ambulance at 7:50 a.m. to Porter Memorial Hospital on October 16, 1987. P. Ex. 13 at 1. The ER report states that Rory was a two-month old healthy male found unresponsive in bed that morning. He had been okay at his 4 a.m. feeding. He had been taking Pediazole for otitis. His prior medical history was negative. He had probable SIDS, no signs of trauma. His anterior fontanelle was flat. The diagnosis was cardiac arrest and SIDS. P. Ex. 13 at 2.

In the resuscitation record, the-team leader notes that Rory had an unknown down-time in his crib. He was seen last at 4:00 a.m. and had been on Pediazole for otitis. P. Ex. 13 at 3.

The time of death was inscribed as 8:22 a.m. P. Ex. 13 at 5. A consultation record at 8:40 a.m. notes that the doctor writing the report was asked to assist in the resuscitation. He records a history that Rory was a two-month old male found apneic. At the hospital, resuscitation was continued for ten to fifteen minutes without response. He was pronounced dead. Then the doctor lists six things about which he informed the parents:

1. he discussed the likely cause of death:

2. he told them not to feel guilty; nothing could have prevented it;

3. Rory's death was not subsequent, i.e., due to his recent DPT;

4. an autopsy was important to see if obscure causes might be present (and the coroner might want to do one);

5. Mrs. Cox should hold the body; and

6. he would call Dr. Caplan and inform him. P. Ex. 13 at 7.

On October 16, 1987, the date of Rory's death, the Colorado SIDS Program, Inc. received three telephone calls concerning Rory, two from the Porter Memorial ER and one from Dr. Caplan's office. On that same day, V. Mierau, a SIDS counselor?;: telephoned Rory's maternal grandmother, Laura Fryman, who said that the family was at Dr. Caplan's office. Mr. Cox was feeling very responsible for Rory's death. If he had stayed up after the early morning feeding, Mr. Cox thought Rory would still be alive. Mrs. Fryman had questions about the DPT. Rory had had flu for two weeks and still received the DPT two days ago. He had been on flu medication and Mrs. Fryman wondered if that had caused SIDS. Mrs. Cox worked nights and had come home and found Rory dead while Mr. Cox was asleep. R. Ex. K (unpaginated).

The Denver coroner's office called Marty Leer at the Denver SIDS Program and told him Rory had SIDS. Mr. Leer telephoned and had a long conversation with Mr. and Mrs. Cox on October 16, 1987. He told them the autopsy was completed. Then he discussed with them Rory's having the flu, a cold, the DPT, being wrapped in blankets, why he was blotchy and blue, etc. R. Ex. K.

On that same date, October 16, 1987, Sheila Marguez, R.N., Executive Director of the Colorado SIDS Program, Inc., wrote a letter to Mr. and Mrs. Cox stating that "SIDS affects apparently

normal, healthy, well-cared-for infants. There are no symptoms prior to the death; therefore, it is completely unpredictable and unpreventable." R. Ex. K.

The autopsy report, dated October 16, 1987, diagnosed pulmonary edema and congestion and splenic congestion. Dr. Jill Gould concluded that Rory's death was consistent with SIDS. In the external examination, Dr. Gould stated that Rory was well-developed and well-nourished. The stomach contained approximately 300 cc. of partially digested curdled milky-with light yellow clear fluid. Med. recs. at Ex. 10.

The Coxes continued with the Denver SIDS Program for an extensive period of time. A Family Contact Report dated January 13, 1989 (fifteen months after the initial contact) states that Mrs. Cox telephoned with concern about her new four-month old daughter Courtney who had a cold and whom she was taking to the doctor for an immunization which had been put off since two months. Mrs. Cox stated that Rory died twenty-four hours after his DPT. R. Ex. K.

TESTIMONY

Mrs. Joy Cox testified first for petitioners. Tr. at 9. She stated that Rory had been very healthy until he got a cold and ear infection at the end of September 1987. Tr. at 10. He got better. Tr. at 11. She testified that she saw Dr. Caplan on October 15, 1987. Tr. at 11-12. Rory cried when he received the DPT at 8:00 a.m. and cried all the way home. Tr. at 12-13. She nursed him and he seemed all right. Tr. at 13.

They went home and had breakfast. Id. She took Rory and his older brother to the park at 11:00 a.m. for two hours and they had lunch there. Id. Rory was lethargic, whereas normally he was very active.' Tr. at 14. She checked his color. IL. He was unresponsive, chalky, pasty, and translucent. Id. Rory's older brother Cody did not have problems with DPT. Id. Mrs. Cox was concerned. Id.

Mrs. Cox went home, put Cody down for a nap, and nursed Rory. Tr. at 14-15. He had a high fever. Tr. at 15. Mrs. Cox called her husband and gave Rory Tylenol. Id. She called Dr. Caplan's office at 1:00 or 2:00 or 3:00 p.m. and they said to give him Tylenol and watch him. Tr. at 16-17. Rory did not eat well and he had a chalky color. Tr. at 16. He was not very responsive. Id. He had 102 or 103 degree fever. Id. Rory napped for two hours in the afternoon. Tr. at 43. Mrs. Cox bathed him in the afternoon. Tr. at 32.

This continued through the evening. Tr. at 16. She woke him up to nurse him and he would not eat well. Tr. at 16-17. Normally, Rory nursed every three to four hours. Tr. at 43. She went to bed at 9:00 or 10:00 p.m. and got up at 2:00 a.m. to nurse. Tr. at 17. That evening she kept getting up with Rory because he was fussy. Id. She changed his diaper about two to three times during that day. Tr. at 45. At midnight, Rory 's crying was not uncontrollable. Tr. at 46. His eyes were glassy and he did not respond to her although he would look at her. Tr.

at 49. Later at night, he would look at her but it was like a blank stare. Tr. at 51.

Rory would turn his head when nursing. Tr. at 36-37. He was sweaty. Tr. at 37. He did not respond and there were jerky movements in his hands and arms. Tr. at 37-38. He was crying as if in pain. Tr. at 38. It was a high cry as if he did not want to be touched. Id. He was hysterical for a while. Id. She walked him from midnight to 1:00 or 2:00 a.m. Id.

Mrs. Cox left for work at 2:45 a.m. Tr. at 18. Rory was awake and fussy. Id. He was crying a little when she left for work, but it was not a terrible cry. Tr. at 52-53. He was tossing his head. Tr. at 52. Mr. Cox was sleeping when she left for work. Tr. at 35. She told him Rory was fussy and that there was a bottle in the refrigerator. Id.

Mrs. Cox returned at 7:15 a.m. and found Rory's bassinet had been moved to the living room and Rory was dead. Tr. at 18. She grabbed him and went into the bedroom. Id. Mr. Cox administered CPR. Tr. at 18-19. They went to the hospital, but Rory was dead. Tr. at 19.

They spoke with the chaplain at the hospital. Id. Dr. Caplan, their pediatrician, called them into his office. Id. He said he knew they were thinking it was shot-related. Id. He tried to explain SIDS to them. Tr. at 19-20. Dr. Caplan talked to family members. Tr. at 20.

Mr. Troy Cox testified next for petitioners. Tr. at 54. He was sleeping on October 16th when Rory woke him almost

immediately after his wife left for work. Tr. at 55-56. Rory was crying, screaming, a high-pitched'wailing. Tr. at 56. Mr. Cox got up, picked up Rory, and got a bottle. Id. Rory would not take the bottle. Id. Mr. Cox put him in bed with him, but that did not work. Id. He was up for a couple of hours, walking around, watching television. Id. Rory was pale. Tr. at 57. Mr. Cox carried him on his shoulder, and patted him on the back. Id. Rory stayed the same, upset. Id.

Mr. Cox could not stay up any more. Id. He put Rory in the bassinet and put the bassinet in the living room. Id. Rory had drunk most of the bottle, about three-quarters, which Mr. Cox stated was nine ounces, but Mrs. Cox stated was three ounces since the bottle was four ounces. Tr. 70-71. It took an hour for Rory to drink the milk. Tr. at 72. He sipped and cried. Id. He was yelling, not crying. Id. He would not respond to him. Tr. at 74. Mr. Cox did not turn the light on. Tr. at 76. Mr. Cox put Rory on his stomach and side in the bassinet. Tr. at 59.

Dr. T. Edgar Huang testified next for petitioners. Tr. at 79. He is a pathologist with a subspecialty in neuropathology. Tr. at 80. His opinion was that the most likely cause of Rory's death was pulmonary edema or fluid in the lungs. Tr. at 82. Pulmonary edema can come from shock, anaphylaxis, or hyperthermia (high temperature). Id. Anaphylaxis is a hypersensitivity reaction, but one needs to correlate that diagnosis with clinical symptoms. Tr. at 83.

Dr. Huang stated that he could not form an opinion about the cause of death based solely on the slides. Tr. at 84. Rory could also have had SIDS. Id. Dr. Huang said he could not form an opinion about DPT causing Rory's death, although it was possible. Id. If Rory's clinical symptoms were not improving, DPT possibly caused his death. Tr. at 86. A neurogenic pulmonary edema occurs in people with central nervous system (CNS) problems, but there was no CNS morphology here. Tr. at 90-91. Dr. Huang testified he cannot select any of these causes as the probable cause of Rory's pulmonary edema. Tr. at 92.

He also stated he is not competent to make a clinical diagnosis of probable cause of Rory's death. Id. Dr. Huang did not have the autopsy report, but only the nine slides. Tr. at 93. Rory had moderately severe pulmonary edema, which is more than the pulmonary edema one sees as an agonal event. Tr. at 96. There was no regurgitation. Id. Rory did not have hyperthermia. Tr. at 96-97.

Dr. Gary Trock testified next for petitioners. Tr. at 98. He is a pediatric neurologist. Tr. at 98-99. His opinion was that DPT caused Rory to have HHE which led to shock as the terminal event. Tr. at 102. By listening to the parents, Dr. Trock surmised that Rory had a dramatic change in neurologic status. Id. The pathological findings neither help nor hinder his diagnosis. Tr. at 103.

Known reactions to DPT are paleness (which is non-specific: a variety of processes lead to paleness); inconsolable crying:

and lethargy (which is also non-specific). Tr. at 104-05. His unresponsiveness was not a seizure. Tr. at 105. However, Rory might have seized after Mr. Cox went to sleep. Tr. at 106. Fever is a common occurrence after DPT. Id. Prolonged, inconsolable crying is uncommon. Id.

SIDS is a conglomerate of disorders in which the brain stem shuts down. Tr. at 107-08. This would be unlikely in Rory, who was constantly crying. Tr. at 108. This causes intense brainstem stimulation. Id. If Rory had received DPT vaccine on October 14th, he could not have had anaphylaxis under the situation the parents described. Tr. at 112. If Rory had received DPT vaccine on October 15th, a diagnosis of anaphylaxis would be stretching it. Id. A more common cause of death is HHE. Tr. at 113.

If Rory had shock, it was unwitnessed because it occurred after Mr. Cox put him in the bassinet. Tr. at 118-19. Dr. Trock has never seen a DPT reaction like Rory's. Tr. at 121. Rory had two different syndromes: inconsolable crying and shock. Tr. at 124. The two were reactions to DPT but unrelated to each other. Tr. at 124-25. If Rory did not have shock, Dr. Trock stated he did not know the cause of death. Tr. at 126-27. Similarly, if Rory did not seize, he does not know the cause of death. Id. Dr. Trock has never seen an HHE result in death. Tr. at 129-30.

Dr. Rita Lee testified for respondent. Tr. at 133. She is a pediatric neurologist. Tr. at 134. She stated that

anaphylaxis was not the cause of Rory's death. Tr. at 136. Anaphylaxis is a very intense reaction with rapid onset and can produce death. Tr. at 137. The symptoms are intense itching, redness, swelling, loud wheezing (stridor), possible diarrhea, and occasional cardiovascular collapse. Id. Dr. Lee has seen anaphylaxis in the emergency room on six occasions. Tr. at 138.

Dr. Lee also testified that Rory did not have HHE. Tr. at 140. During the first period of time after his immunization, Rory was pale. Tr. at 142. This is a non-specific finding. Id. He was not described as extremely lethargic and obtund. Id. He opened his eyes and looked at his mother. Id. Neither parent described him as limp. Id.

HHE is pretty dramatic. Id. The parents' description does not match HHE. Id. At midnight, Rory was awake and yelling. He moved around and drank almost a full bottle. Tr. at 142-43. At 4:30 a.m., he did not have HHE. Tr. at 143. If Rory had the vaccination on October 15th, it is awfully late to have HHE twenty-one hours later. Tr. at 143-44. HHE usually occurs within an hour to ten hours of DPT vaccination. Tr. at 144.

There is no evidence for shock collapse: paralysis, loss of muscle tone, limpness. Tr. at 145-46. All Rory's symptoms post-DPT were common reactions except the prolonged screaming which is more than would be expected. Tr. at 148-49. He did not die of prolonged screaming. Tr. at 149. His constant crying was not HHE. Id. The 300 cc. of milk in his stomach at autopsy is a substantial amount (10 ounces). Tr. at 152-53. It meant that

Rory fed well. Tr. at 153. Normally, a two-month old would not have that much milk in him. Tr. at i55. A sick child does not digest food well. Id. Normally, digestion occurs over a three- to four-hour period. Tr. at 156.

Rory had a reaction that was stronger than usual to DPT. Tr. at 160. But there is no logical connection to Rory's having a later, more severe reaction. Id. Prolonged screaming is not a prelude to anything lethal. Id. He did not die from exhaustion. Tr. at 164-65.

Dr. Virginia Anderson was respondent's next witness. Tr. at 169. She is a pediatric pathologist. Tr. at 170. She is also a pediatrician. Tr. at 171. She has twenty-five years of experience and has done 600-700 infant autopsies herself. Tr. at 171. She also supervises residents so the total number of autopsies she has reviewed or consulted on is approximately 2000. Tr. at 172. Her opinion is that Rory did not have HHE. Tr. at 173. Most HHE occurs within ten hours of DPT. Id. She believes Rory's pulmonary edema is an epiphenomenon and not the cause of Rory's death. Tr. at 173-74.

Sixty-three percent of cases of SIDS have pulmonary edema. Tr. at 175. Fifty-one percent of explained (non-SIDS) deaths have pulmonary edema. Id. The edema is either agonal (happened at the instant of dying), or perhaps is a result of leakage of fluid after death. Tr. at 178. Rory was incredibly healthy. Tr. at 180. He doubled his birth weight at two months of age. Id. His tissues were normal. Tr. at 183. Therefore, Dr.

Anderson could not give a cause of death. Id. She stated that Rory had moderate to severe edema in his lungs, which is an incidental finding with no deep meaning. Tr. at 193-94.

Rory's death was sudden, not gradual. Tr. at 195. He had 300 cc. of curdled milk in his stomach. Tr. at 195. For an infant to suck that much milk takes a tremendous amount of effort. Tr. at 196. It would have been impossible for him to have HHE. Id. Dr. Anderson would have expected his stomach to empty in two to three hours, but the nerves in the stomach did not do their job. Tr. at 196-97. Any stress can affect digestion. Tr. at 197.

At the resumption of the hearing on November 26, 1996 on the issue of encephalopathy, Dr. Mark R. Geier testified first for petitioners. Tr. at 245. He is an obstetrical geneticist. Tr. at 247. His opinion is that Rory had symptoms of HHE or encephalopathy, but Dr. Geier prefers encephalopathy. Tr. at 251. Rory was depressed in his interactive environment, i.e., he did not respond to his parents. Id. He had high-pitched, uncontrollable screaming. Id. The autopsy showed his brain weight increased. Id.

Dr. Geier stated there is no pathognomonic autopsy for a DPT death. Id. But, he ascribed the mechanism of Rory's increased brain weight to the effect of endotoxin in the pertussis vaccine which breached the blood-brain barrier (as demonstrated in animal studies) along with pertussis toxin, which is the main poison in the vaccine. Tr. at 251-54. The high-pitched screaming is due

to fluid leaking into the brain, putting pressure on the meninges and causing pain. Tr. at 254. The effect of the poison is that various areas of the brain shut down. Tr. at 255. If those areas involve heartbeat and breathing, the person dies. Id. Rory's failure to react to his environment depicts depressed brain function. Id. Rory died from a neurotoxic reaction to DPT. Tr. at 259. An intramuscular injection such as Rory had always takes at least three hours before the onset of a reaction because it is sporadic and erratic, hitting blood vessels and fat pads. Tr. at 273-74, 276. It lasts a maximum of seven days and probably only five days. Tr. at 277. Rory started exhibiting symptoms within a few hours of vaccination, which waxed and waned and generally got worse. Id.

Rory's brain weight at death was 583 grams. Tr. at 289. (At this point in the hearing, there was an extensive discussion on the significance of Rory's brain weight in which Drs. Anderson and Wiznitzer also participated). Dr. Anderson testified that Rory had an extraordinary growth rate, doubling his weight at two rather than five months which is normal. Tr. at 301. Dr. Anderson also stated his fontanelle was flat indicating no cerebral edema. Tr. at 311.

Dr. Geier testified that Rory's brain weight was off the chart which showed a top limit for a normal brain weight of 506 grams +/- 67. Tr. at 311-12.

Dr. Geier stated that one cannot ever show that a child died from DPT pathologically. Tr. at 336. However, crying beginning

a number of hours after DPT is typical of a reaction. Tr. at 337. Its cause is meningeal irritation. Tr. at 338. Rory did not have massive brain swelling, but his brain weight was high. Tr. at 344. Five minutes before he died, Rory would have had to have been somnolent and difficult to arouse. Tr. at 345. Even without the higher brain weight, Dr. Geier's opinion is that Rory had DPT-encephalopathy. Tr. at 346.

Dr. Paul Maertens testified next for petitioners. Tr. at 352. He is a pediatric neurologist. Id. Something was-going on in Rory soon after his DPT: fever, lethargy, but not coma, some responsiveness. Tr. at 355-56. He progressively got worse. Tr. at 356. In the evening of the 16th, after midnight, Rory became more irritable. Id. He was upset, inconsolable. Id. This was fluctuating, not constant. Id. At 2:00 a.m., his crying was worse to the point where eventually his father put him out of the room. Id.

Rory's early phase was lethargy and then he became more combative. Tr. at 357. In his irritated state, he cried and screamed. Id. Anything could have happened. Id. Rory could have had seizures. Id.

Dr. Maertens testified that Rory's encephalopathy began around or after midnight. Tr. at 359. To a degree, he was encephalopathic earlier. Id. The severity increased over time. Id. Dr. Maertens was not sure of the mechanism of death: seizure, damage to the respiratory center, brain swelling. Id. He was not surprised that the autopsy did not show damage as Rory

had early encephalopathy and a very rapid course without the time to produce pathologic change. Tr. at 360. There was no sign of coma or herniation. Id.

Dr. Maertens stated that with encephalopathy, there is hyperexcitability of the nervous system involved. Tr. at 365. If Rory did not have a seizure, Dr. Maertens would not know what caused his death. Tr. at 369. Rory's brain weight appeared heavy at death, but Dr. Maertens said he was not an expert in brain weights and would trust the pathologist's report. Id.

Dr. Maertens testified that lethargy never kills anyone. Tr. at 371-72. What kills people is coma, which Rory did not have. Tr. at 372. Although the Coxes did not mention any seizures, Dr. Maertens thinks that Rory could have had one, perhaps with his decreased responsiveness. 374-75, 378. SIDS involves a child who was healthy beforehand, and Rory was not healthy. Tr. at 380.

In his opinion, Rory had minor encephalopathy before midnight and a more severe encephalopathy -(based on the severity of crying) after midnight. Tr. at 383. Dr. Maertens testified that a seizure must have occurred while Rory was crying at some undefined time which no one saw. Tr. at 383-84. Highly irritable children will eventually develop seizures. Tr. at 385-86. Rory was not eating at a normal pace. Tr. at 386. He drank three ounces of milk, but his stomach had ten ounces (300 cc.) of milk at autopsy. Tr. at 387. One digests better asleep, but if one is highly stressed or anxious, one does not digest well. Tr.

at 388. Rory could have ingested the milk many hours earlier. Tr. at 389.

Rory's brain weight was only mildly increased if at all. Tr. at 392. He did not have coma leading to death because his brain weight was not increased enough. Tr. at 392-93. In a seizure, however, the brain weight would be only slightly increased, if any. Tr. at 394. He admitted that not all children who die of an unknown cause have a seizure. Tr. at 395.

Dr. Constance Bowe testified for respondent. Tr. at 397. She is a pediatric neurologist with an interest in pediatric peripheral nervous system problems. Tr. at 398-99. She sees fifty to seventy-five patients a year with acute neurological problems, but has never seen a DPT-encephalopathy where that was the clear diagnosis. Tr. at 399.

Dr. Bowe found elements compatible with encephalopathy here. Tr. at 402. With an encephalopathy leading to death, there is an initial loss of balance between inhibitory and excitatory impulses leading to lethargy and irritability. Tr. at.403. It would steadily progress toward decreased responsiveness, and finally evolve into coma where there is no response. Tr. at 403-04.

This is not the sequence that occurred with Rory. Tr. at 404. He had the initial lethargic, unresponsive period. Tr. at 405. This evolved to hyperirritability. Id. However, sixteen hours after DPT, Rory was still able to feed and keep the milk down. Id. In order to suck and eat, Rory's cortical neurons had

to be functioning. Tr. at 406. They would have had to be less functional in order to affect his breathing center. Id. Dr. Bowe was hard-pressed to explain his death. Id.

A seizure is just a hypothesis. Tr. at 406-07. The Coxes did not describe seizure activity: sudden arrest of motor activity, arching, rhythmic movements. Tr. at 407.

Dr. Bowe thought Dr. Geier's explanation most reasonable. Tr. at 408. Intracranial pressure would first manifest., dysfunction in the cortex. Id. It would either lead to a swelling of cells or a poisoning of the cells that control the blood-brain barrier. Id. But Rory had an open fontanelle which could have accommodated increased pressure. Tr. at 409.

Rory's prolonged feeding time may have been due to irritability. Tr. at 410. If he had mild encephalopathy, he might still be able to suck and swallow. Tr. at 411. Dr. Bowe thought that Rory had encephalopathy but not to the degree that would lead to death. Id. The intensity of his screaming would not explain his death. After hours of crying, Rory was exhausted, but exhaustion does not cause death. Tr. at 417.

Dr. Bowe did not think that Rory's jerking motions were seizures because they were not rhythmic. Tr. at 419-20. She could not explain the sequence of symptoms that the parents described. Tr. at 422. The history the parents gave in the Emergency Room was that, as of 4:00 a.m., Rory was feeding and was okay. Id.

In order to link Rory's death to his prior condition, Dr. Bowe would need a description of a progressive loss of function of neurons at various levels of the nervous system. Tr. at 423. DPT changes the permeability of the blood-brain barrier. Tr. at 431. Animal literature is more compelling in showing a relationship between toxins and death since they are more controlled. Tr. at 426. The studies show a steady deterioration and ultimate demise of the experimental animal. Id. Dr. Bowe would expect a cumulative effect of toxins on neurons and would expect to see a steady course. Tr. at 425.

An insult to the brain results in a reorganization of cellular functions to compensate for what is not functioning correctly. Tr. at 427. Waxing and waning of the nervous system is more evident, i.e., increased lethargy followed by more reactivity. Id. One tends to hover between the two. Tr. at 428. People with these symptoms eventually recover. Id.

A fulminating course is different because it is rapidly progressive. Id. One goes from the compromise of higher cortical function to manifesting signs that lower and lower levels of the nervous system are malfunctioning until you get loss of brain stem functioning which is brain death. Id. The brain stem functions include cough reflex, ability to suck, eye movements, and respiration. Id.

Dr. Rita Lee again testified for respondent: Tr. at 437. She opined that Rory did not have encephalopathy. Tr. at 438. There were elements in his condition compatible with

encephalopathy, such as lethargy and screaming, but these are also common in many illnesses. Tr. at 339-40. She did not know why Rory felt bad after his DPT. Tr. at 441. He did react to his DPT, but not encephalopathically. Id.

Dr. Lee stated that she would not expect an encephalopathic child to eat. Tr. at 444. He could have had a mild encephalopathy and fed, but not a diagnosable one. Id. Dr. Lee said she would need a significant change in Rory's consciousness lasting several hours in order to diagnose encephalopat-hy. Tr. at 445. Rory should have showed change in tone and strength, bulging fontanelle, and repeated projectile vomiting. Tr. at 445-46. Rory, instead, had an increase in tone while yelling. Tr. at 450.

Dr. Max Wiznitzer, a pediatric neurologist, testified for respondent. Tr. at 453-54. He sees two acute encephalopathies a week. Tr. at 455. His opinion is that Rory did not have encephalopathy. Tr. at 458. There was no indication in the Emergency Room, the coroner's report, or in the SIDS Program records that Rory had acute encephalopathy. Tr. at 458-59.

Dr. Wiznitzer thought that the parents' testimony was inconsistent with the course of encephalopathy. Tr. at 459. They told the Emergency Room that Rory was okay at his four a.m. feeding and that his past medical history had nothing significant (signified by a zero with a line across it in the'records). Tr. at 461. Moreover, Rory's fontanelle was flat. Id. At the Emergency Room, the parents had a lengthy conversation with Dr.

Connors, who told them that DPT did not kill Rory. Tr. at 461-62. The coroner's report reflects only that Rory fed at 3:30 a.m. Tr. at 467. The ability to feed strongly argues against a diagnosis of encephalopathy. Id.

If Rory's brain had been sufficiently swelled, Dr. Wiznitzer would expect Rory's fontanelle to bulge and for him to progress to'a lethargic state. Tr. at 475. Moreover, the coroner would have seen swelling on autopsy. Id. Rory screamed because he had a DPT reaction. Tr. at 476. The vaccine site hurt. Id. He had a fever and was not sleeping well. Tr. at 478. He was fussy. Id. Dr. Wiznitzer said he did not know why Rory died. Id.

Rory's jerking his arms and crying was not a seizure. Tr. at 486. One cannot cry and seize at the same time. Id. Children can be irritable without having a seizure. Tr. at 487.

Dr. Virginia Anderson testified again for respondent. Tr. at 500. She said there was no evidence pathologically for encephalopathy. Tr. at 501. Irritability leading to lethargy and death would show brain edema and neuronal degeneration. Tr. at 502. Twelve hours is sufficient to have encephalopathy show up pathologically. Tr. at 504.

Rory's brain weight was at the upper limit of normal, but so was his body weight. Tr. at 508. His brain did not have neuronal degeneration. Tr. at 510-11. Rory was found in a prone (on his stomach) position. Tr. at 520. He was full of a huge amount of fluid, i.e., 300 cc. (ten ounces), which is more than

the weight of his liver or of his lungs and heart together. Id. He had a distended abdomen. Tr. at 520-21.

OTHER EVIDENCE

On September 27, 1990, petitioners filed with the petition a report from Dr. Roger M. Morrell where he opined that based on Rory's post-DPT symptoms of lethargy, pallor and irritability, and the autopsy findings, that DPT probably caused Rory's death. P. Ex. 8. Petitioners submitted a supplemental report from Dr. Morrell on May 17, 1991. P. Ex. 17. The report is dated March 27, 1991 and states that because of the temporal relation between the DPT and Rory's death, and the absence of another cause, Dr. Morrell believed it was reasonably medically probable that DPT was the cause. He said the terminal or death-producing event could have been a seizure or shock-like episode. Id.

DISCUSSION

When the court initially heard the parents' testimony, it found insufficient evidence to prove HHE because Rory was not in a shock-like state during the early morning hours of October 16, 1987. On July 19, 1994, the court issued a Report to the Parties in effect encouraging them to settle and finding that, although petitioners had failed to prove HHE, they might succeed on a theory of encephalopathy. For the purpose of the Report to the Parties, the court assumed that Rory received his DPT vaccination on October 15, 1987, as the parents testified, not on October 14, 1987, as the medical records and the record of the Colorado SIDS

Program (after a conversation on the date of death with Rory's maternal grandmother, Laura Fryman) reflect.

The court,, upon review of the entire record, now thinks it more probable that Rory received his DPT vaccination on October 14, 1987. Firstly, to believe otherwise would be to accept that Dr. Caplan's nurse inscribed the wrong date on the medical record, that Dr. Caplan did not correct it, and that Laura Fryman was incorrect when she told the representative of the Colorado SIDS Program on the day Rory died that his vaccination was two days before. At the hearing, Mrs. Cox testified that her mother had to have had a conversation with Dr. Caplan on October 16, 1987 and he must have told her that the vaccination was two days earlier. But the court does not understand why Dr. Caplan, who took such pains to examine Rory's ears to make sure that the otitis media was gone and that he was healthy before accepting his nurse's suggestion that Rory receive DPT on that day, would not remember accurately if his office administered DPT the very day before Rory died.

Moreover, Mrs. Cox stated that she telephoned Dr. Caplan's office on October 15, 1987 to report Rory's reaction to the DPT, yet the medical records do not record her telephone call. Considering that the medical records do reflect telephone calls from Mrs. Cox on October 5, 1987 (Rory was fussy and crying, and awake all day: Mrs. Cox was concerned Rory's ear was not healing) and on October 7, 1987 (Rory was vomiting on the Pediazole; Dr. Caplan decreased the dosage), it seems contrary to the regular

business procedure of Dr. Caplan for his office not to record Mrs. Cox's telephone call on October 15, 1987. In addition, after the October 5th phone call, Mrs. Cox brought Rory in to see Dr. Caplan because Rory seemed really tense. This suggests a concerned pediatric practice. If Mrs. Cox had called on October 15, 1987, it seems that the office similarly would have had her bring Rory in. On October 16, 1987, the nurse did record the telephone call from Dr. Conners concerning Rory's death.

In light of the care and efficiency of Dr. Caplan's office practice and procedure, the court finds it mystifying that Mrs. Cox's telephone call of October 15, 1987 did not find its way into the medical records. The court understands the terrible stress of Rory's death on his parents, particularly on his mother. The parents participated actively in the Colorado SIDS Program for almost three years. Their pain is in every page of the SIDS Program's notes.

But the court finds it more probable that the medical records and the interview of the Colorado SIDS Program. representative with Mrs. Fryman are more accurate as to the date of Rory's DPT vaccination than the parents' subsequent recollection. The first notation in the records that Rory's vaccination was on October 15, 1987, not October 14, 1987, comes in the family contact report of the Colorado SIDS Program, dated January 13, 1989 (fourteen months after Rory's death) when Mrs. Cox stated in a telephone call that she was concerned about

vaccinating her new daughter Courtney at four months because Rory had died one day after DPT.

It is difficult to understand how the Coxes came to believe the vaccination was one day before death, but the likelihood of three people (Dr. Caplan, his nurse, and Mrs. Fryman) being accurate at the time of the vaccination or two days later is greater than the parents, after the most traumatic experience of their lives, being accurate in the very emotional context of risking another child's health.

No doubt Rory had a reaction to the DPT vaccination. He was feverish and irritable. However, he was not in shock and he was able to eat an enormous amount of milk. The court does not believe that Rory had anaphylaxis because of the long interval between vaccination and symptoms or that he had HHE because he was functional (crying, urinating, eating). Dr. Huang's diagnosis of pulmonary edema seems unrelated to Rory's clinical symptoms. Dr. Trock's diagnosis of HHE ignores the fact that Rory was not in shock.

The issue at the second part of the hearing was whether or not Rory had encephalopathy and, if he did, whether that led to his death. The date of his vaccination is not legally relevant (although the issue bears on the credibility of his parents) because Rory's death was either one or two days after vaccination, obviously on-Table.

The Vaccine Act includes a section titled "Qualifications and aids **to interpretation." 42 U.S.C.** § 300aa-14(b). **Subsumed** under that section is **subsection (3)(A), which states:**

> 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,[2] 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 documented by slow wave activity on an electroencephalogram.

The court believes that Rory had unusual crying and irritability. But if his symptoms had been as pronounced as the parents stated at the hearing, surely they would have informed Dr. Connors at the Emergency Room of those symptoms. Instead, the history they gave was that Rory fed at 4:00 a.m. and was okay and that his prior history was not significant.

Obviously, Dr. Connors engaged in a lengthy discussion with the Coxes at the hospital. One of the numerous items of discussion (which he inserted in the hospital notes) was to the effect that the DPT vaccination did not cause Rory's death. This

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[2] One **would presume that an encephalopathy which is temporary and results in complete recovery (as described in the aids to interpretation in section 14) would not be compensable pursuant to the Act in contradistinction to an encephalopathy which results in permanent impairment.**

leads to the inevitable conclusion that the Coxes described Rory's symptoms to Dr. Connors. If they had described a child whose symptoms were markedly severe, Dr. Connors would at least have recorded them'and perhaps have opined an encephalopathy, if not that the DPT vaccine caused the encephalopathy.

The hospital checked Rory's anterior fontanelle. It was flat. Dr. Geier's theory of brain swelling is attractive but the facts of this case do not support his conclusion. Although DPT may indeed cause encephalopathy (see this court's opinion in Misenko v. Secretary, HHS, No. 92-0013V (Fed. Cl. Spec. Mstr. Dec. 7, 1995)), the symptomatology has to show a progressive course downward. In Misenko, the baby's symptoms were confirmed by the ambulance attendant report and showed a gradual decline from irritability, to failure to eat and sleep, to unresponsiveness.

Rory, on the other hand, ate an enormous amount of food. He had trouble sleeping, but he did sleep. He was irritable, but he had previously been irritable when he had left otitis media before receiving the vaccination. In fact, Mrs. Cox had brought him in to see Dr. Caplan because of his ear infection and his tenseness. If she could have been so alarmed by his irritability and tenseness with an ear infection, the court does not doubt that she would have brought Rory in to an emergency room if his symptoms on the morning of October 16th were alarming.

Doubtless, Mr. Cox tried very hard to comfort Rory from 2:30 to 4:30 a.m. on October 16, 1987. But he did not succeed in

quieting Rory and so put him back in his bassinet in the prone position, a position common among SIDS victims. Rory had not digested.the enormous amount of fluid in his system. Whether or not this impeded his diaphragm from functioning was not fully fleshed out at trial. The court does not think that the symptoms that the parents testify about now are sufficient to equal encephalopathy, unless it was an encephalopathy so mild that it could not have caused death.

On the day that Rory died, the Colorado SIDS Program sent a condolence letter to the Coxes as well as to both sets of grandparents. In that letter, the Program states that "SIDS affects apparently normal, healthy, well cared for infants. There are no symptoms prior to the death: therefore, it is completely unpredictable and unpreventable." R. Ex. K (unnumbered).

If Rory had symptoms that were serious enough to cause death, it is inconceivable that the Coxes, on receiving this letter, would not have responded verbally to the SIDS counselors that their baby indeed had symptoms and could not have died of SIDS. The Coxes spoke with the SIDS counselors on October 16th (a long conversation, including the fact that Rory had had flu, cold, the DPT, was wrapped in blankets, etc.), October 17th, October 20th, October 25th, October 27th, November 3rd, November 11th, **etc. With the numerous phone calls recorded and frequent counseling sessions, one would expect that some reference to severe symptoms would be evident, but none is.**

Tragically, when Mrs. Cox found Rory's body on her return from work at 7:30 a.m. on October 16, 1987, she accused Mr. cox of causing Rory's death. She said, "What did you do to him?" over and over. On November 9, 1988, a year after Rory's death, the SIDS counselor notes a telephone call from Mrs. Cox, who had been watching the Oprah Winfrey show on the topic of parents who had killed their children. A doctor on the show indicated that SIDS can hide abuse. Mrs. Cox wanted to send a letter to Oprah Winfrey and discussed this with her SIDS counselor. Apparently, Mrs. Cox was still harboring suspicions about the cause of Rory's death, but not directing her suspicions toward the DPT but toward her husband.

The court has no doubt that Mr. Cox is entirely blameless in Rory's death. What strikes the court is that Mrs. Cox would not have been ready to blame him if Rory's death seemed consonant with his prior symptoms. True, she was not there when he was crying uncontrollably, but she had sat up with him since midnight and been with him the prior afternoon. From the facts of this case, the court agrees with Mrs. Cox that Rory's condition would not have disposed her to think him in dire circumstances. He was not becoming comatose; he was still urinating, looking at her, feeding, and sleeping. She had been with him through pre-vaccination episodes of irritability and tenseness.

This court could rely on Jav v. Secretary of HHS, 998 F.2d 979 (Fed. Cir. 1993), in which the Federal Circuit held that death may substantiate the existence of an encephalopathy. In

Jay, however, the symptoms were far more serious than in the instant action. The child in Jay screamed with pain for six hours after vaccination, slept that night without nursing, was limp, and died the.following morning, eighteen hours after vaccination. The testimony of the parents was not in question.

The Federal Circuit, in two other decisions, established that the mere fact of death may not prove that a vaccine injury occurred. The diagnosis of an on-Table injury must precede the issue of whether or not the injury led to the death. One cannot bootstrap a diagnosis of a Table injury from the fact of death. Hodges v. Secretary of HHS, 9 F.3d 958 (Fed, Cir. 1993) (child died a few hours after vaccination: no one saw any symptoms of alleged HHE, obviating proof of its occurrence): Hellebrand v. Secretarv of HHS, 999 F.2d 1565 (Fed. Cir. 1993)(cardiac and respiratory arrest, i.e., SIDS, do not establish HHE).

Dr. Geier's thesis of a toxic invasion of brain cells is not borne out by the pathology (the coroner did not identify brain edema) and the clinical signs (Rory's fontanelle was flat). Dr. Maertens' assumption of a seizure that no one saw which caused his death is pure speculation. Clinical symptoms of a post-DPT reaction (crying, fever, irritability) do not by themselves establish encephalopathy. Lankford v. Secretarv. HHS, No. 90-2941 (Fed. Cl. Dec. 3, 1996) (systemic reaction to DPT does not equate encephalopathy).

That the Coxes told the Emergency Room personnel that Rory was okay when he had his 4:00 a.m. feeding suggests at the very

least that Mr. Cox did not find Rory's behavior remarkable enough to report to Dr. Connors. The parents' testimony at trial, however, was a depiction of an uncontrollably upset and screaming child. Where the contemporaneous records do not reflect the testimony of the'parents, the court may reasonably find that those symptoms either did not exist or were not as severe as later recounted for the purpose of litigation. Buxkemper v. Secretary, HHS, 32 Fed. Cl. 213, 220-22 (1994); cf. Misenko, supra.

Assuming there was inconsolable screaming and irritability, the court finds they alone do not equate encephalopathy. Thus, either Rory did not have encephalopathy, or his encephalopathy was so mild as not to lead to death. Petitioners have failed to prove a Table injury leading to death.

CONCLUSION

Mr. and Mrs. Cox have suffered the worst tragedy parents can have: the death of their child. Their suffering is recounted in detail through almost three years of notes of the telephone calls and counseling sessions of the Colorado SIDS Program. The court's decision does not lessen the gravity of their loss.

But the court needs to look at all the evidence, both from the parents and their medical experts, as well as the medical documentation and respondent's experts' testimony. Based on all the evidence, the court cannot find that Rory suffered severe, life-threatening symptoms starting the afternoon of his DPT which inexorably led to encephalopathy and death. What the court finds

is a robust child who has a history of ear infections and antibiotic medication who becomes feverish and cranky the day after his DPT vaccination, drinks a tremendous amount of milk, cries uncontrollably, digests poorly, and dies while face down in his bassinet. The court does not know why he died.

This petition is dismissed with prejudice. 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.

DATED: Feb. 18, 1997

Laura D. Millman
Special Master