OFFICE OF THE SPECIAL MASTERS
April 25, 1997

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KATHERINE RENEA BOSCH, as Legal	*	
Representative of the Estate	*	
of JUSTIN BOSCH,	*	
	*	
Petitioner,	*	
	*	
vs.	*	No. 95-0313V
	*	PUBLISHED
SECRETARY OF THE DEPARTMENT	*	
OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

James D. Huegli, Portland, OR, for petitioner.

Vincent Matanoski, Washington, DC, for respondent.

MILLMAN, SPECIAL MASTERDECISION

On behalf of Justin Bosch (hereinafter, "Justin"), petitioner filed a petition on April 25, 1995 for compensation under the National Childhood Vaccine Injury Act of 1986[(1)] (hereinafter, the "Vaccine Act" or the "Act"). Petitioner initially alleged that Justin suffered anaphylaxis as a consequence of a DPT vaccination that he received on May 3, 1993 that led to his death on May 4, 1993. Subsequently, petitioner alleged that DPT caused in fact Justin's death.

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

The court heard the evidence in this case on February 10, 1997. Testifying for petitioner were Katherine Bosch, Richard Bosch, and Dr. William J. Brady, a forensic pathologist. Testifying for respondent were Dr. Archie Hamilton, the coroner who performed Justin's autopsy, and Dr. Virginia Anderson, a pediatrician and pediatric pathologist.

FACTS

Justin was born on December 30, 1992 with acute hypoxia. He was bagged with oxygen for one and a half minutes. Med. recs. at Ex. 5, p. 5. On January 1, 1993, tests for serum calcium and phosphorus were ordered because Justin had grossly excessive repetitive jerking of his arms and legs, and flailing in response to minor stimulation. His deep tendon reflexes were depressed. Med. recs. at Ex. 7, p. 3.

Justin was taken to the doctor on March 3, 1993, and he received his first DPT vaccination on that day at the age of two months. Med. recs. at Ex. 8, p. 5. Justin was taken to the doctor on May 3, 1993 with the complaint of poor sleep and reflux. He received his second DPT vaccination on that day at the age of four months. Med. recs. at Ex. 8, p. 1. He died a day later, on May 4, 1993. Med. recs. at Ex. 8, pp. 1 and 5.

Justin was taken to the Southwest Washington Medical Center Emergency Room on May 4, 1993. A history was given that he was found unresponsive by his parents that morning. He had previously been in good health. Med. recs. at Ex. 9, p. 3. The Outpatient/Emergency Record for May 4, 1993 notes that Mr. Bosch, Justin's father, found him under the covers at about 5:30 a.m., pulseless and apneic. He had last seen him at 10:00 p.m. the prior evening. Justin had a history of frequent emesis (vomiting). Med. recs. at Ex. 9, p. 4.

Dr. Archie Hamilton performed an autopsy on May 4, 1993 and concluded that the cause of death was Sudden Infant Death Syndrome (SIDS). Justin had acute passive hyperemia and edema of the lungs with petechial hemorrhages. He had petechial hemorrhages of the thymus and epicardium. Med. recs. at Ex. 10, p. 1. Justin's death certificate, dated May 5, 1993, lists SIDS as the cause of death. Med. recs. at Ex. 11.

Deputy Coroner Brian Miller filled out a Clark County Coroners Report Form on May 4, 1993 at 8:00 a.m. after having arrived at the hospital ER and spoken with Richard Bosch, who told him that Justin was put down for the night at about 10:00 p.m. and was heard during the night making his usual sounds. At 5:30 a.m., Mr. Bosch awoke and went into Justin's room, finding him unresponsive. He drove Justin to the hospital, which was near his home.

Deputy Coroner Miller then called Justin's pediatrician, Dr. Alison Kirby, who stated that Justin had pneumonia after birth, but this had cleared up. Justin was brought in for his four-month check up and vaccinations. She would file a report with the drug company, although she did not believe the DPT caused Justin's death. R. Ex. I.

On May 4, 1993, Dr. Kirby filled out a Vaccine Adverse Event Reporting System (VAERS) form. There was a history of Justin having mild gastroesophageal reflux. Justin did not have an intercurrent illness at the time of his vaccination. He was found dead in bed the next morning in the prone position. P. Ex. 1.

TESTIMONY

Katherine Bosch testified first for petitioner. Tr. at 5. Justin was her first boy. Tr. at 8. She has five children. Tr. at 6. Justin had been hospitalized for pneumonia at six weeks. Tr. at 8. He was very healthy and happy before his first DPT vaccination. Id. He did not have a reaction to the first DPT. Tr. at 9. After the second DPT on May 3, 1993, at 11:00 a.m., he began to run a fever and get fussy at noon. Tr. at 9-10. He had not been a fussy child previously. Tr. at 10.

Justin's vaccine site was red, tender, and swollen. Id. Justin did not want to be put down. Id. He had a high-pitched scream as if in pain. Id. However, he was consolable at times. Id.

Prior to the second DPT, Justin was a healthy eater. Tr. at 11. He had gained five to six pounds since

birth. Id. He was breastfeeding. Id. After noon on May 3, 1993, Justin would not eat at all. Id. Mr. Bosch returned from work at 5:00 p.m. Id. They could get Justin to stop crying, but only temporarily. Tr. at 11-12.

In the evening, Justin was hot to the touch. Tr. at 12. Mrs. Bosch gave Justin liquid Tylenol. Id. He was crying, irritable, and inconsolable. Id. Mr. Bosch went out with their eldest daughter and returned at 10:00 p.m. Tr. at 12-13. Mrs. Bosch gave Justin Tylenol every four hours. Tr. at 13. He was still hot, although she did not take his temperature. Id. She put Justin to bed at about 11:00 p.m. Tr. at 14.

Justin did not normally sleep through the night, usually waking every four hours. Id. They had been speaking to the doctor about letting him cry himself to sleep. Id. She put Justin on his side. Id. He would spit up a lot and she did not want him to choke on his spit. Tr. at 14-15. Then, she went to bed. Tr. at 15.

At 2:30 a.m., Justin started to cry. Id. It was high-pitched, as if he were in pain. Id. She waited until he stopped crying and did not go into his room. Tr. at 15-16. At 5:30 a.m., her husband got up and brought Justin into their room, saying something was wrong with him. Tr. at 16. She screamed. Id. Mr. Bosch took Justin to the hospital while she stayed at home with the girls. Tr. at 17. He telephoned her from the hospital. Id. Mrs. Bosch stated that no one from the coroner's office spoke to her. Id.

When asked on cross-examination if she had changed Justin's diaper after his receipt of the second DPT, Mrs. Bosch said that she had. Tr. at 18. He was irritable. Tr. at 19. He arched his back when crying. Tr. at 20. His cry was louder than usual. Id. She tried to feed Justin all day. Tr. at 21. She used her breast pump because Justin was not eating. Tr. at 22. She found a little clear spit on Justin's sheet that morning. Tr. at 21-22.

Richard Bosch, Justin's father, testified next for petitioner. Tr. at 26. Justin was a very healthy baby who developed quickly. Tr. at 27-28. His hands and feet were big. Tr. at 28. On May 3, 1993, Justin was crying, fussing, inconsolable, and in pain. Tr. at 28. He was not interested in eating. Tr. at 29. He would be okay for a few minutes and then begin to cry again. Id. Normally, they laid him at a forty-five degree angle because he spat up a lot. Tr. at 29-30.

Mr. Bosch slept through Justin's crying at 2:30 a.m. Tr. at 30. At 5:30 a.m., he went into Justin's room and found his head under the covers and his fists clenched. Id. Justin was not breathing and his body was rigid. Tr. at 30-31. He took Justin to the hospital two blocks away. Tr. at 31. The doctors said it was SIDS. Id. No one got a history of the events. Id.

Mr. Bosch testified that he was home on May 3, 1993 only for a brief time. Tr. at 33. He took his daughter out to dinner at 5:30 or 6:00 p.m. and did not return until 10:00 p.m. Id. He went out because he did not think Justin was sick enough that he should change his plans. Tr. at 42.

When he returned, Justin was on the floor on a blanket on his back, fussing. Tr. at 33. He had normal color. Tr. at 34. He kicked his feet and hands. Tr. at 33. Mr. Bosch prayed with Justin usually. Tr. at 34. He thinks he did at 11:00 p.m. Id. Justin looked at him when he talked to him (the same with Mrs. Bosch). Id. Mrs. Bosch did not call the pediatrician on May 3, 1993. Tr. at 43.

When he found Justin the next morning, the covers were partially over his head. Tr. at 35. He had not put him down that way. Id. Justin had balled himself up and was on one side in the fetal position. Tr. at 35-36. He was pale. Tr. at 36.

Dr. William J. Brady testified next for petitioner. Tr. at 45. He is a forensic pathologist, in court

frequently. Tr. at 46. He does 250 autopsies a year. Tr. at 46-47. A SIDS death is not uncommon. Tr. at 49. It is the sudden and unexpected death of a previously healthy child. Id. You start off with a death scene investigation. Tr. at 51. There was none done here. Tr. at 52. It is fundamental to talk to the parents to find out what happened. Tr. at 51.

No tissue was saved and no microscopic slides were made or examined in this autopsy. Tr. at 52-53. To diagnose SIDS, Dr. Brady said one must have a competent and thorough autopsy. Tr. at 53. Here, the autopsy without microscopic sections and tissue does not meet accepted standards. Id. Moreover, Justin was not healthy before he died. Tr. at 56-57.

Dr. Brady's opinion is that DPT caused Justin's death from fatal shock collapse. Tr. at 57. The basis of his opinion is that Justin was healthy, active, and normal prior to the second DPT vaccination. Tr. at 59. After the DPT, he had a reaction. Id. There is a reasonable, solid, temporal relationship between DPT and fever, fussiness, lack of appetite, crying, and late bedtime (11:00 p.m. vs. 9:00 p.m.). Id. Also, Justin had swelling and redness. Tr. at 60.

If Justin had not died, his vaccine reaction would not be uncommon. Tr. at 63. DPT reactions range from none to fatal shock collapse. Id. Justin's body reacted to foreign material. Tr. at 64. He entered into shock between 2:30 a.m. and 5:30 a.m. on May 4, 1993. Tr. at 64-65.

Justin demonstrated physical reaction to the DPT: swelling, pain, redness at the vaccine site, fever, loss of appetite, intense discomfort (crying). Tr. at 65-66. DPT toxin produces a physical reaction. Tr. at 66. There is a biochemical reaction from the sudden situation in which the protein reaction has progressed to cause expansion and dilation of the blood vessels to the extent that the heart cannot maintain a normal pressure. Tr. at 67. The lungs and other internal tissues are filled with blood which is not circulating. Id. It has flowed into the inter- and intra-cellular spaces, causing sudden fatal collapse. Id.

Dr. Brady did not know why Justin did not react to the first DPT vaccination two months earlier. Tr. at 68. He was sensitized to protein, analogizing to anaphylaxis. Id. Justin's lungs were hemorrhagic, whereas a normal lung is dry. Tr. at 69-70. Dr. Brady believes the liver was congested because the lungs were congested. Tr. at 70-71. There was not a prolonged delayed building up of tissue change. Tr. at 76.

Dr. Brady's opinion was that Justin had clear evidence of shock at his death. Tr. at 87. The clinical manifestation of shock is paleness, inactivity, and poor attention focus. Tr. at 88-89. No one saw Justin go into shock. Tr. at 89-90. Justin did not die from aspiration. Tr. at 89. DPT has a toxic effect on a child. Tr. at 90. Diphtheria bacteria has toxin. Tr. at 91. Dr. Brady could not pick among the proteins in the diphtheria, pertussis, and tetanus components of the vaccine as to which affected Justin. Tr. at 92. There have not been any toxin-related cases to diphtheria in fifty years, according to the Institute of Medicine. Tr. at 93-94.

Dr. Archie Hamilton testified for respondent. Tr. at 130. He is the coroner who performed the autopsy on Justin. Tr. at 133. He is the former president of the Clark County Medical Society and former president of the Oregon Pathology Association. R. Ex. J. He has also been an instructor in forensic medicine. Id.

Dr. Hamilton said that he never heard what the parents testified to in court before. Tr. at 134. Brian Miller was a senior investigator. Tr. at 135. He went to the hospital at 7:00 a.m. and interviewed Mr. Bosch. Tr. at 136. (Mr. Bosch did not remember talking to Deputy Coroner Miller.) Tr. at 142. Dr. Hamilton stated that the incidence of SIDS in the county changed when parents no longer put their babies to sleep on their stomachs. Tr. at 143.

Justin did not have any lividity. Tr. at 147. There were no marks, not even a sign of vaccine irritation at the site. Tr. at 147-48. Justin was not dehydrated. Tr. at 148. Dr. Hamilton did not see anything abnormal. Tr. at 149.

There was no sign of shock or infection in Justin. Tr. at 150. The blood in Justin's lungs is characteristic of SIDS. Tr. at 153. There is a different pattern in shock: most fluid is confined to the lower lobes of the lungs and is not in the apex. Tr. at 155-56. In Justin's lungs, the blood was blotchy, cyanotic, and segmental. Tr. at 155. There was no edema of Justin's liver or spleen. Tr. at 157-58.

Because nothing was abnormal on gross examination, Dr. Hamilton did not do a microscopic examination. Tr. at 161. He did take blood and tissue samples and stored them for one year. Tr. at 149, 160.

If Justin had reacted to a foreign protein, he would have followed an absolute pattern. Tr. at 162. An enterotoxin causes an immediate reaction; it does not sit around for twelve to eighteen hours. Tr. at 163. Dr. Hamilton has not seen a baby die from shock. Tr. at 165. In the case of enterotoxin, there would be a short onset, and a violent reaction. Tr. at 166. Dr. Hamilton never considered anything besides SIDS in this case. Tr. at 166-67.

On cross-examination, Dr. Hamilton admitted that his autopsy stated Justin was uncircumcised, but he was circumcised. Tr. at 173. Dr. Hamilton stated he does not know what a child would look like if he died from DPT. Tr. at 185.

Testifying next for respondent was Dr. Virginia Anderson. Tr. at 199. She has done 2,000 autopsies on infants directly. Tr. at 200. She trains pediatric pathologists. Id. She practiced pediatrics for twenty years. Tr. at 201. The symptoms of a child in shock are limpness, ashenness, rapid and thready pulse, difficulty in arousing, and a problem with peripheral perfusion. Tr. at 201-02. The parents' testimony does not describe shock. Tr. at 202. Justin was irritable, fussy, anorexic, but in contact with the environment. Id.

There are several types of shock. Id. Anaphylaxis is a massive release of histamine, which affects vasomotor tone and takes twenty minutes. Tr. at 203-05. Shock is a loss of blood pressure. Tr. at 206. There is no evidence of shock here clinically. Tr. at 206-07. Any blood in Justin's lungs is a function of the death process itself. Tr. at 207-08. Progressive shock leads to organ damage which would be seen on gross examination, but was not here. Tr. at 210-11.

DISCUSSION

Petitioner does not allege a Table injury (although initially she did). She alleges that DPT caused in fact Justin's death. To satisfy her burden of proving causation in fact, petitioner 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); Strother v. Secretary of HHS, 18 Cl. Ct. 816, 818 (1989), aff'd mem., 950 F.2d 731 (Fed. Cir. 1991). Petitioner's expert's opinion must be "supported by a sound and reliable medical or scientific explanation." Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994).

"[E]vidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149.

As Dr. Brady testified, no one saw Justin in shock, if indeed he was in shock. The only clinical

symptoms that Mr. and Mrs. Bosch saw were typical of a DPT reaction: fever, fussiness, crying, and refusal to eat. But Justin was still able to make eye contact, and capable of falling asleep at 11:00 p.m. Dr. Brady stated that if Justin had not died, he would not have expected these symptoms to have led to his death.

Although Dr. Brady stated that Justin's autopsy indicated shock, both the coroner who performed the autopsy and respondent's expert disagreed. This is truly a battle of the experts except for Dr. Hamilton, whose involvement predates litigation. Dr. Hamilton would have no reason to have concluded Justin's death was from unknown causes, that is, SIDS, except for finding that there was nothing abnormal or pathological in his autopsy to which he could ascribe a reason.

The absence of a reason other than DPT for the cause of death is not legally sufficient. Grant, 956 F.2d at 1149. Dr. Hamilton's statement that Justin's lungs would have been heavy with blood only in the bottom of the lobes, rather than uniformly throughout, if he had died of shock is perhaps the only pathologic evidence contrary to petitioner's theory. However, there is no affirmative credible evidence pathologically that Justin died of shock. The toxin theory is attractive, but there is no proof of it either pathologically or clinically.

The clinical symptoms that Justin suffered were not deemed serious enough to keep Mr. Bosch home. Instead, he took his daughter out and did not return until 10:00 p.m. Justin did not have any trouble making eye contact. He was consolable at times. He was capable of falling and staying asleep.

When Deputy Coroner Miller interviewed Mr. Bosch at the ER (an interview Mr. Bosch does not recall), Mr. Bosch did not inform Mr. Miller that Justin had experienced anything untoward the evening before he died.

Dr. Hamilton stated that a child who experiences fatal shock should have the onset before the eighteen hours that would be the case here if Justin indeed had shock between 2:30 and 5:30 a.m., having been inoculated at noon on the prior day.

What the court is left with is a child with typical post-DPT symptoms of crying, fussiness, anorexia, and fever who inexplicably dies the next morning. According to petitioner's expert Dr. Brady, he went into shock at the time that no one saw him. Dr. Brady also said that Justin's organs would have shown shock if a microscopic examination had been performed, and the autopsy was deficient without a microscopic examination (but not so deficient that Dr. Brady was unable to testify that it showed shock).

Dr. Hamilton testified that he did not perform a microscopic examination because there was nothing abnormal about the organs on gross examination. Although he did not accurately describe Justin's circumcision status in the autopsy, there is no reason for the court to assume that everything Dr. Hamilton did and saw was incorrect. Dr. Hamilton is apparently highly respected by his colleagues since they made him president of the local medical society and of the state pathology association. He also teaches forensic medicine. He apparently does not make a living as an expert witness. The court finds him believable and believes as well that Deputy Coroner Miller took a thorough history from Mr. Bosch. The court has the impression that Dr. Brady was hired to perform a job--testify that DPT caused Justin's death--and he has performed that job in the absence of any evidence except the act of vaccination and the occurrence of death. In between were ordinary, normal, post-vaccinal symptoms.

It is extremely disturbing for a parent not to have a reason for a tragedy such as this. Considering that Justin died one day from his inoculation makes DPT understandably suspect. But the court needs proof of illness sufficient to cause in fact that death and medical expertise that can explain in a logical and

reliable way how the vaccination caused the death.

In this case, neither the clinical symptoms nor the pathologic findings lead to any known cause of death, much less DPT. Dr. Hamilton did not even notice a red or swollen vaccine site. Mrs. Bosch never called the pediatrician to report on Justin's condition after the vaccination. The supposed severity of the vaccination and its aftermath are not well-founded. Based on the lack of evidence of the means of Justin's death, the court must conclude that petitioner has failed to make a prima facie case of causation in fact.

CONCLUSION

Mr. and Mrs. Bosch have suffered a terrible tragedy. Its cause is a mystery medically. Neither Justin's clinical symptoms nor the autopsy's pathological findings indicate that DPT caused in fact Justin's death.

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: _____ _____

Laura D. Millman

Special Master

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.