OFFICE OF SPECIAL MASTERS

November 15, 2001

JOSHUA GUERRA, a minor, and MARIA CRISTINA VELIZ, his natural mother,	*	
Petitioner,	*	No. 00-535V **PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Sina Negahbani and George M. Nachwalter, Miami, FL, for petitioner.
Ann K. Donohue, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On September 5, 2000, petitioner filed a petition on behalf of her son, Joshua Guerra (hereinafter, "Joshua"), for compensation under the National Childhood Vaccine Injury Act of 1986[1] (hereinafter the "Vaccine Act" or the "Act"). Petitioner has satisfied the requirements for a

[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.

prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) she has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine injury; and (2) DPT vaccine was administered to Joshua in the United States.

Petitioner alleges that Joshua's DPT caused him on-Table anaphylaxis and, in the alternative, was a substantial factor in causing or significantly aggravating Joshua's hypoagammaglobulinemia.[2] Respondent denies that Joshua had on-Table anaphylaxis and that DPT caused or significantly aggravated his hypoagammaglobulinemia. Moreover, respondent contends that even if Joshua suffered a vaccine injury, its sequelae did not last more than six months as the statute requires.

The court held a hearing in this case on August 23, 2001. Testifying for petitioner were Maria Cristina Veliz, Mercedes Garcia, Maria Elena Gonzalez, and Dr. Michael Geraldi. Testifying for respondent was Dr. Melvin Berger.

FACTS

Joshua was born on June 1, 1997. At the age of three months, on September 2, 1997, he received his first DPT vaccination, as well as vaccinations against HiB, polio, and hepatitis B. Med. recs. at Ex. 3. He was taken to Baptist Hospital two days later, on September 4, 1997, at 11:27 a.m., with respiratory rupture, pneumothorax, and pneumomediastinum. Med. recs. at Ex. 4, p. 2. The admission note of September 4, 1997 states that he had a history of sudden respiratory distress since the prior night (September 3, 1997). Med. recs. at Ex. 4, p. 8. The

[2] At the hearing, petitioner's counsel also alleged that Joshua had suffered a vaccine injury under subsection VI of 42 CFR 100.3, which deals with polio. The undersigned called petitioner's counsel's attention to the fact that the vaccine injury under this subsection requires the vaccinee to have contracted polio, which Joshua did not. Petitioner withdrew the allegation. Tr. at 6.

history Ms. Veliz gave on September 4, 1997 was that he was well until the prior day, September 3, 1997. Med. recs. at Ex. 4, p. 26.

Also on September 4, 1997, Ms. Veliz gave a history to Dr. Kunjana Mavunda that Joshua's sister had had a viral illness diagnosed by a pediatrician ten days earlier and Joshua had had his immunizations two days prior to admission. Med. recs. at Ex. 4, p. 33.

Joshua was seen in consultation with Dr. Antonia R. San Jorge the next day, September 5, 1997. Ms. Veliz gave a history that, five days previously, Joshua's two-year-old sister broke out with a rash without fever which had since resolved. After Joshua's vaccinations, he was a little bit cranky, but did not have fever, vomiting or diarrhea. He started coughing two days previously (September 3, 1997) and had increased congestion with decreased oral intake. That morning, he was very irritable, had respiratory distress, and was breathing very hard. He went from his local medical doctor to the emergency room. Joshua was afebrile and extremely ill, with a flat fontanelle. Med. recs. at Ex. 4, p. 28.

TESTIMONY

Maria Cristina Veliz, Joshua's mother, testified first. Tr. at 9. Joshua had a cold at the time he was vaccinated. Tr. at 35. Ms. Veliz testified that about one and one-half hours after the vaccinations, Joshua had fever and difficulty breathing. Tr. at 14. He was wheezing, did not want to eat, and his skin was becoming dark. *Id.* He had a fever of 102.2° F. Tr. at 15. She gave him Tylenol and his temperature went down to normal. Tr. at 16. The wheezing continued. Tr. at 18. In the evening of September 3, 1997, she called the doctor who told her to take him immediately to his office. Tr. at 19. Dr. Martinez, her pediatrician, speaks Spanish. Tr. at 38.

The EMTs were called to take Joshua to the hospital. Tr. at 20. Joshua was purple, could not breathe, was lethargic, and looked as if he were dying. Tr. at 21.

When Ms. Veliz came to the hospital, her friend Idania was waiting for her and translated for her and the doctors. Tr. at 35. The staff put Joshua in an oxygen chamber. Tr. at 21. Joshua was in the hospital ICU for 21 days. *Id.* Ms. Veliz stayed in the hospital with him. *Id*. He could have died at any time. Tr. at 22. When he came home, he started improving a great deal under treatment. *Id.* He still receives gamma globulin three times a week. Tr. at 35. Before Joshua became ill, his sister had a rash from an allergy. Tr. at 24.

Mercedes Garcia testified next for petitioner. Tr. at 39. She rented a room from Ms. Veliz in September 1997 and saw Joshua on the day he received his DPT vaccination. *Id*. He was quite alert and his skin color was good. *Id*. He had a routine cold. *Id.* When Ms. Veliz and Joshua returned from the doctor, Joshua was agitated, he had a high fever, and his skin was purple. Tr. at 43. Joshua made a noise with his throat like a cat. *Id*. He did not want to drink milk. Tr. at 44. It seemed as if he could not swallow. *Id*. Ms. Garcia asked Ms. Veliz what was wrong with Joshua, and Ms. Veliz thought this was a normal reaction to the vaccinations. *Id.* Ms. Veliz tried to give Joshua milk, but he would not take it. *Id.* She gave him Tylenol, which came up again and he became more agitated. Tr. at 44-45. Joshua looked purple or cyanotic to her. Tr. at 45. He would drink small amounts of milk. *Id*. Joshua's sister had a rash like measles but was not ill. Tr. at 46. Joshua's symptoms got worse by the hour. Tr. at 48.

Maria Elena Gonzalez testified for petitioner. Tr. at 152. She was at work. Tr. at 154. Joshua's sister Ana had a rash but Ms. Gonzalez does not remember what it was. Tr. at 162. Ana was given Benadryl. *Id.* Joshua had a little cold when he went for his vaccinations. Tr. at

154. He came home with a fever and was breathing through his mouth because his nose was congested. Tr. at 155. Ms. Veliz gave him Tylenol and suctioned his nose. Tr. at 155-56. Ms. Gonzalez got home from work at 5:30 p.m. and his condition worsened. Tr. at 154. That night, Joshua would not eat. Tr. at 156. On September 3, 1997, Joshua had fever on and off. *Id.* At the hospital, Ms. Veliz was hysterical. Tr. at 157. Idania was there to translate for her before Ms. Gonzalez arrived. *Id.* Joshua was transferred to Miami Children's Hospital. Tr. at 158. Today, he is less active. Tr. 160-61.

Dr. Michael Geraldi testified for petitioner. Tr. at 49. He is not board-certified in any specialty. Tr. at 55. He has practiced for 26 years as a pediatrician and has a special interest in Down's syndrome, having adopted 16 children with Down's syndrome and starting a foundation for those with this disease. Tr. at 50, 51 and 52. He has had two other patients with hypoagammaglobulinemia in his practice. Tr. at 57. They did not react to DPT vaccine but were born very sickly. Tr. at 58. They were not given vaccines until later in life. *Id.* Joshua was probably born with his condition. *Id.*

Dr. Geraldi saw Joshua twice: one and one-half years ago and recently for a general check-up. Tr. at 59. Joshua is doing quite well. *Id.* He is not getting gamma globulin, but has antibiotic therapy (Amoxicillin) and Bactrin. *Id.* Dr. Schiff, an immunologist, is treating Joshua. Tr. at 59.

Dr. Geraldi's opinion is that Joshua suffered an anaphylactoid reaction to DPT vaccine. Tr. at 62. Joshua's congestion and pneumonia were due to his cold, but the DPT made him worse. Tr. at 64-65. "Hypoagammaglobulinemia" means that Joshua has less gamma globulin.

Tr. at 67. Dr. Geraldi does not know if he was born with this condition. *Id.* By three to six months of age, a baby's maternal antibodies disappear. Tr. at 68.

Dr. Geraldi testified that DPT's significant aggravation of Joshua's condition was over when Joshua was cured of his pneumonia.[3] Tr. at 71. The treatment that Joshua received was oxygen and a saline aerosol, appropriate for pneumonia. Tr. at 76-77. It is not treatment for anaphylactic shock, which would be adrenaline and antihistamine. Tr. at 74-75.

Dr. Geraldi stated he is not a pediatric immunologist and has not published articles in peer-reviewed journals. Tr. at 72, 73. In 1991, he received a reprimand from the State of Florida for failing to practice medicine with appropriate care because of his prescribing Percoset and Percodan. Tr. at 73.

Dr. Geraldi said that one of the reasons for his opinion of causation in fact is the time factor. Tr. at 65-66. Another reason for his opinion is that Joshua was significantly sick after receiving DPT. Tr. at 66. He does not know if Joshua were born with or acquired hypoagammaglobulinemia. Tr. at 67. In 26 years of practice, he has not had a pneumocystis carinii case except in children with immunologic compromise. Tr. at 57-58.

Dr. Melvin Berger testified for respondent. Tr. at 80. He is a pediatric immunologist who is board-certified in allergy and immunology. Tr. at 82. He is a professor at Case Western and Director of the Board of Allergy and Immunology. Tr. at 82. The US Army recognizes his expertise. Tr. at 83. He is also co-chairman of recertification. *Id.*

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[3] This statement of Dr. Geraldi defeats petitioner's claim since Joshua was cured of his pneumonia before six months had elapsed since the onset of his illness.

In his professional practice, Dr. Berger has 75 patients now with agammaglobulinemia and hypoagammaglobulinemia. Tr. at 83. In his career, he has seen 100 patients with these conditions. *Id*.

Dr. Berger's opinion is that Joshua did not have anaphylaxis after his vaccinations. Tr. at 85. Anaphylaxis is an acute, severe, life-threatening condition. *Id*. The patient has red skin, usually hives, low blood pressure, and shock. *Id.* The patient gets better in time unless he dies. *Id.*

After his vaccinations, Joshua got worse by the hour. Tr. at 85. He already had pneumocystis carinii (which he contracted from airborne exposure). Tr. at 86. DPT did not significantly aggravate his pneumocystis carinii. *Id.* Joshua's case of pneumocystis carinii was typical. *Id.* He had congestion, cough, and thrush. Tr. at 87.

With maternal antibodies, the half-life of IgG is 22 to 28 days. Tr. at 86. At one month of age, he would have 500 IgG. *Id.* At two months of age, he would have 250 IgG. *Id.* At three months of age, he would have 125 IgG. *Id.* At three months of age, his IgG was 174, showing he had hypoagammaglobulinemia. Tr. at 86.

DPT does not significantly aggravate hypoagammaglobulinemia. Tr. at 86. Others with hypoagammaglobulinemia have not have significant aggravation after receiving DPT. Tr. at 89. A normal child would produce antibodies to DPT vaccine, but a child with hypoagammaglobulinemia would not. Tr. at 91-92.

Joshua's pneumocystis carinii produced his symptoms of tachypnea (fast breathing) and dyspnea (difficulty breathing). Tr. at 94-95. His cold was a subacute presentation of his

pneumocystis carinii. Tr. at 95. He was subacute for one to two days. Tr. at 96. His cyanosis (dark purple skin) was caused by pneumocystis carinii. Tr. at 99.

If Joshua had had anaphylaxis, his skin would have been red and he would have had hives. Tr. at 99. He also would have had low blood pressure. Tr. at 98. Irritability has nothing to do with anaphylaxis. Tr. at 101. Moreover, anaphylaxis is systemic with symptoms in different parts of the body. Tr. at 102. This is not what happened to Joshua. *Id.* He had progressive respiratory problems with secondary effects. *Id.* His subacute infection progressed over two days to systemic problems. *Id.* Anaphylaxis lasts a few hours, not two days. Tr. at 104.

Dr. Berger stated that DPT would not significantly aggravate hypoagammaglobulinemia or agammaglobulinemia, conditions in which someone fails to produce antibodies. Tr. at 108. DPT does not induce failure to produce antibodies. Tr. at 109.

Someone can acquire hypoagammaglobulinemia. Tr. at 109. Dr. Berger cannot say when or why Joshua failed to produce sufficient antibodies. Tr. at 110. Nothing in DPT decreases antibody production. DPT does not cause pneumonia. Tr. at 114. Pneumocystis carinii occurs in 75 percent of children without symptoms. Tr. at 115.

At three months of age, Joshua had a 174 IgG level. Tr. at 115. His maternal immunoglobulin was decaying at a normal rate. *Id.* Joshua's failure to produce antibodies on his own was going on for months, not days. *Id.* He does not have an x-linked hypoagammaglobulinemia. *Id.* Dr. Berger does not know what causes someone to acquire hypoagammaglobulinemia or when Joshua acquired his hypoagammaglobulinemia. Tr. at 116-17. At three months, Joshua's IgG level should have been at least 400, not 174. Tr. at 127. What is needed for protection at that age is 400-500 mg/dl. *Id.* A normal adult has 600-1200 mg/dl

(which is what a baby is born with). Tr. at 128. Joshua did not make the additional immunoglobulin to take up the required amount when his mother's maternal antibodies declined. Tr. at 131.

When asked why Joshua did not manifest hypoagammaglobulinemia at two months when he had a viral upper respiratory infection and a cough on August 5, 1997, Dr. Berger responded that Joshua was not exposed to pneumocystis carinii at that time and had a lower IgG at the age of three months. Tr. at 132, 135-36.

Joshua had pneumonia the day before he received his DPT vaccination. Tr. at 136. After he became seriously ill, Joshua was treated with aerosol and oxygen, the treatment for pneumonia. Tr. at 144. If he had had anaphylaxis, he would have been treated with adrenaline and antihistamine. Tr. at 141.

DISCUSSION

The court finds Dr. Berger's testimony much more credible than Dr. Geraldi's. Firstly, Dr. Berger is a pediatric immunologist, board-certified in allergy and immunology, as well as in pediatrics. (R. Ex. B.) He is the Chief of the Allergy/Immunology/Rheumatology Division of the Department of Pediatrics at Rainbow Babies and Children's Hospital. He is also a professor of pediatrics, general medical science, oncology, and pathology. In 1998, the US Army Surgeon General awarded Dr. Berger the highest proficiency designation in allergy-clinical immunology. He is on the Ohio State Medical Board. He is an ad hoc reviewer for eight peer-reviewed journals. He has chaired a symposium on neonatal infections and the role of immunotherapy. He was a director of the American Board of Allergy and Immunology from 1996 to 2001. He has

published studies and given talks and courses on immunodeficiency diseases. He has written 69 published articles, 30 chapters and reviews, and 94 abstracts. He has written for, inter alia, the following: *Journal of Immunology, Journal of Pediatrics, Journal of Clinical Investigation, Journal of Biologic Chemistry, Blood, Journal of Allergy and Clinical Immunology,* and *Proceedings of the National Academy of Sciences*. Dr. Berger's professional accomplishments are staggering.

By contrast, Dr. Geraldi is not board-certified in any specialty. The State of Florida has reprimanded him for prescribing controlled substances without approval. He has written for *Redbook, Parenting, Mary Englebreit's Home Companion, Me,* and *First for Women.* (Unmarked P. Ex., filed November 20, 2000.) Dr. Geraldi has a good heart for adopting 16 Down's syndrome children and starting a foundation with his wife for Down's syndrome individuals. However, that does not make his diagnostic ability or understanding of hypoagammaglobulinemia more believable than the accomplished Dr. Berger.

Moreover, professionally, Dr. Berger has had 100 patients with agammaglobulinemia or hypoagammaglobulinemia. Dr. Geraldi has had two besides Joshua. There is no contest here over Dr. Berger's greater credibility.

Petitioner has the option to plead a Table injury or, in the alternative, causation in fact. The Table injury she has alleged is anaphylaxis. However, none of Joshua's symptoms remotely resembles anaphylaxis. He was not red with low blood pressure. He was purple, coughing and wheezing. He was treated for pneumonia, not for anaphylaxis.

Dr. Geraldi testified that Joshua experienced an "anaphylactoid" reaction, but he had to admit that the treatment Joshua received (aerosol and oxygen) was for his pneumocystis carinii,

not for anaphylaxis (which would have required adrenaline and antihistamine). As Dr. Berger testified, someone with anaphylaxis does not have it for days, but for hours. Someone with anaphylaxis is red not purple (as Joshua was). Joshua does not fit this pattern, either in the medical histories that Ms. Veliz gave to the hospital personnel through her friend Idania or in her testimony and her friends' testimony in court. The undersigned holds that Joshua did not have the Table injury of anaphylaxis.

That leaves petitioner with her allegation that DPT caused or significantly aggravated Joshua's hypoagammaglobulinemia, an allegation she has the burden of proving under the theory of causation in fact. 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). Agarwsal 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).

Without more, "evidence 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. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must not only show that but for the vaccine, Joshua would not have had the injury, but also that the vaccine was a substantial factor in bringing about his injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

Dr. Geraldi stated that the basis for his opinion that DPT significantly aggravated Joshua's hypoagammaglobulinemia is that Joshua became so sick after the vaccination. But an opinion of causation based strictly upon the temporal association between vaccination and illness is not legally sufficient for petitioner to satisfy her burden of proof. See Hasler, supra. Moreover, Dr. Geraldi testified that the significant aggravation ended when Joshua's pneumocystis carinii was cured, an event which occurred before the passage of six months after the administration of DPT. The Vaccine Act, 42 U.S.C. § 300aa-11(c)(1)(D)(I), requires petitioner prove that the sequelae of the vaccine injury lasted more than 6 months after the administration of the vaccine. Later in his testimony, Dr. Geraldi seemed to back away from his statement with the testimony that Joshua still needs treatment for his hypoagammaglobulinemia. But if DPT did not significantly aggravate his hypogammaglobulinemia, continued treatment is irrelevant.

Dr. Berger testified that DPT did not significantly aggravate Joshua's hypoagammaglobulinemia, which is a condition in which the individual's immune system does not produce appropriate antibodies. DPT does not cause or aggravate a failure to produce antibodies. On the contrary, DPT produces antibodies or it has no effect at all. Moreover, Dr. Berger testified that Joshua's "cold" at the time he received his vaccinations was actually his pneumocystis carinii becoming manifest, having been subacute for the prior one to two days. It is such a common bacterium that 75 percent of individuals have it, but they develop immune responses to it unless, like Joshua, they are immune deficient. Since Joshua could not produce immunoglobulin sufficient to defend against the infection, he developed clinical signs of pneumocystis carinii and became progressively worse over the two days after vaccination until

his mother, Ms. Veliz, brought him to the doctor. (If Joshua had been as severely ill as he became the evening of September 3rd, Ms. Veliz would have brought him to the doctor sooner. Ms. Veliz told the hospital personnel through her friend Idania that Joshua did not become ill until the evening before his hospitalization.)

Everything that occurred to Joshua is fully explainable by his underlying condition of hypoagammaglobulinemia and exposure to pneumocystis carinii. Although the fact witnesses testified that he had a fever and was irritable starting one and one-half hours after vaccination, Ms. Veliz informed the medical personnel that he was afebrile and had been well until the night before she brought him in. Clearly, there is a discrepancy between the histories Ms. Veliz gave at the hospital on September 4, 1997 and her testimony and that of her friends.[4] However, the discrepancy is not as damaging to petitioner's case as the weakness of Dr. Geraldi's testimony.

Most probably, Joshua's symptoms of pneumocystis carinii gradually worsened after the vaccination and did not alarm Ms. Veliz until the evening of September 3rd. His symptomatology has nothing to do with his DPT vaccination and everything to do with his pneumocystis carinii for which he was successfully treated.

That Joshua's hypoagammaglobulinemia manifested itself when Joshua was three months is amply explained by the passage of time while his immunoglobulin level was declining due to the normal decrease of maternal protective antibodies and his correlative failure to produce his own antibodies. That he had an upper respiratory infection at the age of two months without

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[4] When there is a discrepancy between contemporaneous medical records and testimony for the purpose of recovering damages, courts generally find the medical records more credible because the history was given with the strong motive of helping hospital personnel treat the patient's condition. Beddingfield v. Secretary, HHS, No. 90-2654V, 2001 WL 1298807, at *5 (Fed. Cl. Oct. 2, 2001).

manifesting hypoagammaglobulinemia is insignificant because he had a higher IgG level at two months and did not have pneumocytis carinii at the time, as Dr. Berger testified. Moreover, neither Dr. Geraldi nor Dr. Berger knows the onset of Joshua's hypoagammaglobulinemia.

Petitioner has failed to present a prima facie case of Table injury anaphylaxis or causation or significant aggravation of hypoagammaglobulinemia.

CONCLUSION

This case 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.

_____ _____

DATE Laura D. Millman
Special Master