

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-783V

Filed: May 8, 2009

NOT TO BE PUBLISHED

VACHE and NAIRA KARAPETIAN, *
legal representatives of their minor child, *
THOMAS KARAPETIAN, *
*
Petitioners, *
*
v. *
*
SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *
*
Respondent. *

Dismissal; DTaP; Table Injury;
Encephalopathy; Infantile Spasms
Hearing Impairment; Seizures
Speech and Language Disabilities

Armond Marcarian, Law Offices of Armond Marcarian, Sherman Oaks, CA, for petitioner

Althea W. Davis, United States Department of Justice, Washington, DC, for respondent.

DECISION¹

Vache and Naira Karapetian filed a Petition for vaccine compensation on behalf of their minor son, Thomas, pursuant to the National Vaccine Injury Compensation Program² (“the Act” or “the Program”). Petition (hereinafter Pet.) at 1, filed Nov. 21, 2006. Petitioners alleged that

¹The undersigned intends to post this decision on the United States Court of Federal Claims’s website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id.

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (2006) (“Vaccine Act” or the “Act”). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

Thomas suffered an acute encephalopathy following his November 25, 2003, DTaP vaccination. Id. Petitioners alleged further that the DTaP vaccine “alone or in combination with” IPV and Comvax (Hib and HepB combination vaccine) vaccines given that same day caused the initial encephalopathy as well as subsequent seizures, hearing impairment, speech and language disabilities, and “such other disabilities as may develop in Thomas in the future.” Id. at 6.

An abbreviated history of Thomas’ pertinent medical course follows. Following his immunizations, Thomas was taken to his pediatrician, Dr. Yalzadeh, on December 2, 2003 - seven days following his immunization - for a possible reaction to eating carrots and for “involuntary movements.” P Ex 5 at 7. The doctor’s impression was colic and advised a return visit in one week. Id. However, Thomas continued to exhibit the involuntary movements and petitioners returned the next day. Id. Thomas was referred to Dr. Lubens, a pediatric neurologist. Id.

Petitioners scheduled an appointment with Dr. Lubens for December 8. Prior to his appointment petitioners took Thomas to the Little Company of Mary Hospital Emergency Department on December 6 for “funny shaking episodes.” P Ex 6 at 30. The diagnosis was “possible” infantile spasms and Thomas was discharged the same day. Id. at 28. Later the same day, Thomas returned to the Emergency Department and was later admitted to Miller Children’s Hospital for seizure-like activity. P Ex. 7 at 43, 76. The initial diagnosis was probable infantile spasms. Id. at 2-3. On December 9, 2003, Thomas was seen by Dr. Lubens. P Ex 7 at 81. Dr. Lubens noted that Thomas had flurries of extensor spasms, was fine between spasms, and experienced no behavioral changes. Id. Thomas was started on ACTH injections and discharged from the hospital on December 12. Id. at 3. At the one week follow-up visit with Dr. Lubens on December 16, 2003, Thomas had not experienced any spasm since his discharge from the hospital. P Ex 8 at 11.

Dr. Lu took over Thomas’ primary pediatric care on December 24, 2003. P Ex 12 at 2. Dr. Lu noted at the initial visit the history of infantile spasms and a normal physical examination. Id. Dr. Lu began tapering the ACTH dosage on January 6, 2004, noting that Thomas had been seizure free for twenty-five days. P Ex 8 at 9. Dr. Lu appeared to note some developmental delay on February 9, 2004. Id. at 6-8. Thomas was seen at John Tracy Clinic on December 9, 2004 because petitioners believed he was not responding consistently to sounds. P Ex 10 at 1. Thomas was referred for a hearing aid. Id. at 1-2.

There is additional medical history in the medical records, however the brief summary above is sufficient for purposes of this decision.

Petitioners initially pursued this matter as both a Table and causation in-fact case. However, after a series of conference calls and court Orders initiated by the previously assigned special master, petitioners clarified that they were not pursuing the causation in-fact portion of the case. Petitioners’ Notice of Filing, Oct. 8, 2008 (“Petitioners’ have opted to pursue their claim for compensation through the statutorily-prescribed presumption of causation, as a Table-

injury case.”). As the previous special master noted in her Order, a series of opinions from the special masters have declined to award compensation for infantile spasms, the initial diagnosis that Thomas carried. However, petitioners maintained that Thomas suffered an encephalopathy as defined by the Vaccine Injury Table. Id.

The Vaccine Injury Table defines an acute encephalopathy as “one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).” 42 C.F.R. § 100.3 (b)(2)(i) (2008). It is further defined in a child under the age of 18 months “who present without an associated seizure event” as a “significantly decreased level of consciousness.” Id. § 100.3 (b)(2)(i)(A). In turn, to show a “significantly decreased level of consciousness” one has to prove one of three clinical signs lasting at least 24 hours:

- (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
- (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

Id. § 100.3 (b)(2)(i)(D).

In addition, the encephalopathy must be chronic, that is lasting more than 6 months. Id. § 100.3 (b)(2). Importantly, “[i]ndividuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event.” Id. § 100.3 (b)(2)(ii).

The evidence presented in this case was measured against this legal standard for presumed causation. Despite the fervent views of petitioners that the vaccine caused harm to their son Thomas, the evidence was indisputably deficient when measured against the statutory standard. The global issue in this case was the absence of any contemporaneous medical histories documenting the arguably encephalopathic symptoms alleged by petitioners in their affidavits. Based upon these affidavits, Dr. Lubens opined that Thomas suffered a Table encephalopathy. Respondent contested that opinion with an opinion from Dr. Guggenheim. Accordingly, a Hearing was conducted on April 21 to take the testimony of petitioners and the experts. The Hearing was abbreviated because Dr. Lubens testified contrary to his reports.

Dr. Lubens testified very credibly for petitioners. Unfortunately, he testified consistent with the medical records - there were no signs of acute encephalopathy within 72 hours. Throughout his testimony he made clear that Thomas did not suffer a severe encephalopathy, and stated matter of factly that Thomas did not require hospitalization within the 72 hours - one of the requirements for a Table encephalopathy. 42 C.F. R. § 100.3 (a)(II)(B). Most critically however was a family video petitioners had of Thomas within the 72 hour period. Petitioners celebrated Thanksgiving at their home two days following Thomas’ immunizations. They filmed

Thomas with their family. Petitioners claimed that the film showed how different Thomas was. To the undersigned, Thomas looked completely normal; Dr. Lubens agreed. At various points in the film, Thomas was shown being carried by family members - his eyes were wide open, his body movements and head control appeared completely normal. Thomas was put in his crib and once again he could be seen reacting appropriately to the person interacting with him. Counsel and the court asked Dr. Lubens if he saw at any point an encephalopathic child. He responded "no." He was asked if he saw an unresponsive child; he responded "no." Dr. Lubens stated that Thomas appeared normal. Dr. Guggenheim stated the same.

The undersigned is unsure why Dr. Lubens gave the opinions in his report stating that Thomas suffered a Table encephalopathy. However, Dr. Lubens could not have been more clear that viewing the film of Thomas two days following immunization that Thomas exhibited no signs of an encephalopathy. While petitioners passionately believe otherwise, and stated so following Dr. Luben's testimony, the Hearing was abbreviated following Dr. Luben's testimony - the evidence simply did not support petitioners' case.

Accordingly, petitioners' case must be dismissed. Neither the medical records nor petitioners' expert supports petitioners' allegations. The statute forbids a finding for petitioners based upon their claims alone. §13(a)(1). The Clerk of Court shall dismiss the Petition.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master