OFFICE OF SPECIAL MASTERS

Filed: November 4, 2005

WILLIAM and CARLA WHITESIDE, as the Legal Representatives of the Estate of their Daughter, LAUREN WHITESIDE, deceased,	*	
Petitioners,	*	
v.	*	No. 04-266V
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Curtis R. Webb, Twin Falls, Idaho, for Petitioners.

Lynn E. Ricciardella, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

SWEENEY, Special Master

On February 27, 2004, William and Carla Whiteside, as the legal representatives of the estate of their daughter Lauren Whiteside ("Lauren"), filed a petition for compensation under the National Childhood Vaccine Injury Act ("Vaccine Act"). 42 U.S.C. § 300aa-1 to -34 (2000 & Supp. II 2003). The timely-filed petition, as amended, alleges that Lauren received a diphtheria, tetanus, and acellular pertussis ("DTaP")[2] vaccination on April 18, 2001, and as a result, suffered

[1] The court encourages the parties to review Vaccine Rule 18, which affords each party 14 days to object to disclosure of (1) trade secret or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy."

[2] The DTaP vaccine is "a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis." Dorland's Illustrated Medical Dictionary 1998 (30th ed. 2003).

an encephalopathy[3] and subsequently died. Unfortunately, the Whitesides have not offered any medical evidence to support their allegation that Lauren's encephalopathy and death were caused in fact by the DTaP vaccination. Sadly, because the Whitesides were unable to present sufficient expert medical testimony in support of the allegations set forth in the petition, the special master is compelled to deny their claim and dismiss the petition.

Background

Lauren was born on February 16, 2001.[4] Pet. at 1. According to her mother, Lauren was a normal, healthy, and happy baby. Pet. Ex. 16 at 1. Prior to April 18, 2001, Lauren was developing normally. Id. at 2.

On April 18, 2001, at her two-month well-child examination at Catawba Pediatrics in Lincolnton, North Carolina, Lauren received DTaP; haemophilus influenzae type b ("Hib")[5]; inactivated polio virus ("IPV")[6]; pneumococcal conjugate[7]; and hepatitis B[8] vaccinations. Id. at 2; Pet. at 1-2. Immediately after the vaccinations, Lauren began to scream. Pet. Ex. 16 at 2. Ms. Whiteside had difficulty consoling Lauren until Lauren suddenly fell asleep. Id. Ms. Whiteside was concerned with this behavior and consulted the nurse. Id. The nurse responded that Lauren was having a typical vaccine reaction. Id. Eventually, while Lauren remained in a deep sleep, the staff told Ms. Whiteside that she could take Lauren home. Id.

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[3] Encephalopathy is a term used to describe "any degenerative disease of the brain." Dorland's Illustrated Medical Dictionary, supra note 2, at 610.

[4] All references to the Petition shall be designated herein as "Pet. at __." All references to the pertinent Petitioner's Exhibit shall be designated herein as "Pet. Ex. __ at __."

[5] The Hib vaccine protects against infection by the Haemophilis influenzae type b bacteria. Dorland's Illustrated Medical Dictionary, supra note 2, at 1999.

[6] The IPV vaccine is "a suspension of formalin-inactivated poliovirus . . . administered intramuscularly or subcutaneously for immunization against poliomyelitis." Dorland's Illustrated Medical Dictionary, supra note 2, at 2000.

[7] The pneumococcal conjugate vaccine protects against infection by the Streptococcus pneumoniae bacteria. Dorland's Illustrated Medical Dictionary, supra note 2, at 1505, 1999.

[8] The hepatitis B vaccine is "a noninfectious viral vaccine derived by recombination from hepatitis B surface antigen and cloned in yeast cells; administered intramuscularly for immunization of children and adolescents and of persons at increased risk for infection." Dorland's Illustrated Medical Dictionary, supra note 2, at 1999.

Ms. Whiteside described Lauren's behavior during the next 11 days as "unhappy, moody, fussy and sleepy." Id. Additionally, Lauren tended to sleep longer and more deeply and she began to experience progressively longer staring spells. Id. at 3; Pet. at 2-4. Further, Lauren's eating habits became abnormal. Pet. at 3; Pet. Ex. 16 at 2. Prior to the vaccinations, Lauren nursed regularly and vigorously and drank almost all of the eight to ten bottles of breast milk that Ms. Whiteside left with the day care center. Pet. at 3; Pet. Ex. 16 at 2. However, after the vaccinations, Lauren was no longer interested in nursing and only drank three bottles of breast milk at the day care center. Pet. at 3; Pet. Ex. 16 at 2-3. All of these symptoms were worrisome to Ms. Whiteside and so she contacted Catawba Pediatrics. Pet. Ex. 16 at 3. Once again, she was reassured by a nurse that Lauren was experiencing a typical vaccine reaction. Id.

During the nighttime hours of April 30, 2001/May 1, 2001, Lauren awoke with a high-pitched scream. Id. at 3; Pet. at 4. When she screamed, her entire body stiffened, and when she stopped screaming, she would relax and fall back asleep. Pet. at 4; Pet. Ex. 16 at 3. Lauren experienced several screaming episodes during the night. Pet. at 4; Pet. Ex. 16 at 3-4. Thus, Ms. Whiteside called Catawba Pediatrics, but there was no after-hours telephone number. Pet. at 4; Pet. Ex. 16 at 4. She instead called her former pediatrician, who instructed her to take Lauren to the emergency room. Pet. at 4; Pet. Ex. 16 at 4.

At the emergency room, Lauren was diagnosed with an upper respiratory infection. Pet. Ex. 16 at 4. Lauren refused to nurse or drink from a bottle. Id. After awhile, the emergency room staff sent Lauren home. Id.; Pet. at 4.

Lauren continued to experience episodes of alternating high-pitched screaming and sleeping after she returned home. Pet. at 4; Pet. Ex. 16 at 4. Ms. Whiteside repeatedly called Catawba Pediatrics to express her concerns. Pet. at 4; Pet. Ex. 16 at 4. The staff, who had been in contact with the emergency room, insisted that Lauren was suffering from a respiratory infection. Pet. at 4; Pet. Ex. 16 at 4. Eventually, during one of the telephone calls, a nurse heard Lauren's high-pitched scream and arranged for Lauren to see the pediatrician. Pet. at 4; Pet. Ex. 16 at 4.

At Catawba Pediatrics, Lauren was seen by a nurse practitioner, who arranged for a blood test to check Lauren's white blood cell count. Pet. at 4; Pet. Ex. 16 at 5. Lauren's white blood cell count was abnormally high, so the nurse practitioner arranged to have Lauren admitted to the hospital for a septic work up. Pet. at 4; Pet. Ex. 16 at 5.

Lauren was admitted to the hospital during the afternoon of May 1, 2001. Pet. at 4-5. Lauren continued to experience the screaming episodes. Pet. Ex. 16 at 5. Eventually, Ms. Whiteside was able to get a nurse to observe one of the episodes. Id.; Pet. at 5. An electroencephalogram ("EEG")[9] was performed, which revealed that Lauren was experiencing

[9] An EEG is "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. . . . Fluctuations in potential are seen in the form of

almost constant seizures. Pet. Ex. 16 at 5. Lauren was transferred to the neonatal intensive care unit, where she remained until May 10, 2001. Id.; Pet. at 2. Lauren was diagnosed with an acute meningoencephalitis,[10] and was left severely disabled, with a seizure disorder, profound developmental delays, and cortical blindness. Pet. at 2; Pet. Ex. 16 at 5-6.

After her hospitalization, Lauren never returned to normal. Pet. Ex. 16 at 5. She had a more difficult time recovering from colds. Id. at 6. In February 2002, Lauren came down with a bad cold. Id. Throughout the month, on numerous occasions, Ms. Whiteside took Lauren to see the pediatrician. Id. Because Lauren was getting worse, on February 25, 2002, Ms. Whiteside again took Lauren to the pediatrician. Id. The nurse practitioner dismissed Ms. Whiteside's concern about a possible respiratory syncytial virus ("RSV") infection. Id. Ms. Whiteside called the nurse practitioner again on February 26, 2002. Id.

Lauren died in the early morning of February 27, 2002. Id.; Pet. at 1-2. An autopsy revealed that contributing factors to Lauren's death included global hypoxic-ischemic brain injury[11] and an RSV infection. Pet. Ex. 15 at 1.

Respondent's Rule 4(b) Report and Petitioners' Request for a Ruling on the Record

Counsel for the respondent filed the Rule 4 Report on January 3, 2005, indicating that in the government's view, this case was not appropriate for compensation because petitioners had proved neither a Vaccine Injury Table ("Table") injury nor actual causation. Resp't Rep. at 9-14. Specifically, respondent avers that the petitioners have not shown Lauren to have a Table encephalopathy nor have petitioners shown that the DTaP vaccination Lauren received on April 18, 2001, caused Lauren's encephalopathy and subsequent death. Id.

At the Rule 5 status conference on January 13, 2005, petitioners' counsel proposed a fact hearing to determine whether the symptoms observed by petitioners, but not found in the medical records, constituted an encephalopathy or encephalitis as defined in the Table. The special master requested that counsel retain an expert to interpret Lauren's behavior. During a March 23, 2005 status conference, petitioners' counsel reported that he had received a preliminary commitment from an expert neurologist to provide a report on Lauren's behalf.

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waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." Dorland's Illustrated Medical Dictionary, supra note 2, at 596.

[10] Meningoencephalitis is the "inflammation of the brain and meninges." Dorland's Illustrated Medical Dictionary, supra note 2, at 1126. The meninges are "the three membranes that envelop the brain and spinal cord . . . ." Id. at 1124.

[11] A hypoxic-ischemic brain injury, also known as a hypoxic ischemic encephalopathy, is encephalopathy resulting from a lack of respired oxygen. Dorland's Illustrated Medical Dictionary, supra note 2, at 165, 611.

On September 14, 2005, petitioners' counsel filed a status report indicating that the expert neurologist declined to provide an opinion after reviewing Lauren's medical records. The status report also indicated that counsel had contacted two of Lauren's treating physicians to determine whether they would testify on her behalf. One physician refused, and counsel had not yet heard from the other physician. However, in a status report filed on October 11, 2005, petitioners' counsel reported that the other physician declined to provide an opinion. Thus, counsel requested that the special master decide this case based upon the existing record. On October 14, 2005, respondent's counsel orally stated that she did not object to the request and that she did not intend to file any additional materials.

The Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if petitioners[12] prove, by a preponderance of the evidence, all of the elements set forth in § 300aa-11(c)(1)[13] of the Vaccine Act and that the illness is not due to factors unrelated to the administration of the vaccine.[14] Section 300aa-11(c)(1)(C) describes the substantive elements petitioners must prove to recover in the Vaccine Program. In this case, petitioners can recover in one of two ways. First, petitioners can recover if they prove a Table injury; in other words, if they show that Lauren received a vaccine listed in the Table, 42 C.F.R. § 100.3(a), and suffered from an injury associated with that vaccine within the prescribed time period. 42 U.S.C. § 300aa-11(c)(1)(C)(i).

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[12] Section 11(b)(1) requires that: (1) only the "person who sustained a vaccine-related injury, [or] the legal representative of such person if such person is a minor or is disabled" can bring an action for vaccine injury-related claims (so long as the requirements of subsection (c)(1) are satisfied) and (2) that no previous civil action was filed in the same matter. Petitioners, the parents of the child who allegedly died as the result of the administration of a Table vaccine, are the appropriate people to maintain this action.

[13] Subsection (c)(1) requires, inter alia, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Table; (2) that the vaccine was received in the United States or in its trust territories; (3) that the minor child either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that petitioners, as their daughter's legal representatives, have not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury or death. Here, petitioners were unable to offer the testimony of a qualified medical expert to support petitioners' theory of liability. Thus, the lack of expert opinion evidence supporting the allegations of the petition defeats the underlying claim.

[14] Of course, the petition must also be filed within the statutory period. 42 U.S.C. § 300aa-16(a). The petition in this case was timely filed.

Specifically, in this case, petitioners can recover if they demonstrate that Lauren suffered from an encephalopathy within 72 hours of receiving the DTaP vaccination. Unfortunately, petitioners were unable to meet this burden. Although the undisputed facts show that Lauren received the DTaP vaccination on April 18, 2001, Lauren's subsequent symptoms do not meet the Table definition of encephalopathy.

The Table defines encephalopathy as an acute encephalopathy followed by a chronic encephalopathy persisting for more than six months past the date of vaccination. 42 C.F.R. § 100.3(b)(2). For children under the age of 18 months who present without a seizure, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" lasting for at least 24 hours. Id. § 100.3(b)(2)(i)(A). For children presenting with a seizure, the significantly decreased level of consciousness must persist more than 24 hours and cannot be attributed to the seizure or medication. Id.

Further, a "significantly decreased level of consciousness" is defined by the presence of at least one of the following three clinical signs for 24 hours or longer: (1) decreased or absent response to the child's environment, (2) decreased or absent eye contact, or (3) inconsistent or absent responses to external stimuli. Id. § 100.3(b)(2)(i)(D). More importantly,

> [t]he following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness . . . : Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

Id. § 100.3(b)(2)(i)(E) (emphasis added). Ms. Whiteside indicated that Lauren's postvaccination behavior included sleepiness, fussiness, unhappiness, moodiness, staring spells, and changed eating habits. From the above definitions, it is apparent that Lauren did not suffer from a Table encephalopathy as a result of the administration of the DTaP vaccination within the prescribed 72-hour period. Thus, petitioner proceeded on an actual causation theory.

Under an actual causation theory or "off-Table" claim, 42 U.S.C. § 300aa-11(c)(1)(C)(ii), petitioners must prove that Lauren's encephalopathy and subsequent death were caused in fact by her DTaP vaccination. Congress explained what it intended by this causation requirement:

> [T]he petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific

> studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.

H.R. Rep. No. 99-908, pt. 1, at 15 (1986). The United States Court of Appeals for the Federal Circuit amplified congressional intent:

> To prove causation in fact, petitioners must show a medical theory causally connecting the vaccination and the injury. Causation in fact requires 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. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted); Bunting v. Sec'y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991) ("A petitioner's burden is not to show a generalized 'cause and effect relationship' with listed illnesses, but only to show causation in a particular case."). As the Federal Circuit explained in Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999), two separate elements must be demonstrated by a preponderance of the evidence, namely, "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Thus, both the Vaccine Act and the case law require an expert medical opinion in off-Table cases.

Section 300aa-13(b)(1) specifically requires consideration of all relevant medical and scientific evidence presented to the court including:

> (A) any diagnosis, conclusion, medical judgment, . . . regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and
>
> (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

A review of the record now under consideration reveals no medical evidence[15] to support petitioners' theory that Lauren suffered an encephalopathy and subsequently died as a result of the administration of the DTaP vaccination on April 18, 2001. Specifically, petitioners were unable to provide the necessary expert opinion and there was no other medical evidence in the record that proved that the vaccine was the cause in fact of Lauren's injury and subsequent death.

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[15] Although the Federal Circuit made clear in Knudsen v. Secretary of HHS, 35 F.3d 543, 548-49 (Fed. Cir. 1994), that when proceeding under an off-Table theory, a petitioner is not required to identify and provide proof of the specific biological mechanism that caused the alleged vaccine injury, a reputable medical explanation of a logical sequence of cause and effect to support petitioner's theory of liability is necessary.

The Vaccine Act specifically provides that "the special master or court may not make a finding [of eligibility and compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion." 42 U.S.C. § 300aa-13(a)(1). Thus, because petitioners are unable to prove by a preponderance of the evidence the matters required in § 300aa-11(c)(1),[16] petitioners have not met the burden of proof required in off-Table cases demonstrating that Lauren's encephalopathy and subsequent death were more likely than not the result of the DTaP vaccination at issue here. There is no doubt that Lauren, and by extension, her family, have endured great suffering and that Lauren's death is a tragic loss. Nevertheless, the statutory requirements have not been satisfied and therefore petitioners cannot prevail.

CONCLUSION

Because petitioner is unable to present medical records and/or expert testimony to support a theory of causation, the special master finds that petitioners have not and cannot meet their burden to prove that the DTaP vaccination of April 18, 2001, caused Lauren's encephalopathy and subsequent death. Therefore, the special master finds that petitioners must be denied compensation under the Vaccine Program.

Accordingly, this petition is DISMISSED with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

Margaret M. Sweeney
Special Master

[16] See 42 U.S.C. § 300aa-13(a).