OFFICE OF SPECIAL MASTERS

Filed: June 27, 2005

BILL WILSON and BETH WILSON, as Legal Representatives of the Estate of MITCHELL WILSON,	*	
Petitioners,	*	No. 02-1797V
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

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

David L. Terzian, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

SWEENEY, Special Master

On December 9, 2002, Bill and Beth Wilson, as the legal representatives of the estate of their son Mitchell Wilson ("Mitchell"), 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 alleges that as a result of the measles, mumps, and rubella ("MMR")[2] vaccination Mitchell received on December 1, 2000, Mitchell suffered from encephalitis[3] and eventually died. Unfortunately, the Wilsons have not offered any medical

[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 MMR vaccine is "a combination of live attenuated measles, mumps, and rubella viruses, administered subcutaneously for simultaneous immunization against measles, mumps, and rubella." Dorland's Illustrated Medical Dictionary 1999 (30th ed. 2003).

[3] Encephalitis is the "inflammation of the brain." Dorland's Illustrated Medical Dictionary, supra note 2, at 608.

evidence to support their allegation that Mitchell's encephalitis and death were caused in fact by the MMR vaccination. Sadly, because the Wilsons are 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

Mitchell was born on March 21, 1999.[4] Pet. at 1; Pet. Ex. 1 at 1. Mitchell was a happy, healthy, and easy-going child before his December 1, 2000 vaccinations. Pet. Ex. 1 at 1.

On December 1, 2000, at the office of James M. Pellegrin, M.D., in Los Gatos, California, Mitchell received diphtheria, tetanus, and acellular pertussis ("DTaP")[5]; inactivated polio virus ("IPV")[6]; haemophilus influenzae type b ("Hib")[7]; and MMR vaccinations. Id. at 1-2; Pet. at 2.

On December 2, 2000, Mitchell had a low fever and was tired and irritable. Pet. Ex. 1 at 2. Ms. Wilson called a health line to inquire about Mitchell's symptoms. Id. The nurse who took Ms. Wilson's telephone call explained that Mitchell was experiencing a normal vaccine reaction and recommended watching him and giving him Tylenol for his fever. Id.

Then, on December 4, 2000, Ms. Wilson noticed that Mitchell had fluid-filled blisters on each of his knuckles. Id. Ms. Wilson called the physician's office as soon as it opened. Id. A nurse told Ms. Wilson that the blisters were likely complications of Mitchell's vaccinations. Id. The blisters disappeared on December 6, 2000. Id. Mitchell appeared fine, but remained more tired than usual. Id.

Throughout the rest of December 2000, Mitchell continued to be more tired than usual. Id. Prior to his December 1, 2000 vaccinations, the length of his typical nap was about two

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[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 __." Any references to Petitioner's Exhibits 1-11 refer to the exhibits filed on December 13, 2002.

[5] 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, supra note 2, at 1998.

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

hours. Id. But in the month following these vaccinations, the length of Mitchell's naps increased to about three hours or occasionally longer. Id. In addition to longer naps, the Wilsons noticed the following symptoms: glassy eyes, crankiness, inconsolability, the appearance of being "out of it," lack of appetite, and fatigue. Id. at 2-3; Pet. at 2.

At about 7:00 a.m. on January 9, 2001, Mr. Wilson heard Mitchell "talking" and peeked in his room. Pet. Ex. 1 at 3. After taking a shower, Mr. Wilson returned to Mitchell's room to get him up but Mitchell had fallen back asleep. Id. Mitchell had never done this before. Id. About thirty minutes later, Mitchell woke up again, and the Wilsons proceeded with their daily activities. Id. at 3-4. Mitchell took a short nap after lunch. Id. at 4. In the afternoon, Mitchell and his older brother were playing in the garage when Mitchell appeared to stumble and become instantly fatigued. Id. Ms. Wilson took Mitchell inside to her bedroom for another nap. Id.

While laying down for his nap, Mitchell rubbed his eyes and said "owie." Id. Involuntary tears ran down his eyes but he told Ms. Wilson that he was okay. Id. Mitchell squirmed around a bit and fell asleep at about 4:20 p.m. Id. Ms. Wilson checked on Mitchell every fifteen minutes so that he would not be disoriented when he woke up in his parents' bed. Id. The house was completely quiet while Mitchell was napping and Ms. Wilson never heard any noise coming from her bedroom. Id. Just before 5:00 p.m., Ms. Wilson checked in on Mitchell and found him to be laying face down on the bed. Id. When Ms. Wilson turned Mitchell over, he was limp and not breathing. Id. Ms. Wilson performed cardiopulmonary resuscitation ("CPR")[8] but was unsuccessful in reviving him. Id.

The paramedics were called to the Wilson's home. Pet. Ex. 5 at 2. Mitchell was taken to the Emergency Department at Santa Clara Valley Medical Center, where he was pronounced dead at 6:31 p.m. Id. at 1, 3-18; Pet. at 2. Diane R. Vertes, M.D., the assistant medical examiner-coroner of Santa Clara County, performed an autopsy on January 10, 2001. Pet. Ex. 6 at 1. Dr. Vertes determined Mitchell's cause of death to be "probable brainstem encephalitis of an undetermined etiology." Id. at 7.

Dr. Vertes retained blood, fluid, and tissue samples, including samples of brain tissue. Id. at 6. Dr. Vertes sent brain tissue samples to the Centers for Disease Control and Prevention ("CDC") on May 10, 2001, for further analysis. Id. at 27-28. The CDC found no evidence of enterovirus, Epstein-Barr virus, human herpesvirus, or influenza A virus. Id. at 28. Dr. Vertes also sent heart tissue samples to Stanford Pathology Consultants at Stanford University Medical Center on July 9, 2001. Id. at 29-30. The pathologist at Stanford found no histopathological abnormalities in the heart tissue. Id. at 30.

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[8] Cardiopulmonary resuscitation is "the artificial substitution of heart and lung action as indicated for cardiac arrest or apparent sudden death resulting from electric shock, drowning, respiratory arrest, and other causes. The two major components of CPR are artificial respiration and closed chest cardiac massage." Dorland's Illustrated Medical Dictionary, supra note 2, at 1617.

On October 9, 2001, tissue samples from Mitchell's brain were sent to Hannah C. Kinney, M.D., a neuropathologist at Harvard Medical School and Children's Hospital in Boston, Massachusetts. Pet. Ex. 12 at 2. Dr. Kinney's diagnoses were "[m]ild brainstem encephalitis, etiology undetermined," "[a]bnormalities of the left and right hippocampus, etiology undetermined," and "cerebral edema . . . , nonspecific, consistent with agonal hypoxia-ischemia complicating the terminal cardiopulmonary arrest." Id.

Ms. Wilson submitted a report to the Vaccine Adverse Event Reporting System ("VAERS")[9] on December 3, 2001, and attached many of Mitchell's medical records. See Pet. Ex. 10.

On May 23, 2002, Somayeh Honarmand and James Sejvar, M.D., of the California Encephalitis Project, wrote a letter to Ms. Wilson thanking her for discussing Mitchell's case with them. Pet. Ex. 7.

Dr. Vertes also sent Mitchell's medical records and tissue samples to the Pathology Department at Children's Hospital in San Diego as part of a study of sudden unexpected death in childhood. Pet. Ex. 8 at 1-2; Pet. Ex. 12 at 5. In a letter dated May 23, 2002, the pathologist, Henry F. Krous, M.D., noted that no organism had been identified within Mitchell's brain. Pet. Ex. 8 at 2.

Petitioners' Counsel's Efforts to Obtain a Medical Expert's Opinion

At a status conference conducted on July 2, 2003, petitioners' counsel informed the court that he was seeking an expert report from Dr. Kinney but that she had not yet provided one. Then, in a status report filed on September 15, 2003, petitioners' counsel reported that a pediatric neurologist was reviewing Mitchell's medical records in order to provide an opinion regarding whether Mitchell suffered from an injury listed in the Vaccine Injury Table ("Table") associated with the MMR vaccine or, in the alternative, whether the MMR vaccination caused Mitchell's death. Counsel explained that petitioners would decide how to proceed with the case upon receipt of the opinion of the pediatric neurologist.

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[9] VAERS is

> a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. . . . By monitoring such events, VAERS helps to identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

VAERS–Frequently Asked Questions, at http://www.vaers.org/vaers.htm (last visited April 8, 2005). Any person can file a report with VAERS. Id.

In a status report filed on January 22, 2004, petitioners' counsel explained that the pediatric neurologist, John Menkes, M.D., had requested the results from any testing done to detect the mumps virus. If no testing had been done previously, Dr. Menkes requested that the tests be performed prior to his rendering an opinion. Petitioners' counsel filed another status report on May 3, 2004, which indicated that testing for the presence of the mumps or rubella viruses had not been done. Counsel identified a laboratory that could conduct the testing and reported that he had been attempting to obtain a frozen sample of Mitchell's brain tissue from the Santa Clara County Medical Examiner-Coroner's office, without success.

Petitioners' counsel filed another status report on June 4, 2004, reporting that Diane Hunter, M.D. of the Santa Clara County Medical Examiner-Coroner's office informed him that she could not locate any frozen samples–only formalin-preserved samples existed. Against the advice of counsel, petitioners decided to attempt testing of the formalin-preserved sample for the presence of mumps and rubella viruses.

On May 9, 2005, petitioners' counsel filed another status report. Petitioners had been able to locate frozen samples of Mitchell's brain tissue at the California Encephalitis Project. These samples were sent to a laboratory and tested for the presence of mumps and rubella viruses. Neither virus was detected. Accordingly, petitioners requested that the court make a ruling on the record presently before the court.

Respondent's Rule 4(b) Report

Counsel for the respondent filed his Rule 4(b) Report on March 10, 2003, indicating that in the government's view, this case was not appropriate for compensation because petitioners had proved neither a Table injury nor actual causation. Resp't Rep. at 5-6. Specifically, respondent avers that petitioners have not shown Mitchell to have a Table encephalitis nor have petitioners shown that the MMR vaccination Mitchell received on December 1, 2000, caused Mitchell's encephalitis and subsequent death. Id.

The Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if petitioners prove, by a preponderance of the evidence, all of the elements set forth in §§ 300aa-11(b)[10] and (c)[11] of the Vaccine Act and that the illness is not due to factors unrelated to the administration of

[10] The two pertinent provisions of the statute require that: (1) only the legal representative of the child 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 petition was filed in the same matter.

[11] Assuming, as is the case here, that the petitioners are the valid legal representatives, subsection (c)(1) requires, inter alia, the following elements be set forth in the petition: (1) that

the vaccine.[12] 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 Mitchell 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).

Specifically, in this case, petitioners can recover if they demonstrate that Mitchell suffered from an encephalitis, a form of encephalopathy,[13] within five to fifteen days of receiving his MMR vaccination. Unfortunately, petitioners were unable to meet this burden. Although the undisputed facts showed that Mitchell received the MMR vaccination on December 1, 2000, Mitchell's subsequent tiredness, glassy eyes, crankiness, inconsolability, the appearance of being "out of it," lack of appetite, and fatigue do not meet the statutory 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 aged eighteen months or older, an acute encephalopathy is an encephalopthy that lasts for at least twenty-four hours and is characterized by at least two of the following symptoms: (1) a significant change in mental status (specifically, a confusional state, delirium, or psychosis) not related to medication, (2) a significantly decreased level of consciousness, or (3) a seizure associated with loss of consciousness. Id. § 100.3(b)(2)(i)(B).

Further, a "significantly decreased level of consciousness" is defined by the presence of at least one of the following three clinical signs for twenty-four 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

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the vaccine in question is set forth in the Vaccine Injury Table; (2) that the vaccine was received in the United States or in its trust territories; (3) that the petitioners (or as here, the petitioners' 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 the petitioners have not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury. 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.

[12] Of course, the petition must also be filed within the statutory period. 42 U.S.C. § 300aa-16(a).

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

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." Id. § 100.3(b)(2)(i)(E).

Mitchell's symptoms, which began the day after his December 1, 2000 MMR vaccination, do not rise to level of an encephalopathy as described by the Vaccine Act. The symptoms began less than five days postvaccination and Mitchell died more than fifteen days postvaccination. Further, the symptoms described by Ms. Wilson–tiredness, glassy eyes, crankiness, inconsolability, the appearance of being "out of it," lack of appetite, and fatigue–do not demonstrate an acute encephalopathy. Accordingly, it is apparent that Mitchell did not suffer from a Table encephalopathy as a result of the administration of the MMR vaccination. Thus, petitioners 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 Mitchell's encephalitis and/or death was caused in fact by his MMR 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 clearly require an expert medical opinion.

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
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> (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[14] to support petitioners' theory that Mitchell suffered from an encephalitis and then died as a result of the administration of the MMR vaccination on December 1, 2000. Specifically, petitioners were unable to provide the necessary expert opinion.

As described above, petitioners' counsel retained a neurologist, Dr. Menkes, to review Mitchell's medical records in order to determine whether the MMR vaccine was the cause in fact of Mitchell's death. Based upon his review of the records, Dr. Menkes advised that he could not opine without mumps and rubella test results. After a painstaking search by petitioners' counsel, Mitchell's frozen brain tissue samples were eventually discovered and analyzed by the John Welsh Cardiovascular Diagnostic Laboratory. The April 18, 2005 laboratory report revealed that neither virus was detected. See Petitioners' May 9, 2005 Status Report and attachment. The negative test results, which confirmed that neither the mumps nor the rubella virus was present, precluded petitioners' expert from rendering an opinion. The absence of expert testimony defeats petitioners' claim. Thus, the need to proceed to a hearing in this matter was obviated. Counsel's inability to obtain an expert to present favorable testimony notwithstanding, the special master would be remiss if she did not compliment both the petitioners' counsel for his diligence in exploring every possible avenue to advance his clients' claim as well as the respondent's counsel's spirit of cooperation, which accommodated petitioners' need for additional time to pursue testing. By their conduct, counsel demonstrated their commitment to the highest standards of their profession, thereby ensuring that petitioners were afforded every opportunity to present their case. Counsels' professionalism is much appreciated by the special master and their conduct commended.

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

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[14] 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.

in § 300aa-11(c)(1),[15] petitioners cannot carry the "heavy burden" required in off-Table cases to prove that Mitchell's encephalitis and/or death was more likely than not the result of the MMR vaccination at issue here. There is no doubt that Mitchell's family has endured great suffering and loss and the special master is very sympathetic to the Wilsons' devastating circumstances. However, the statutory requirements have not been satisfied and dismissal is the only possible outcome under these facts.

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 of proof to prove that the MMR vaccination of December 1, 2000, caused Mitchell's encephalitis and/or 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

[15] See 42 U.S.C. § 300aa-13(a).