

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 31, 2000
(Reissued for Publication September 21, 2000)¹

VICTORIA FRANCIS, a minor, by her Parents, *
THOMAS and KIMBERLY FRANCIS, *

Petitioners, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

No. 99-0286V

No. 98-0853V

TO BE PUBLISHED

Lawrence R. Cohan, Philadelphia, PA, for petitioners.
Gabrielle Manganiello, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Statement of the Case

Petitioners allege that DPT caused in fact Victoria Francis's (hereinafter, "Victoria") cerebrovascular accident (CVA) and encephalopathy whose onset was approximately eleven days post-vaccination.

Petitioners previously filed their petition on November 6, 1998 (No. 98-0853V). But because they had filed a civil action in state court in Pennsylvania on October 27, 1998, Special Master Wright dismissed their petition on January 13, 1999. Petitioners dismissed their civil action on April 7, 1999, before refileing their petition in the U.S. Court of Federal Claims. (The filings in No. 98-0853V are considered to be filed with this petition, No. 99-0286V.)

¹ This decision was originally entered by the court on August 31, 2000 as an unpublished decision. The reissuance as a published decision follows in response to respondent's motion to publish, filed September 14, 2000, which the court granted on September 21, 2000. The reissuance of this decision *shall not affect the time for filing motion for review pursuant to Vaccine Rule 23.*

Their filings in the 1998 petition include an affidavit from Dr. Michael Goodman, a pediatric neurologist, dated December 28, 1998. (They refiled this affidavit as Ex. 13 of their medical records.) Dr. Goodman states that DPT caused Victoria's CVA. He does not give a basis for his opinion. He also does not discuss the diagnosis at The Children's Hospital of Philadelphia (CHOP) of viral sepsis and patent ductus arteriosus.²

Petitioners filed further medical reports (discussed below), but have failed to make a prima facie case of causation in fact. A special master has the discretion to decide a case on written submissions alone, without holding an evidentiary hearing. Vaccine Rule 8(d).

FACTS

Victoria was born on June 22, 1996. Pet. ¶ 1. She received DPT vaccine in the morning of October 28, 1996. Pet. ¶ 3. At 5:00 p.m. on November 8, 1996, more than eleven days after vaccination, she was unresponsive, had a faint pulse, rapid heartbeat, and a temperature of 102 degrees.³ At the Chester County Hospital Emergency Room (ER), she was diagnosed with sepsis and respiratory distress. Pet. ¶ 4.

Victoria's pediatric records show that she had a physical examination when she was two months of age on August 22, 1996. *Id.* The next visit Victoria made to her pediatrician after August 22, 1996 was on October 3, 1996 when her mother complained that Victoria reacted to pear juice. Mrs. Francis gave approximately three ounces of pear juice to Victoria and, in five minutes, Victoria started screaming and drew her legs up. This lasted 45 minutes to an hour. In the doctor's office, she was quiet and alert. *Id.*

The medical records are replete with histories that Mrs. Francis gave that Victoria was healthy until November 8, 1996. The Chester County Hospital Consultation Record of November 8, 1996 at 5:30 p.m. states that Victoria had no prior medical history and was well until noon that day when she took only two ounces of formula from her babysitter. Victoria was initially cranky. Then after three hours, the babysitter found her barely responsive, floppy, cold, breathing hard, and congested. The doctor opined possible septic shock. Med. recs. at Ex. 7, p. 7.

On November 9, 1996, Victoria received a diagnosis of sepsis syndrome secondary to strep pneumonia. Med. recs. at Ex. 8, p. 9.

Victoria was transferred to CHOP where she was diagnosed with viral sepsis, CVA, seizure disorder, and patent ductus arteriosus. A Physical and Occupational Transfer Summary of CHOP, dated November 22, 1996, states that Victoria had viral sepsis. Med. recs. at Ex. 8, p. 56. The discharge summary, dated January 10, 1997, states that Victoria had viral sepsis, CVA, seizure disorder, and patent foramen. The history recounted is that on November 8, 1996, Victoria was well and taking a normal bottle on the morning of the day of admission. She later took only half of a normal feeding and was put down for a nap at 3:00 p.m. When the sitter

² Patent ductous arteriosus is an "abnormal persistence of an open lumen in the ductus arteriosus after birth, the direction of flow being from the aorta to the pulmonary artery, resulting in recirculation of arterial blood through the lungs." Dorland's Illustrated Medical Dictionary 512 (27th ed. 1988).

³ Petitioners' affidavits, dated November 4 and 7, 1998, in their prior petition are in accord with this recitation of facts.

checked on her at about 5:00 p.m., she was floppy, diaphoretic, warm to the touch, and pale. She had been previously healthy with no history of vomiting or diarrhea, and had had only one ill contact with her grandmother who had had an upper respiratory infection for three weeks. Victoria had been having normal fluid intake prior to this episode and normal urine output as well. At the Chester ER, she had copious amounts of loose non-bloody stools. Her temperature was 102.4 degrees. She was lethargic and pale, and had poor tone and perfusion. Her pulse was 200. Her blood pressure was 72/56. Med. recs. at Ex. 12, p. 58.

On neurological examination, she was paralyzed. In the hospital, the doctors thought she had a sepsis syndrome and she was started on broad spectrum antibiotics. Her cultures were negative. The etiology of her stroke remained unclear. Med. recs. at Ex. 12, pp. 59-60.

On May 22, 1997, Dr. Stephen G. Ryan, attending neurologist at CHOP, wrote a letter stating that Victoria's chronic encephalopathy was due to hypoxic ischemic insult on the basis of presumed viral sepsis. Med. recs. at Ex. 10, p. 8. Victoria's family history is significant for seizures. Her father had a nocturnal seizure in May 1992 and has been on Dilantin since then. She has a distant maternal cousin with muscular dystrophy. Med. recs. at Ex. 17, p. 10.

Submissions

Dr. Goodman submitted a supplemental affidavit, dated November 10, 1999, on behalf of petitioners, stating again that Victoria's DPT caused in fact her injuries but not giving a basis for his opinion. (Filing dated November 12, 1999.)

Petitioners filed a report dated February 28, 2000 from Dr. Frank A. Briglia, who dated the onset of Victoria's symptoms to eight days after her DPT vaccination. He notes that shock, encephalopathy, or encephalitis have been reported seven days after DPT vaccination. He opines that Victoria had a less severe reaction (i.e., mild encephalopathy) after her first DPT based on Mrs. Francis' report that Victoria had unusual screaming spells and persistent, inconsolable crying after it. He also opines that Victoria had encephalitis after her second DPT. (Filing dated March 1, 2000.) Dr. Briglia is a board-certified pediatrician with a specialty in pediatric critical care. P. Ex. 19.

Dr. Goodman submitted a third report, dated June 19, 2000, stating that Victoria was unlikely to have had viral encephalitis because of the absence of appropriate signs (absence of pleocytosis in the cerebrospinal fluid and normal cerebrospinal fluid glucose and protein) and unlikely to have had viral gastroenteritis because she had no history of prior fever, diarrhea, vomiting or irritability. He notes no documented problems following her second DPT vaccination of October 28, 1996. However, he thinks her symptoms on November 8, 1996 and her CT scan, showing a stroke, suggest an evolving process. He opines she had a mild encephalopathy following her first DPT because of reported unusual screaming spells and persistent crying and this is compatible with her problems after her second DPT. P. Ex. B.

Dr. Briglia submitted a supplemental report, dated June 13, 2000, stating that Victoria suffered a major complication from her DPT (shock) and it was impossible to pinpoint the onset (whether seven, eight, or nine days post-vaccination), but the likely causal relationship exists. P. Ex. A.

Respondent filed an expert report from Dr. Michael H. Kohrman, a pediatric neurologist. R. Ex. A. He opines that Victoria developed overwhelming sepsis and shock while having profuse diarrhea 11 days after her second DPT. There was no behavior change or evidence of encephalopathy recorded between the first and second DPT vaccinations. The diarrhea suggests

a viral gastroenteritis as the cause of her sepsis. He thinks her underlying cardiac abnormality predisposed her to stroke. Id.

DISCUSSION

To satisfy their burden of proving causation in fact, petitioners 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). Agarwal 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).

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

Petitioners' evidentiary support includes three reports from Dr. Goodman, who gives no basis whatsoever (much less a reputable medical explanation) for his opinion of causation, and two reports from Dr. Briglia. Each of them assumes that Victoria had a "mild encephalopathy" after her first DPT and that her encephalitis after her second DPT is consistent with this. Their opinions are without a proper foundation in the medical records which are totally silent as to Victoria having an encephalopathy following her first DPT. Mrs. Francis took Victoria to see her pediatrician six weeks after her two-month visit because Victoria seemed to be reacting to pear juice. There is no mention of encephalopathy. That Mrs. Francis may have told Drs. Goodman and Briglia a very different story about Victoria's behavior, in the context of litigation, does not have persuasive effect.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

The court does not believe that Victoria had encephalopathy at all before her unfortunate stroke on November 8, 1996. In fact, the numerous histories Mrs. Francis gave to medical

personnel at the time of her daughter's serious illness were that she had been normal and healthy before November 8, 1996.

That no one has arrived at a cause for Victoria's stroke does not mean that the DPT she received 11 days earlier must be the cause. Legally, petitioners must submit valid, affirmative proof, not the absence of any proof. "[E]vidence 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.

Dr. Goodman's and Dr. Briglia's opinions are conclusive without any credible basis. They rely upon purported symptoms of "mild encephalopathy" which did not occur, and they link Victoria's stroke to her vaccination 11 days earlier without any credible medical reason for doing so. Apparently, they are doing what they can in a tragic circumstance to help out petitioners, but their sympathy for petitioners does not constitute sufficient legal proof. Petitioners have failed to prove a prima facie case of causation in fact from the DPT vaccine.

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