

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 10-288V

October 28, 2010

Not for Publication

* * * * *

MELINDA GUSTIN, legal representative *
of a minor child, JESSIE WEBB, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *

Respondent. *

* * * * *

Randall G. Knutson, Mankato, MN, for petitioner.

Ann D. Martin, Washington, DC, for respondent.

Dismissal based on petitioner's
request for a ruling on the record;
Gardasil; Sydenham's chorea due
to streptococcus; vasculitis; strokes

MILLMAN, Special Master

DECISION¹

Petitioner filed a petition on May 13, 2010, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that Gardasil vaccine which her daughter Jessie Webb

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub.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). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

(hereinafter, “Jessie”) received on July 19, 2007, caused her ischemic strokes in her right frontal lobe, Sydenham’s chorea, and vasculitis.

During the first telephonic status conference held on July 16, 2010, petitioner’s counsel stated that he wanted to get an expert opinion.

During the second telephonic status conference held on September 23, 2010, petitioner’s counsel stated that he had tried to hire four experts but was unsuccessful. He wanted to speak with his client about dismissal.

During the third and final telephonic status conference held on October 13, 2010, petitioner’s counsel stated that petitioner wanted to sue civilly and asked for a ruling on the record.

On October 22, 2010, respondent filed a Rule 4(c) Report stating that petitioner had failed to make a prima facie case of causation in fact.

FACTS

Jessie was born on July 3, 1995.

On February 23, 2004, Jessie had a fever of 102-103°, headache, and presumptive strep throat. Med. recs. at Ex. 7, p. 3. She had 3+ streptococcus, beta-hemolytic group A. Med. recs. at Ex. 7, p. 4.

On January 3, 2007, she went to the Huntsville Hospital pediatric emergency department with fever, pharyngitis, strep throat, congestion, lower back pain, leg pain, purpura,² and a history of ADHD (attention deficit hyperactivity disorder). Med. recs. at Ex. 3, pp. 196-99.

² Purpura are small hemorrhages in the skin. Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 1547. Possible causes “include blood disorders, vascular abnormalities, and trauma.” *Id.*

On January 3, 2007, she had a positive rapid strep test. Med. recs. at Ex. 3, p. 202.

Two months later, on March 16, 2007, Jessie had another positive rapid strep test. She had fever and a sore throat. She had strep two months previously, with fever to 103°, cervical lymphadenopathy, and tonsillar exudate left greater than right. Med. recs. at Ex. 3, pp. 207-09. Jessie had a headache, pain in both ears, cough, and body aches. *Id.* at 210. She had 103° the night before. A rapid strep was obtained. *Id.* at 212.

On May 16, 2007, Jessie received her first Gardasil vaccination.

On June 20, 2007, she went to Huntsville Hospital emergency department with a cut on her left foot. Med. recs. at Ex. 4, p. 15.

On June 22, 2007, Jessie returned to the emergency department because of left knee pain. Med. recs. at Ex. 4, p. 15.

On July 19, 2007, Jessie received her second Gardasil vaccination.

From August 10-11, 2007, Jessie was at Huntsville Hospital. Dr. Tonya T. Zbell diagnosed Jessie with Sydenham's chorea.³ By history, Jessie had four or five bouts with strep within the prior year and tonsillar abscess the prior year. She was scheduled for a tonsillectomy and/or possible adenoidectomy considering the amount of group A beta-hemolytic strep that she

³ "Sydenham chorea (SD) is a neurological disorder of childhood resulting from infection via Group A beta-hemolytic streptococcus (GABHS), the bacterium that causes rheumatic fever. SD is characterized by rapid, irregular, and aimless involuntary movements of the arms and legs, trunk, and facial muscles. It affects girls more often than boys and typically occurs between 5 and 15 years of age. Some children will have a sore throat several weeks before the symptoms begin, but the disorder can also strike up to 6 months after the fever or infection has cleared. Symptoms can appear gradually or all at once, and also may include uncoordinated movements, muscular weakness, stumbling and falling, slurred speech, difficulty concentrating and writing, and emotional instability." Cleveland Clinic: http://my.clevelandclinic.org/disorders/sydenham_chorea/hic_sydenham_chorea.aspx

had had in the past and the correlation between strep pharyngitis and Sydenham's chorea. Med. recs. at Ex. 4, p. 17.

On November 19, 2007, Jessie received her third Gardasil vaccination.

On December 6, 2007, the medical records state that Jessie had been diagnosed with Sydenham's chorea six months previously caused by strep throat. Med. recs. at Ex. 4, p. 30.

From December 30, 2007 to January 3, 2008, Jessie was at Huntsville Hospital, where Dr. Barbara J. Richman noted possible cerebritis,⁴ left facial numbness, and left-sided pain. Med. recs. at Ex. 4, p. 45. By history, she was diagnosed with Sydenham's chorea in August 2007 which resolved in September 2007. A tonsillectomy and adenoidectomy had been done in August 2007 secondary to Sydenham's chorea. On December 25, 2007, she had the return of intermittent left arm chorea. A brain MRI done in the emergency department showed enhancement of the right frontal area with the possibility of either cerebritis or vasculitis. *Id.*

On January 2, 2008, Jessie had a consultation with Dr. Lucille A. Ferrante who noted that an MRI/MRA revealed an acute cortical gyral ischemic infarct in the right middle and inferior frontal lobes with near total occlusion of the right proximal M1 segment and tight stenosis⁵ of the left mid-A1 segment. Med. recs. at Ex. 4, p. 47. Dr. Ferrante recommended that Jessie stop using oral contraceptives which might be the etiology of these infarcts especially considering the interaction of Depakote and oral contraceptives. Med. recs. at Ex. 4, p. 49. The ischemic infarct could be due to atherosclerotic vascular disease, emboli from cardiac sources, heredity or an

⁴ Cerebritis is focal inflammatory infiltrates in the brain parenchyma. Stedman's Medical Dictionary, 27th ed. (2000) at 323.

⁵ Stenosis is "an abnormal narrowing of a duct or canal." Dorland's, *supra* note 2, at 1757.

acquired thrombophilic state, metabolic disorders, dehydration, infection/inflammation, or moyamoya disease. Jessie's clinical condition was further complicated by her history of Sydenham's chorea and bipolar disorder which could possibly be explained by previous vasculitis and/or micro infarcts. *Id.* In August 2007, Jessie had choreoform movements and a high ASO (antistreptolysin-O) titer with a history of recurrent strep infections. Med. recs. at Ex. 4, p. 51.

On January 11, 2008, Jessie went to the Huntsville Hospital emergency department with facial pain, uncontrolled movements of her right arm, and slurred/thick speech. Med. recs. at Ex. 5, p. 4.

On January 27, 2008, Jessie went to Huntsville Hospital emergency department with chest pain, numbness, weakness, generalized pain, and rashy raised splotches diagnosed as hives. Med. recs. at Ex. 5, p. 28.

From August 10-12, 2008, Jessie was at Huntsville Hospital where Dr. Robbie F. Dudley diagnosed her with acute onset of bilateral facial numbness. She had had visual and auditory hallucinations in the prior week and seizures in the past. Med. recs. at Ex. 6, p. 2.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” *i.e.*, “evidence in the form of scientific studies or expert medical testimony[.]”

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said “we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. *Id.* at 1148.

Petitioner must show not only that but for the vaccine, Jessie would not have had strokes, Sydenham's chorea, and vasculitis, but also that the vaccine was a substantial factor in bringing about Jessie's strokes, Sydenham's chorea, and vasculitis. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Federal Circuit in Capizzano emphasized the opinions of petitioner's four treating doctors in that case in concluding causation of rheumatoid arthritis from hepatitis B vaccination. 440 F.3d at 1326. In the instant action, none of Jessie's doctors attributed her symptoms to Gardasil vaccine. All of them attributed her symptoms to Sydenham's chorea whose cause was her repeated strep infections. Unfortunately, Jessie's medications or the nature of the disease led to vasculitis and strokes. There is not a single medical record in support of petitioner's allegations.

Section 300aa-13(a)(1) of 42 U.S.C. states:

The special master or court may not make such a finding [awarding compensation to petitioner] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

Here, there is no medical record or medical opinion supporting petitioner's claim that Gardasil caused Jessie's Sydenham chorea, infarcts, and vasculitis. Petitioner attempted to find medical expert support from four physicians and was unsuccessful. Jessie had strep throat numerous times before her Gardasil vaccinations and was diagnosed with Sydenham's chorea afterward her multiple bouts of strep. Her unfortunate illnesses have been linked to Sydenham's chorea or the synergy between her anticonvulsive Depakote and oral contraceptives.

Petitioner has failed to prove a prima facie case of causation in fact that Gardasil vaccine caused Jessie's strokes, Sydenham's chorea, and vasculitis.

CONCLUSION

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.⁶

IT IS SO ORDERED.

October 28, 2010
DATE

s/Laura D. Millman
Laura D. Millman
Special Master

⁶ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.