

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 12-747V

Filed: July 8, 2014

Redacted: July 25, 2014

Not to be Published

K.L.,

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Petitioner,

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v.

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Flu Mist; pediatric infection-triggered autoimmune neuropsychiatric disorder (“PITAND”); sleep disorder; no expert witness; failure to prosecute; dismissal

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

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Richard H. Moeller, Sioux City, IA, for petitioner.

Lisa A. Watts, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

On November 2, 2012, when petitioner was still a minor, her parents filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2006), alleging that Flu Mist vaccine administered on November 2, 2009 caused K.L. to suffer pediatric

¹ Because this decision contains a reasoned explanation for the special master’s action in this case, the special master 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). 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 constitute a clearly unwarranted invasion of privacy. In this case, petitioner made a timely motion to redact the decision on July 22, 2014. Respondent filed a response on July 23, 2014, stating she takes no position on petitioner’s motion. The undersigned granted petitioner’s motion and issued a redacted decision on July 25, 2014. The redacted decision redacts petitioner’s full name and birth date.

infection-triggered autoimmune neuropsychiatric disorder (“PITAND”). On January 24, 2013, K.L. having reached her majority, the undersigned issued an Order changing the caption to reflect K.L. as petitioner.

On July 1, 2013, the undersigned issued a Formal Notice under 42 U.S.C. § 300aa-12(d)(3)(A)(ii), informing petitioner that 240 days had expired since the petition was filed, and petitioner had the option of moving to continue or to withdraw her petition pursuant to 42 U.S.C. § 300aa-21(b).

On July 30, 2013, petitioner filed a statement saying, “I would like to withdraw my petition,” citing 42 U.S.C. § 300aa-21(b). On July 31, 2013, the undersigned issued an Order Concluding Proceedings under Vaccine Rule 21(a)(3).

On August 1, 2013, petitioner filed a statement saying she wanted to withdraw her prior statement withdrawing her petition. She added, “I wish to continue my claim and I am in the process of interviewing attorneys.” On August 1, 2013, the undersigned issued an Order rescinding her prior Order Concluding Proceedings and reinstating the case.

On August 22, 2013, the undersigned held a telephonic status conference, during which petitioner said she was looking for an attorney. Another status conference was set with petitioner’s approval for September 27, 2013, but petitioner failed to appear at it.

On October 1, 2013, the undersigned held a telephonic status conference, during which petitioner said she was looking for an attorney but had not contacted an attorney.

On November 4, 2013, petitioner obtained the services of her current attorney, Mr. Richard Moeller.

On November 12, 2013, the undersigned held a telephonic status conference, during which petitioner’s counsel stated he wanted to gather all of petitioner’s medical records and file them. Respondent noted medical records missing from those already filed.

On February 3, 2014, the undersigned held a telephonic status conference, during which petitioner’s counsel said he had obtained a few more medical records, but he had not filed them yet. Counsel said he had not yet reached any conclusions about the case.

On March 5, 2014, the undersigned held a telephonic status conference, during which petitioner’s counsel stated he thought he received all the medical records. He stated he could not obtain an expert report from petitioner’s treating allergist, Dr. Denis A. Bouboulis. The undersigned suggested that petitioner file an amended petition alleging significant aggravation, since before petitioner received Flu Mist, she had the same symptoms of constant fatigue and sleepiness. Petitioner’s counsel said he had contacted Dr. David Axelrod as a prospective expert for petitioner.

On May 5, 2014, the undersigned held a telephonic status conference, during which petitioner's counsel stated that Dr. David Axelrod would not supply an expert report in the case. Petitioner's counsel reported he had recommended to his client that she dismiss the case, but petitioner wanted to find another attorney.

On June 5, 2014, the undersigned held a telephonic status conference, during which petitioner's counsel stated that petitioner had e-mailed four attorneys to inquire if any would represent her, but none had answered her e-mails so far.

On July 7, 2014, the undersigned held a telephonic status conference, during which petitioner's counsel stated that petitioner had not found another attorney to replace him. The undersigned told counsel that she was going to dismiss the petition for failure to prosecute.

Under Rule 41(b) of the Rules of the United States Court of Federal Claims, the undersigned may dismiss a case for failure to prosecute. The undersigned **DISMISSES** this case for failure to prosecute.

FACTS

Petitioner was born on [REDACTED] 1995.

On July 13, 2007, K.L. saw Dr. Kenneth B. Liegner, complaining of fatigue. Med. recs. Ex. 22, at 1. She said she was tired all the time. Id. K.L. and her father arrived for the scheduled appointment almost one hour late because of the difficulty of getting K.L. up from sleep. Id. at 3. She was in excellent health until January 2007. Id. at 4.

On December 10, 2007, K.L.'s pediatrician noted that she had Lyme disease, which was treated with antibiotics. Med. recs. Ex. 15, at 14. Her pain persisted, and she saw a Lyme specialist who prescribed Amoxicillin for two months. Id.

On April 14, 2008, K.L.'s father sent a letter to a Dr. Steere at Massachusetts General Hospital, a copy of which he sent to K.L.'s pediatrician, saying that K.L.'s personality had changed since her Lyme disease. Med. recs. Ex. 24, at 42. K.L.'s father stated that before February 2006, K.L. was an A/B student and frequently made the honor roll at school. Id. In fifth grade, she was on time for school every day for the whole school year and did not miss one day of school. Id. She was full of energy and played basketball, softball, and other sports whenever she could. Id. K.L.'s father stated that after the tick bite, K.L. became fatigued easily. Id. She tolerated the 30-day course of Amoxicillin that her pediatrician prescribed, but the second course of antibiotics given in March and April of 2007 had a number of side effects, including stomach pain, headaches, and sun rashes. Id. She experienced what K.L.'s father described as the "die-off effect" twice, once in March following the Amoxicillin and once in April following the Doxycycline, when K.L. became totally exhausted for a few days and could

not go to school. Id. K.L.'s father stated that K.L. had a bad case of flu in February 2008 and could not get out of bed for two weeks. Id. at 41. In March 2008, K.L. would often become so exhausted that she would not be able to get out of bed and missed school two days a week for the last four weeks. Id. K.L.'s father wrote, "K.L.'s demeanor has become brash towards family members when she is asked to do something that would require her getting up at a particular time, or going to bed at a particular time." Id. Her hair got caught in her brother's go-kart the day before Thanksgiving 2007 and was ripped out of her head in several spots. Id. She had a three-inch gash in her forehead that a plastic surgeon stitched up. Id. She had some problems with her neck and back because of her head being pulled over the back of the go-kart seat into the axle. Id. K.L.'s father stated that his main concern was that K.L.'s Lyme disease was not managed correctly. Id. He did not know if her exhaustion and inability to get out of bed were due to the Lyme disease or something else. Id. She tested positive for Epstein-Barr virus and strep. Id.

On April 16, 2008, Dr. Allen C. Steere, a rheumatologist at Massachusetts General Hospital, wrote a letter to Dr. Kenneth Liegner regarding K.L. Med. recs. Ex. 22, at 33. K.L.'s chief complaint was fatigue. Id. She had difficulty getting out of bed in the morning and missed 39 days of school that year. Id. She seemed to need 12 hours of sleep at night. Id. Dr. Steere performed a physical examination and did laboratory testing, resulting in his opinion that she did not have a clinical picture of Lyme disease. Id. at 34. He stated, "I am not certain why she is having difficulty with excessive fatigue." Id. She was doing well in school both academically and athletically. Id.

On October 21, 2008, K.L.'s pediatrician noted she was tired at times. Med. recs. Ex. 15, at 10.

On February 26, 2009, K.L.'s pediatrician noted that she had chronic fatigue and had Lyme disease in the past as well as mononucleosis. Id.

On May 5, 2009, Dr. Harold Chandler Clark, K.L.'s internist, wrote a note that K.L.'s chief complaint was fatigue all the time. Med. recs. Ex. 24, at 6.

On May 13, 2009, petitioner saw Dr. David E. Karas, a pediatric otolaryngologist, complaining of hypertrophy of her nasal turbinates and unspecified sleep disturbance. Med. recs. Ex. 12, at 3. She had a history of chronic nasal sinus complaints and occasional sore throats. Id. She and her father stated that she has had problems with chronic fatigue and difficulty getting out of bed in the morning. Id. They noted that her chronic fatigue and difficulty getting out of bed in the morning had been going on for the prior couple of years and that, the prior year, she missed 59 days of school and was late for 59 days of school. Id. Her past history was notable for some head and neck trauma related to a go-kart injury. Id. On physical examination, she had moderate edema of the nasal turbinates and edematous-appearing mucosa, particularly on the right. Id. Dr. Karas stated he had some concerns about K.L.'s sleep hygiene and how it might be

contributing to her tiredness. Id. at 4. Dr. Karas also believed she might have some obstructive sleep apnea symptoms. Id. He recommended she get a sleep apnea study. Id.

On June 5, 2009, K.L.'s internist, Dr. Clark, wrote a "To Whom It May Concern" letter, stating that K.L. was his patient, was suffering the remains of Lyme disease, and now had mononucleosis. Med. recs. Ex. 24, at 8. She had all the symptoms of Lyme disease: sore throat, fatigue, headache, myalgia, and enlarged lymph nodes. Id.

On November 2, 2009, K.L. received Flu Mist vaccine. Med. recs. Ex. 4, at 38.

On May 5, 2010, K.L. saw Dr. David M. Berkun. Med. recs. Ex. 16, at 24. He noted that K.L. had definite psychological pathology, was defiant, and resisted logical plans. Id.

On March 15, 2013, Dr. Denis A. Bouboulis, K.L.'s allergist, wrote a letter to a member of the Board of Education, stating that K.L. had Epstein-Barr virus and cytomegalovirus. Med. recs. Ex. 23, at 1. He stated, "It is nearly impossible to predict an exacerbation of symptoms or their severity." Id. K.L. was particularly affected by extreme anxiety, fatigue, and sleep disorder. Id. Dr. Bouboulis recommended that the school provide K.L. with a homebound instructor/tutor or online courses. Id.

On September 18, 2013, Dr. Bouboulis wrote a letter to the director of student support services at the Stamford Public Schools, saying that K.L. was diagnosed with post-infectious autoimmune encephalopathy, which vaccines, particularly live vaccines, had exacerbated in the past. Id. at 2. He recommended that K.L. have access to in-home tutoring and/or online programming. Id.

On December 9, 2013, K.L. saw Dr. Dominic J. Roca for her insomnia, sleep disorder, and hypersomnia. Med. recs. Ex. 21, at 8. Dr. Roca noted that her physical examination was normal. Id. at 9. Dr. Roca contemplated treating K.L. with light, melatonin, stimulants, cognitive/behavioral therapy, and perhaps sleeping pills. Id.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(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. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 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[.]”

Althen, 418 F.3d at 1278.

Without more, “evidence showing an absence of other causes does not meet petitioners’ affirmative duty to show actual or legal causation.” Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for her Flu Mist vaccination, she would not have had PITAND, but also that the vaccine was a substantial factor in causing her PITAND. Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Although petitioner alleges Flu Mist vaccine caused her PITAND, the medical records do not prove her allegation, and petitioner has not provided an expert report supporting her allegation. The Vaccine Act does not permit the undersigned to rule for petitioner based on her claims alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1) (2006).

Moreover, petitioner had the same symptoms of sleep disorder, excessive fatigue, inability to rise from bed in the morning, and defiant behavior before she received Flu Mist vaccine. She complained about being tired all the time starting in early 2007, more than two years before she received Flu Mist vaccine in the late fall of 2009. If petitioner were to attempt proving her case, she would have to prove the Flu Mist vaccine significantly aggravated her prior sleeping disorder. Section 300aa-33(4) defines “significant aggravation” as follows:

The term “significant aggravation” means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

42 U.S.C. § 300aa-33(4).

The medical records petitioner filed do not substantiate any difference between her symptoms before and after Flu Mist.

Moreover, petitioner has not obtained the services of a medical expert, not even Dr. Bouboulis, who was willing to write a letter to the Stamford Public Schools to obtain at-home tutoring and on-line courses for her but is not willing to give an opinion in this case. His letter does not give a basis for his opinion that petitioner has an autoimmune encephalopathy, which vaccines, particularly live vaccines, exacerbate. The letter is particularly suspect in light of petitioner’s normal physical examination and diagnosis of defiant disorder.

Petitioner has not satisfied the first prong of Althen in that she has not presented through medical records or an expert medical opinion a theory explaining how Flu Mist vaccine could cause PITAND or could exacerbate a preexisting sleep disorder. Petitioner has not satisfied the second prong of Althen that there is a logical sequence of cause and effect showing that Flu Mist vaccine did cause petitioner to have PITAND or an exacerbation of her preexisting sleep disorder. In fact, she has not proven she has PITAND. Petitioner has not satisfied the third prong of Althen that the onset interval (whatever it was) is a medically appropriate time interval to show causation of PITAND or exacerbation of sleep disorder from Flu Mist vaccine. Thus, petitioner has not made a prima facie case of causation.

The undersigned **DISMISSES** this case for failure to prosecute and failure to make a prima facie case.

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.²

IT IS SO ORDERED.

July 8, 2014
DATE

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

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.