In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-696V
September 4, 2014
Not to be Published

EILEEN CALLAHAN,	*	
	*	
Petitioner,	*	Measles-mumps-rubella (MMR) vaccine;
	*	40-minute onset of multiple sclerosis (MS);
v.	*	dismissal; failure to prove allegations by a
	*	preponderance of the evidence
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Richard H. Moeller, Sioux City, IA, for petitioner.
Lara A. Englund, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On September 30, 2008, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2006), alleging that measles-mumps-rubella ("MMR") vaccine administered on October 2, 2007 caused numbness and weakness in her left leg, progressing within two to three days to left-sided facial numbness and numbness in her left arm and hand. Pet. ¶ 1.

[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. When such a decision is filed, petitioners have 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

The undersigned **DISMISSES** this case for failure to prove by a preponderance of the evidence the allegations in her petition. 42 U.S.C. § 300aa-13(a)(1)(A).

FACTS

Pre-vaccination records

Petitioner was born on August 1, 1962.

On September 7, 2007, petitioner went to Dr. Mandy Uppal at McKinley Health Center, complaining of left foot pain. Med. recs. Ex. 1, at 1. Dr. Uppal diagnosed her with tendinitis secondary to overuse. Id. Petitioner gave a history of two months of left foot pain. Id. at 2. The prior year, she had severe tendinitis of the left foot and went to physical therapy to strengthen the tendon. Id. Dr. Uppal prescribed Motrin and gave her an orthopedic referral. Id.

On September 13, 2007, petitioner went to Dr. David Lawrance at McKinley Health Center, complaining of hypothyroidism, fatigue, low back pain, foot and ankle pain, and lethargy, but no specific injury. Id. at 3–4. She was clinically hypothyroid and overweight. Id. at 4.

On September 21, 2007, petitioner went to McKinley Health Center. Id. at 5. She weighed 192 pounds and was five foot three inches tall. Id. Around midnight, she had a horrible sore throat, sweating, and slight lightheadedness. Id. She had no other upper respiratory symptoms. Id. She took aspirin four to five days earlier and had black stool for two days. Id. The diagnosis was pharyngitis. Id.

Post-vaccination records

On October 2, 2007, petitioner received MMR vaccine. Id. at 8.

Also on October 2, 2007, petitioner saw Dr. Lawrance at McKinley Health Center. Id. at 7. Petitioner's stool guaiac test was positive. Id. She had not had bleeding since discontinuing aspirin. Id. Dr. Lawrance diagnosed petitioner with lethargy, likely obstructive sleep apnea since she snored, and a history of mild elevation of her hemoglobin and platelets, which might be related to her gastrointestinal bleeding. Id.

On October 8, 2007, petitioner saw Dr. Larry dePedro at McKinley Health Center. Id. at 8. She told him that she received MMR on October 2, 2007 and, 40 minutes later, her left leg started to go numb. Id. Two days later, her left cheek went numb. Id. Her left leg started to hurt after five minutes of walking. Id. She had a fever since the beginning of the school year. Id. Dr. dePedro diagnosed petitioner with paresthesias involving her face and left upper thigh. Id. at 9. He questioned whether it was vaccine-related. Id.

On October 8, 2007, petitioner saw another doctor whose signature looks like Palinkas. Id. at 10. Petitioner remembered having similar symptoms twenty years ago after receiving a cholera vaccination. Id. She said her numbness persisted for several months and then spontaneously resolved with intermittent occurrences for several years. Id. She thought she had a fever when she received the vaccine. Id. Dr. Palinkas wrote that petitioner might have an inflammatory polyneuropathy of uncertain etiology, but he doubted it was related to her recent MMR vaccination. Id. at 11.

On October 11, 2007, petitioner saw Dr. Rong Chen, a neurologist. Med. recs. Ex. 2, at 11. He wrote that petitioner's physical examination did not reveal any substantial neurological deficit. Id. She had no signs of myelopathy or neuropathy. Id.

On November 3, 2007, petitioner underwent a brain MRI. Med. recs. Ex. 1, at 69. It showed a small number of scattered focal areas of abnormal increase in signal intensity. Id. at 70. These signs were nonspecific. Id. They could signify end artery infarcts, post-vaccination encephalomyelitis, Lyme disease, Epstein-Barr virus, sarcoidosis, or vasculopathy. Id.

On January 30, 2008, petitioner saw Dr. Anthony Reder, a neurologist at the University of Chicago Medical Center. Id. at 73. He wrote that petitioner's descriptions of her symptoms were consistent with a demyelinating disease, but she had a relatively normal physical examination, although she had cognitive problems and fatigue. Id. at 75.

On March 3, 2008, petitioner underwent an MRI of her cervical spine. Id. at 76. The MRI showed she did not have multiple sclerosis or a demyelinating disease. Id. The MRI also showed she had minimal bulging discs. Id.

On March 25, 2008, petitioner went to Dr. Donald Greeley for a sleep consultation. Id. at 78. Petitioner said she had gained 85 pounds over the prior three years. Id. She had had fatigue since she was seventeen years old due to mononucleosis. Id. The fatigue had worsened over the last five to six years. Id. She had chronic fatigue. Id. She had choking in her sleep. Id. Her current weight was 203 pounds. Id. Her weight five years earlier was 115 pounds. Id. She was five foot three inches tall. Id.

On May 21, 2008, Dr. Daniel L. Picchietti administered a polysomnogram to petitioner and diagnosed her with mild obstructive sleep apnea. Id. at 81.

Expert Reports

Petitioner filed an expert report from a treating physician, Dr. William R. Shaffer, a neurologist at the University of Chicago Medical Center, dated February 11, 2008. Med. recs. Ex. 5, at 1. Dr. Shaffer states petitioner had a reaction to previous vaccinations. Id. at 2. He also states she had post-vaccination encephalomyelitis after MMR, but he does not give a basis for his opinion. He does not explain a medical theory that would connect petitioner's MMR

vaccination to her alleged encephalomyelitis or explain how a 40-minute onset is an appropriate temporal interval to connote causation from the vaccine. Id.

On June 23, 2009, respondent filed the expert report of Dr. Martin Bielawski, a neurologist, as Exhibit A. His opinion is that petitioner did not have a clear-cut history, examination findings, or objective tests to support a diagnosis of post-vaccination acute disseminated encephalomyelitis or any other form of encephalomyelitis. Ex. A, at 6. Dr. Bielawski states that petitioner claimed she had numbness in the left anterior thigh 40 minutes after MMR vaccination in her left upper arm, and concludes: "I am unaware of an autoimmune mechanism that can produce central or peripheral neurological injury or inflammation/demyelination to an area remote from the injection site in 40 minutes." Id. He also states that "[l]eft anterior thigh numbness is a focal symptom," not a manifestation of a brain or spinal cord problem. Id. Thus, "this symptom could not be secondary to encephalomyelitis." Id. It could, however, be due to left lateral femoral cutaneous neuropathy, which is a peripheral nerve commonly compressed in overweight patients. Id. Since petitioner weighed 200 pounds while being only five foot three inches tall, her obesity could have caused an isolated lateral femoral cutaneous nerve symptom. Id. He states, "A vaccination would not produce isolated lateral femoral cutaneous nerve symptoms." Id.

Dr. Bielawski also states that petitioner's physical examinations never showed any objective evidence for encephalomyelitis or any other demyelinating disease. Id. She never had abnormal deep tendon reflexes or Babinski response to suggest an upper motor neuron problem of her brain or spinal cord. Id. Petitioner's brain MRI results were nonspecific and not diagnostic of multiple sclerosis. Id. Her brain MRI results would commonly occur with migraine headache, and petitioner had a history of menstrual-associated migraine. Id. at 7.

On August 25, 2009, respondent filed a supplemental expert report of Dr. Bielawski as Exhibit C. Dr. Bielawski states that if petitioner had reacted to cholera and typhoid vaccinations 25 years earlier, her immune system would have created T-cells with a memory for cholera and typhoid antigens, but not a memory for MMR antigens. Ex. C, at 2.

On April 8, 2014, petitioner filed the report of Dr. Lawrence W. Shields as Exhibit 7. He recounts petitioner's history, including that she has felt fatigue since high school. Ex. 7, at 2. Dr. Shields also physically examined petitioner and found that her strength was adequate throughout, her muscle appearance was normal, she did not have focal atrophy or wasting, her tone was normal throughout, and she did not have fasciculations. Ex. 7, at 4. She had obtainable deep tendon reflexes and no Babinski sign. Id. Her sensation was intact throughout to pin, vibration, joint position, and two-point discrimination. Id. at 5. He concludes that petitioner has an underlying demyelinating process, strongly suggestive of multiple sclerosis ("MS"), and he opines that the MMR vaccination "was the competent producing cause of exacerbation of her underlying condition." Id. Dr. Shields does not give a medical theory as a basis for his conclusion. He does not explain how a 40-minute onset is an appropriate time interval between vaccination and symptoms to connote causation.

On August 26, 2014, respondent filed a supplemental report from Dr. Bielawski as Exhibit D to comment on petitioner's expert Dr. Shields' report. Although Dr. Shields states in his report that petitioner had an underlying demyelinating process strongly suggestive of MS, Dr. Bielawski states there is no objective clinical or diagnostic evidence to support that diagnosis. Ex. D, at 2. Dr. Shields points to Uhthoff's phenomenon as indicative of MS, but Dr. Bielawski says the revisions of the McDonald Criteria to diagnose MS omit Uhthoff's phenomenon. Id.; Ex. D, Tabs 1 and 2. Dr. Bielawski considers petitioner's description of her symptoms deteriorating with heat exposure as subjective. Ex. D, at 2. He notes that her neurological symptoms could also occur in the context of fatigue, which she has had for years, and that her underlying hypothyroidism can also be associated with fatigue. Id. Dr. Bielawski also notes that petitioner did not discuss her supposed worsening of symptoms in the context of heat with her two treating neurologists, Drs. Chen and Reder, after her MMR vaccination. Id.

Dr. Bielawski also disagreed with Dr. Shields' opinion that petitioner had objective findings of MS on his neurological examination of her. Id. Dr. Bielawski notes that petitioner dragging her left leg, walking clumsily, and displaying other neurologic peculiarities are easily voluntary rather than objective. Id. at 2–3. When Dr. Chen, her first neurologist, examined her on October 11, 2007, he found petitioner had "give way" weakness, indicating petitioner's voluntary effort to feign weakness. Id. at 3. In addition, her variable gait before seeing Dr. Chen showed voluntary inconsistency. Id. When petitioner saw Dr. Reder, her second neurologist, in January 2008, she claimed to have loss of concentration during school, yet Dr. Reder described her as a good historian. Id. Dr. Bielawski notes that these neurologists' examinations did not show any objective findings of demyelinating disease: no disc pallor on fundoscopic examination, no afferent pupillary defect, no significant abnormalities in deep tendon reflexes, and no positive Babinski sign to suggest upper motor neuron dysfunction. Id.

Dr. Bielawski states that petitioner's brain MRI findings were nonspecific and not diagnostic of MS. Id. She did not have any callosal or pericallosal lesions on FLAIR sequences, reports of black holes on T1 weighted imagery, or Dawson's fingers. Id. The nonspecific findings on her brain MRI are commonly seen with migraine, for which petitioner has a history associated with her menstruation. Id. Petitioner's cervical MRI did not show abnormalities of the spinal cord to suggest a demyelinating disease. Id. Petitioner was evaluated for lupus, Lyme disease, rheumatoid arthritis, Sjögren's disease, and sarcoidosis with negative results. Id. Dr. Bielawski states that both petitioner's examinations and her brain MRI do not fulfill the revised McDonald criteria for the diagnosis of MS. Id.

Dr. Bielawski refers to Dr. Shields' statement in his report that vaccinations prior to petitioner's MMR vaccination sensitized her, resulting in a reaction to MMR vaccine. Id. Dr. Bielawski recounts petitioner's history that, at age 22, she claimed she had diminished sensation over the left side of her face after receiving vaccines for cholera, typhoid, and perhaps yellow fever. Id. Dr. Bielawski states that if cholera and typhoid vaccines primed petitioner's immune system over 20 years earlier, her immune system would have a memory for cholera and typhoid

antigens, not for MMR antigens. Id. He states no one can infer that these prior vaccines primed her immune system to react to all vaccines. Id.

Dr. Bielawski says he cannot explain petitioner's complaint after her MMR vaccination of left-sided facial numbness. Id. at 4. He notes these symptoms are subjective. Id. Dr. Shields found petitioner had normal corneal reflexes and normal trigeminal nerves, which affect sensation of the face bilaterally. Id. Petitioner's brain and spinal cord imaging did not show any abnormality to explain her complaint of left facial numbness post-MMR vaccination. Id.

Dr. Bielawski also notes that petitioner claimed she had numbness in her left anterior thigh about 40 minutes after she received MMR vaccine in her left upper arm. Id. Dr. Bielawski states, "I am unaware of any autoimmune mechanism that can produce central or peripheral neurological injury or inflammation/demyelination to an area remote from the injection site in 40 minutes." Id. Moreover, Dr. Bielawski explains, left anterior thigh numbness is a focal, not a central nervous system, symptom. Id. Neither the cerebral hemisphere, brainstem, or spinal cord has an isolated anatomic representation of sensation in the left anterior thigh. Id. Therefore, Dr. Bielawski says that left anterior thigh numbness could not be due to demyelination. Id. It could be due to left lateral femoral cutaneous neuropathy, which commonly occurs in patients who are overweight due to compression of the lateral femoral cutaneous nerve, a peripheral nerve. Id. Petitioner was obese at the time she received MMR vaccine, weighing 200 pounds with a height of five feet three inches. Id.

Dr. Bielawski concludes that petitioner did not have either post-MMR vaccine encephalomyelitis or MS before or after MMR vaccination. Id. She did have several unexplained neurological symptoms before and after MMR vaccination, some of which Dr. Bielawski attributes to her hypothyroidism. Id. Her neurological examination and brain MRI do not fulfill the 2010 revised McDonald criteria for diagnosing MS. Id. at 4–5. Petitioner had migraine prior to MMR vaccination, and Dr. Bielawski says that migraine could be the cause of her nonspecific brain MRI result. Id. at 5. He also says that she probably had left lateral femoral cutaneous nerve compression causing her recurrent left anterior thigh numbness. Id.

PROCEDURAL HISTORY

At the very first telephonic status conference on December 18, 2008, petitioner's then-counsel, Sherry Drew, said she was looking for an expert, and petitioner had no diagnosis. On September 4, 2009, Ms. Drew stated at a telephonic status conference that she would discuss with petitioner the fact that her case was not very strong and perhaps she would like to make a demand on respondent for a low figure. On December 7, 2009, during another telephonic status conference, Ms. Drew said she would discuss with petitioner whether or not she would continue representing her. On December 18, 2009, Ms. Drew filed a motion to withdraw as petitioner's counsel.

On January 25, 2010, the undersigned held her first telephonic status conference with petitioner pro se. She said she was looking for an attorney. Over three years later, on March 26, 2013, petitioner obtained the services of Richard Moeller. During the telephonic status conference of April 3, 2013, Mr. Moeller stated he was going to use Dr. Lawrence Shields as petitioner's expert. Dr. Shields saw petitioner almost eleven months later on February 28, 2014, and wrote a report dated April 1, 2014. On April 8, 2014, Mr. Moeller said during a telephonic status conference that he would not be able to get an expert report from Dr. Shields and would see if he could get one from Dr. Shaffer. On July 3, 2014, Mr. Moeller said during a telephonic status conference that he could not find a doctor to support petitioner's allegations and that Dr. Shields had limited his opinion to offering the results of his examination of petitioner without giving any reason for his opinion that MMR exacerbated her MS. Mr. Moeller said petitioner, at Dr. Shaffer's suggestion, wanted two months to obtain an expert report from a neuroimmunologist. The undersigned gave petitioner two months to do this. On September 4, 2014, Mr. Moeller stated during a telephonic status conference that petitioner did not have a neuroimmunologist's expert report. He said petitioner was seeking to have a third law firm take her case and mentioned the name of the firm.

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 MMR vaccination, she would not have whatever illness she has, but also that the vaccine was a substantial factor in causing her illness. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Although petitioner alleges that MMR vaccination caused her neurologic difficulties, the medical records do not prove her allegation. The reports she submitted from Dr. Shaffer and Dr. Shields offer no theory to support their opinions. Dr. Shaffer's report is skeletal and conclusory. He gives no medical theory to connect causally petitioner's MMR vaccination and her alleged neurologic symptoms. He does not discuss her 40-minute onset or state that this short time interval is appropriate for causation. Dr. Shields recounts petitioner's physical examination, showing she has no objective neurological problem, and then he concludes MMR vaccine exacerbated her multiple sclerosis based upon her manifesting peculiar symptoms in walking in front of him. Not only does he offer no basis for his opinion, but also nothing in his physical examination of petitioner, much less her medical records, supports the conclusion that petitioner has a demyelinating disease, including MS. Dr. Shields does not mention, much less explain, how a 40-minute interval between MMR vaccination and onset of alleged neurologic symptoms is appropriate for the causation of demyelinating disease including MS.

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). Those medical opinions which petitioner has filed must be credible. The medical opinions she submitted are deficient in substance, and in Dr. Shields' case, self-contradictory. They are not sufficient to satisfy the three prongs of Althen.

Dr. Shields' opinion raises the issue of significant aggravation. If petitioner were to assert significant aggravation in this case, she would have to satisfy the Vaccine Act's definition of significant aggravation. 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 neurological symptoms, if any, before and after MMR vaccination, much less that she has ever had MS or encephalomyelitis. Thus, petitioner has not proven that she ever suffered from MS or any other neurologic disease or that she had a significant aggravation of same.

Petitioner has not satisfied the first prong of Althen in that she has not presented through medical records or credible expert medical opinion a theory explaining how MMR vaccine could cause numbness in her thigh 40 minutes later or how MMR vaccine could exacerbate her alleged preexisting MS. Petitioner has not satisfied the second prong of Althen that there is a logical sequence of cause and effect showing that MMR vaccine did cause petitioner to suffer an illness or an exacerbation of any preexisting illness. Petitioner has not satisfied the third prong of Althen that the onset interval of 40 minutes is a medically appropriate time interval to show

causation or exacerbation of either MS or any other demyelinating disease. De Bazan v. Sec'y of HHS, 539 F.3d 1347, 1349-50, 1352-53 (Fed. Cir. 2008) (eleven-hour interval between tetanus vaccination and acute disseminated encephalomyelitis too short to cause demyelination). Thus, petitioner has not made a prima facie case of causation.

Petitioner's counsel stated during the final telephonic status conference on September 4, 2014, that petitioner was seeking the services of a third law firm in the hope of continuing this case. At the time of this conference, the case was at the cusp of its sixth anniversary. Petitioner has had the services of two separate attorneys, both familiar with and competent in pursuing and attaining vaccine compensation under the Vaccine Act: Sherry Drew and Richard Moeller. Petitioner's pursuit of further legal representation flies in the face of the paucity of the medical records and of the expert reports she has filed during these last six years. Dr. Shaffer, who provided a skeletal report dated February 11, 2008, refused to provide anything further. Dr. Shields, hired for the purpose of supporting petitioner's case, found nothing abnormal neurologically on his own examination of her, but nevertheless diagnosed her with MS based on petitioner's assertions and her manifesting awkward gait and other peculiarities before him. Yet Dr. Shields refuses to testify for her.

Petitioner has had more than ample opportunity over the last six years, with the assistance of two separate counsel, to prove her case. She has failed to do so. She has had "a full and fair opportunity to present" her case. Vaccine Rule 3(b)(2).

The undersigned **DISMISSES** this case for petitioner's failure to prove by a preponderance of the evidence the allegations in her petition. 42 U.S.C. § 300aa-13(a)(1)(A).

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.

September 4, 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.