In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 13, 2014

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JEFFREY LAND, *	
*	No. 12-474V
Petitioner, *	
*	Special Master Dorsey
v. *	
*	
SECRETARY OF HEALTH *	Ruling on entitlement; trivalent
AND HUMAN SERVICES, *	influenza (flu) vaccine; transverse
*	myelitis; acute inflammatory
Respondent. *	polyneuropathy; Guillain-Barré
*	syndrome (GBS); respondent will
* * * * * * * * * * * * * * * * * * * *	not further defend.

Christina Ciampolillo, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for petitioner.
Tara J. Kilfoyle, United States Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

This matter is before the undersigned on respondent's Motion for Ruling on the Record. On July 27, 2012, Jeffrey Land ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("the Program"),[2] in which he alleged that he suffered from acute inflammatory polyneuropathy and transverse myelitis as the result of a trivalent influenza ("flu") vaccination that he received on October 28, 2010. Petition ("Pet.") at ¶¶1, 3, 5. In support of his petition, petitioner filed his affidavit and medical records. On

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006). In accordance with the Vaccine Rules, each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b); 42 U.S.C. § 300aa-12(d)(4)(B)(2006). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted ruling. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be redacted.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (2012). Hereafter, individual section references will be to 42 U.S.C. § 300aa.

December 5, 2013, petitioner also filed an expert report from neurologist, Dr. Ahmet Höke, who opined that petitioner suffered from transverse myelitis or a residual myelopathy secondary to transverse myelitis, as opposed to GBS. In addition, Dr. Höke opined that petitioner's transverse myelitis is more likely than not related to his influenza vaccine. Petitioner's Exhibit ("Pet. Ex.") 19 at 4.

Respondent has chosen not to further defend this case. Respondent states that although she does not believe petitioner has established entitlement to compensation by a preponderance of the evidence, respondent "elects not to expend its limited resources to retain an expert to respond to Dr. Höke's report." Respondent's Motion for Ruling on the Record ("Resp't's Motion"), filed Feb. 12, 2014, at 7. Petitioner filed a response to Respondent's Motion on February 27, 2014. Petitioner's Response ("Pet'r's Response). Respondent requested that the undersigned decide the case on the record evidence as it stands. Resp't's Motion at 7.

As discussed below, the undersigned finds, based on a review of the record as a whole, that petitioner is entitled to compensation.

BACKGROUND

A review of the petition, Rule 4(c) report, as well as respondent's Motion and petitioner's response thereto, show that the parties do not dispute the relevant facts of this case. Thus, the undersigned will only briefly discuss the facts below.

Petitioner's medical history, prior to receiving the flu vaccination at issue in this case, was significant for chronic back pain, neck pain, pelvic pain, a limb-length discrepancy, and gastro-esophageal reflux disease. Pet. Ex. 2 at 14-15; Pet. Ex. 3 at 5, 22; Pet. Ex. 5 at 28.

On October 28, 2010, petitioner, who was 35-years-old at the time, received a flu vaccine at his place of employment. Pet. Ex. 3 at 4; Pet. Ex. 4 at 1-2. In his affidavit, petitioner states that

> [t]he next night, October 29, 2010, I worked my midnight shift. Throughout my shift, I felt tired, but did not think much of it. After my shift, I went home to sleep. That day, October 30, 2010, I woke up, but still felt very tired . . . . By the next day, October 31, 2010, I felt worse and had trouble moving my toes. I took my children trick-or-treating for Halloween, and it was difficult to walk. I felt like I was dragging my foot behind me. My brother-in-law had to get the car and pick me up. That night, I tried to relax in bed, but I experienced severe back pain. My left leg and foot seemed to stop working . . . . When I woke up on November 1, 2010, I tried to stand up, but fell down because my legs were numb. I felt numbness from below my chest through my body. My wife brought me to the hospital, and I was admitted.

Pet. Ex. 6 at 1-2.

On November 1, 2010, petitioner was admitted to Port Huron Hospital with complaints of leg numbness, unsteadiness, and pain in his mid-back and left hip since October 30, 2010. Pet. Ex. 2 at 8. Petitioner could not move his left leg, and could not walk. Id. at 14. Petitioner was evaluated by neurologist, Dr. Demian Naguib, who noted that petitioner had received a flu vaccine a "couple of days ago." Id. at 18.

On November 2, 2010, petitioner was admitted to the hospital. Pet. Ex. 2 at 14. The admission report noted that petitioner's weakness and numbness began the previous day and that petitioner had received a flu vaccine "a couple of days ago." Id. at 14-15. Upon examination, petitioner's left leg was weak, and a sensory exam revealed decreased sensation in his right leg. Id. at 19. The attending physician, Dr. Ahmad Alabbas, noted that petitioner potentially suffered from transverse myelitis, multiple sclerosis or Guillain-Barré syndrome "even though it is not the typical picture of it." Id. at 14-15. Dr. Alabbas also noted that petitioner's condition was "[s]tatus post recent flu vaccine." Id.

A CT scan of petitioner's brain revealed no acute abnormalities. Pet. Ex. 2 at 18. MRIs of petitioner's brain and spinal cord were normal, and a lumbar puncture revealed no acute issues. Pet. Ex. 2 at 54, 70-71. Petitioner was started on intravenous Solu-Medrol, but his condition did not improve. Id. at 15, 54. On November 3, 2010, the Solu-Medrol was discontinued and petitioner was started on a five-day course of IVIG. Pet. Ex. 2 at 37, 54.

On November 4, 2010, petitioner was re-evaluated by Dr. Naguib. Pet. Ex. 2 at 56. Dr. Naguib stated:

> [Petitioner] is doing much better on the IVIG. He is starting to move his left leg and raised [it] off the bed up to 30 degrees. Still having hyperreflexia. MRI of the brain did not show acute stroke event. MRI of the spinal cord . . . . did not show any evidence of acute intraspinal cord abnormality and no myelomalacia and no transverse myelitis. I right now believe that the patient has acute parainfectious hyperreflexic polyneuropathy similar to the type that we see in people with anterior horn cells. He is improving on IVIG. . . .It came in the context of the flu vaccination.

Id.

By November 5, 2010, petitioner was able to put weight on his left leg with a walker. Pet. Ex. 2 at 57. On November 6, 2010, he experienced vomiting and nausea, which were felt to be a side effect of the IVIG. Id. at 58-59. Dr. Naigub noted in the "Impression and Plan of Care" section of the November 6, 2010 Progress Note that petitioner's symptoms were all "seen after the patient got the flu shot." Id.

By November 7, 2010, Dr. Naguib felt that petitioner had experienced "marvelous improvement." Pet Ex. 2 at 60. Petitioner was able to lift his left leg off of the bed, bend it, and flex it, and put weight on it. Id. Dr. Naguib noted "[a]gain, I do believe that here we were dealing with a case of acute inflammatory infectious/parainfectious polyneuropathy … and I do believe that has to do with the flu vaccine that he received, especially that with the consequences

of the flu vaccine in some people we have seen different variety of inflammatory consequences." Id. at 60-61.

Petitioner was discharged from Port Huron Hospital on November 8, 2010, with a discharge diagnoses of acute inflammatory/infectious polyneuropathy, numbness and weakness of the lower extremities, chronic pain syndrome and lower back pain, and nausea and vomiting. Pet. Ex. 2 at 12. He had improved significantly and was walking. Id. Petitioner was noted to be in stable condition and could resume with a regular diet and activity as tolerated. Id.

On November 11, 2010, petitioner was evaluated by Dr. Naguib as an outpatient. Pet. Ex. 1 at 44-45. Dr. Naguib noted that petitioner was "not back to normal but he is able now to put weight on the left lower extremity." Id. Dr. Naguib prescribed outpatient physical therapy three times a week for a month. Id.

On January 4, 2011, petitioner underwent electromyogram ("EMG") and nerve conduction studies. Pet. Ex. 1 at 33. Dr. Naguib's impression was that petitioner suffered from a mild case of right sided pronator nerve mononeuropathy that was primarily demyelinating without evidence of acute denervation. Id. Petitioner continued to experience right leg numbness, chronic low back pain, bilateral lower extremity tingling, numbness, paresthesias, balance difficulties, gait difficulties, and sensory difficulties. Id. Dr. Naguib extended petitioner's prescription for physical therapy. Pet. Ex. 2 at 189.

On January 12, 2011, petitioner underwent repeat EMG and nerve conduction studies, which revealed bilateral median nerve carpal tunnel syndrome at the wrist and a left ulnar nerve sensory mononeuropathy. Pet. Ex. 1 at 29. Dr. Naguib recommended lumbar epidural steroid injections for petitioner's back pain. Id. Petitioner received a caudal epidural steroid injection on January 26, 2011. Pet. Ex. 1 at 22.

On March 2, 2011, petitioner was re-evaluated by Dr. Naguib. Pet. Ex. 1 at 15-16. He had experienced 75 percent improvement in his back pain from the lumbar epidural steroid injection. Id. Dr. Naguib stated that petitioner suffered from an acute inflammatory polyneuropathy that "happened because of the swine flu vaccine,"[3] in addition to discogenic low back pain, insomnia, and a lumbosacral radiculopathy. Id. Dr. Naguib told petitioner that he could return to work on light duty. Id.

On May 4, 2011, petitioner received another epidural steroid injection to treat his back pain. Pet. Ex. 1 at 11. He began a second course of physical therapy on May 18, 2011. Pet. Ex. 2 at 235. The evaluation indicated that petitioner experienced "mid-lower back pain, [right] leg numbness, [left] leg weakness . . . . Mechanism of injury: Flu-injection – spinal cord swelling – progressive (left) leg weakness." Id. A June 28, 2011 MRI of petitioner's lumbar spine revealed mild disc desiccation at the L5 to S1 level. Pet. Ex. 3 at 19.

Petitioner was seen by Dr. Naguib on June 29, 2011 for lumbar degenerative disc disease, a lumbar sprain with muscle stiffness, and acute inflammatory polyneuropathy. Pet. Ex. 1 at 4. Petitioner continued to experience weakness in his left leg and numbness in his right leg. Id. Dr.

[3] The petitioner in this case did not receive the swine flu vaccine.

Naguib noted that he did not believe that petitioner could return to work with no restrictions at all. Id. at 4-5.

On July 14, 2011, petitioner was re-evaluated by Dr. Naguib. Pet. Ex. 1 at 1. His motor strength had improved in his left leg, and he had improved sensation in his right leg. Id. Petitioner was no longer ataxic, and could run behind his son on the soccer field. Id. Dr. Naguib felt that petitioner could return to work. Id. at 2.

At an October 20, 2011 visit to Dr. Naguib, petitioner had returned to work, but continued to experience back pain, which Dr. Naguib attributed to discogenic pain. Pet. Ex. 8 at 20.

On December 14, 2011, petitioner underwent repeat EMG and nerve conduction studies. Pet. Ex. 8 at 14. Dr. Naguib felt that the studies revealed a right side sural nerve mononeuropathy showing mild demyelination across petitioner's ankle segment without active denervation. Id.

On March 2, 2012, petitioner received another lumbar epidural steroid injection for his low back pain, and was told to return for repeat injections in one month, five months, and nine months. Pet. Ex. 8 at 1-2.

By August 2012, Dr. Naguib's impression was that petitioner suffered from an acute inflammatory polyneuropathy with residual weakness and lumbar radicular pain to the left leg, discogenic back pain, insomnia, and restless leg syndrome. Pet. Ex. 11 at 2-3.

A November 12, 2012 MRI of petitioner's thoracic spine was normal. Pet. Ex. 16 at 5. An MRI of the cervical spine showed a "compromise to multiple neural foramina as discussed in body report. There appears to be a slight increase of signal in the cord at C3-C4 and C5-C6." Pet. Ex. 16 at 3-4.

A December 19, 2012 brain MRI was normal. Pet. Ex. 16 at 1. One month later, Dr. Aboukasm, a neurologist, noted that petitioner had "transverse myelitis with residual myelopathy." Pet. Ex. 18 at 2-3. Petitioner's prescription for physical therapy was renewed.

Petitioner next saw Dr. Aboukasm on August 5, 2013, who noted that petitioner "continues to use Percocet 10/325 four times a day to manage his back pain. He continues to be active at work; however, overall his physical activity has declined significantly since he had the transverse myelitis . . . ." Pet. Ex. 21 at 4-5.

DISCUSSION

Special masters may determine whether a petitioner is entitled to compensation based upon the record. A hearing is not required. 42 U.S.C. § 399aa-13; Vaccine Rule 8(d).

To be awarded compensation under the Vaccine Act, a petitioner must prove either: 1) that he suffered a "table injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question, which creates a presumption that the injury

was caused by the vaccination, or 2) that his medical problems were caused by the vaccine(s) at issue. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). A petitioner may not be awarded compensation based on the petitioner's claims alone. 42 U.S.C. § 300aa-13(a)(1). Rather, the petition must be supported by either medical records or by the opinion of a competent physician. Id.

On the issue of a table injury, petitioner may not take advantage of any presumption because the Table does not compensate for an association between the vaccination at issue here, the flu vaccination, and his alleged injuries. 42 C.F.R. § 100.3(a). Further, petitioner has not alleged that he suffered from a "table injury," and there is no evidence that any "table injury" occurred. As a result, petitioner cannot be deemed entitled to compensation on that basis.

Because petitioner cannot prevail based on a showing that he has a "table injury," petitioner bears the burden of proving that the vaccination caused the injury for which he seeks compensation. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner must demonstrate that the vaccination was a substantial factor in causing his injuries. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321-22 (Fed. Cir. 2010). To do this, petitioner "must show by preponderant evidence that the vaccination brought about [the] injury by providing: (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." Moberly, 592 F.3d at 1322, quoting Althen, 418 F.3d at 1278. As explained below, a review of the record as a whole demonstrates that petitioner has satisfied this burden and demonstrates by preponderant evidence that the flu vaccination caused his injuries.

A. Althen Prong One

Althen Prong One requires that petitioner set forth a medical theory causally connecting the vaccination and the injury. Althen, 418 F.3d at 1278. Petitioner's expert, Dr. Höke, opinioned that petitioner suffered transverse myelitis shortly after receiving a flu vaccine. Dr. Höke states that his opinion is supported by the following facts: "[petitioner's] examination (sensory level, asymmetric lower extremity weakness that partially resolved, hyperreflexia in the lower extremities and subsequent development of a spastic gait);" and ii) "lack of any evidence of a generalized polyneuropathy on his EMG/NCS." Pet. Ex. 19 at 3. Although there were no abnormalities on petitioner's MRI scan, Dr. Höke pointed out that MRI scans have a very high degree of sensitivity in some studies (up to 96%), in other studies up to 40% of all acute transverse myelitis cases have a normal spinal MRI scan. In fact, patients with normal MRI scans tend to have a milder course with better recovery." Pet'r's Ex. 16 at 3.

Dr. Höke opined that the primary theory that drives his opinion is molecular mimicry which is a process by which "antigenic determinants of the microorganisms are recognized by the host's immune system as similar to its own antigenic determinants and, because of the structural resemblances, antibodies and auto-reactive T cells not only destroy the invading pathogen but can react with host tissues as well . . . ." Id. at 4. Dr. Höke also referenced medical literature to support his theory that vaccination is a recognized cause of transverse myelitis. Id.

Based on the evidence presented by petitioner, the undersigned finds that petitioner has provided a reliable medical theory connecting the flu vaccine and his transverse myelitis. Thus, petitioner has satisfied Althen Prong One.

B. Althen Prong Two

Althen Prong Two requires that petitioner demonstrate a logical sequence of cause and effect showing that the flu vaccine is the cause of petitioner's transverse myelitis. Althen, 418 F.3d at 1278. In support of this prong, Dr. Höke stated:

> Review of the medical records indicates that Mr. Land had transverse myelitis soon after receiving his influenza vaccine . . . . [T]here are multiple examples of transverse myelitis occurring after both influenza vaccinations and other vaccines . . . . Due to its strong association with preceding infectious illnesses, it is clear that transverse myelitis is likely to be an autoimmune disease, similar to GBS and others. The primary theory that drives autoimmunity in such cases is molecular mimicry . . . . In summary, it is clear that Mr. Land developed transverse myelitis soon after receiving his influenza vaccine on October 28, 2010 and I believe that his transverse myelitis is more likely than not related to his influenza vaccine. This conclusion is based on numerous case reports of similar cases, potential etiopathological link based on molecular mimicry and close temporal relationship between his vaccination and onset of his transverse myelitis.

Pet. Ex. 19 at 3-5.

Petitioner's treating physicians also noted an association between petitioner's injuries and his flu vaccination as noted above. See Pet'r's Response at 26-28. Based on a review of the records, petitioner's expert's opinion and the medical literature submitted, the undersigned finds that petitioner has satisfied Althen Prong Two.

C. Althen Prong Three

Althen Prong Three requires a showing of a proximate temporal relationship between vaccination and injury. Althen, 418 F.3d at 1278.

Petitioner received his vaccination on October 28, 2010. Pet. Ex. 4 at 1-2. By October 31, 2010, petitioner had difficulty moving his toes and walking. Pet. Ex. 6 at 1-2. On November 1, 2010, he experienced numbness and tingling in his lower extremities. Pet. Ex. 2 at 18-21.

Dr. Höke stated that "A careful review of the literature evaluating the association between transverse myelitis and influenza vaccine between 1970 and 2009 shows that transverse myelitis after influenza vaccine is often underreported and the time from the vaccine to onset of transverse myelitis range from few days to few months." Pet. Ex. 19 at 4; Pet. Ex. 19, Tabs A, C, E, G, M.

Based on the information set forth by petitioner, the undersigned finds that petitioner has satisfied Althen Prong 3.

D. Alternative Cause

In choosing not to defend the case, respondent has not presented any evidence that a factor unrelated to the flu vaccine caused petitioner's injuries. In addition, the medical records do not identify any alternative cause of petitioner's injuries.

E. Conclusion

In view of respondent's position and of the undersigned's review of the entire record, see § 300aa-13(a)(1), the undersigned finds that petitioner is entitled to compensation for an injury that was caused-in-fact by a covered vaccine. 42 C.F.R. § 100.3(a)(XIV); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005). A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master