IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 11-328V
Filed: March 30, 2012
(Not for Publication)

KEVIN M. HINNEFELD,	*	
	*	
	*	Guillain-Barre Syndrome; Influenza
Petitioner,	*	Vaccine; Six Month Requirement;
v.	*	Residual Effect or Complication
	*	
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

David Murphy, Esq., Greenfield, IN, for petitioner
Melonie McCall, Esq., U.S. Dept. of Justice, Washington, DC, for respondent

DECISION[1]

Vowell, Special Master:

On May 20, 2011, Kevin Hinnefeld ["petitioner" or "Mr. Hinnefeld"] filed a petition for compensation under the National Vaccine Injury Program, 42 U.S.C. §§ 300aa-10 to -34 [the "Vaccine Act" or "Program"].[2] The petition alleged that the seasonal influenza vaccination Mr. Hinnefeld received on November 3, 2010, caused him to develop Guillain-Barre Syndrome ["GBS"].[3] Petition ["Pet."] ¶ 14. After considering the record

[1] Because this decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

[3] GBS, or polyneuropathy, is a rapidly progressive ascending motor neuron paralysis. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) ["DORLAND'S"] at 1832. Paralysis typically begins in the feet, then ascends to the trunk, upper limbs, and face. *Id.*

as a whole,[4] I hold that petitioner has failed to establish his entitlement to compensation.

Under the Vaccine Act, the petitioner bears the burden of proving a vaccine-caused injury. There are two ways causation may be demonstrated.[5] First, a petitioner may establish a "Table" injury. Alternatively, a petitioner may prove that a vaccine listed on the Table actually caused or significantly aggravated an injury (an "off-Table" injury). To establish a Table injury, petitioner must show: (1) receipt of a vaccine listed on the Table; (2) an injury listed on the Table for that vaccine; and (3) that the injury occurred within the time period specified for that injury and vaccine. §§ 11(c)(1)(C)(i)-14, as revised by 42 C.F.R. § 100.3 (2010); *see also Walther v. Sec'y, HHS*, 485 F.3d 1146, 1149 (Fed. Cir. 2007). Proof of these three elements excuses petitioner from producing evidence of vaccine causation of the claimed injury. The causal link is established as a matter of law when preponderant evidence demonstrates the Table's requirements. *See Grant v. Sec'y, HHS*, 956 F.2d 1144, 1149 (Fed. Cir. 1992).

For an off-Table injury case, a petitioner must show preponderant evidence of "(1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury." *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). *See* §§ 11(c)(1)(C)(ii), 13(a).

Additionally, in both Table and off-Table cases, petitioner must establish by a preponderance of the evidence: (1) the vaccine was administered in the United States, or that one of the statutory exceptions to this requirement applies; (2) the injury persisted for more than six months; and (3) petitioner has not previously collected an award for damages in connection with the vaccine-related injury.[6] These are separate prerequisites to recovery that petitioner must satisfy even if causation is otherwise established.

Although petitioner initially alleged a Table injury claim, there is no Table injury associated with the influenza vaccine. In his amended petition, filed June 10, 2011, he alleged a cause in fact case. However, regardless of the causation theory utilized in this case, the claim for compensation fails because the claimed injury, GBS or sequelae thereof, did not persist for longer than six months. The evidence fails to demonstrate that Mr. Hinnefeld suffered residual effects of GBS for more than six months.

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[4] *See* § 300aa-13(a)(1): "Compensation shall be awarded . . . if the special master or court finds on the record as a whole—(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1)." *See also* § 300aa-13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

[5] *See* § 11(c)(1)(C).

[6] § 11(c)(1)(B), (D), (E).

I. Relevant Medical History.

On November 3, 2010, Mr. Hinnefeld presented at the Indiana University Health Center with "flu like symptoms," including general weakness, chills, loss of appetite, and headache. Petitioner's Exhibit ["Pet. Ex."] 1, p. 4. He was diagnosed with a viral syndrome and directed to continue taking Advil or Tylenol. *Id.*, p. 6. During the appointment, he received an influenza vaccination. *Id.*, p. 7.

Seven days later, on November 10, 2010, Mr. Hinnefeld was seen at the Indiana University Health Urgent Care and Occupational Services Center. Pet. Ex. 2, p. 4. Mr. Hinnefeld reported that, during the previous day, he began to experience soreness, weak joints, and difficulty moving his hands. *Id.* His symptoms worsened significantly during the evening hours. *Id.* The treating physician noted that Mr. Hinnefeld exhibited an abnormal gait, could not stretch his toes without losing his balance, and could not hyperextend his wrists, especially his left one. *Id.* The doctor recommended Mr. Hinnefeld be transferred to Bloomington Hospital Emergency Department ["BHED"]. *Id.*

After his transfer to BHED, Mr. Hinnefeld was admitted by Dr. Brian Moore. Pet. Ex. 3, pp. 32, 33. Mr. Hinnefeld again complained that he felt "generally weak," and also that he had fallen earlier that morning. *Id.*, p. 34. Doctor Judith Wright performed a lumbar puncture. *Id.*, p. 36. Although Mr. Hinnefeld was oriented and alert, he continued to walk with an abnormal gait and demonstrated diminished reflexes. *Id.* According to Dr. Wright, Mr. Hinnefeld's weakness was "consistent with Guillain Barre syndrome." *Id.* Doctor Moore recommended Mr. Hinnefeld begin treatment with intravenous immunoglobulins ["IVIG"] as soon as possible. *Id.*, p. 47.

On November 10, 2010, Mr. Hinnefeld was admitted to Bloomington Hospital to begin his IVIG treatment. Pet. Ex. 3, p. 60. Over the next five days, Mr. Hinnefeld received IVIG treatments via a peripherally inserted central catheter. *Id.*, pp. 53, 57-58, 262. An electromyogram ["EMG"] performed on November 11, 2010, revealed acute right upper and lower extremity motor axonal neuropathy, "as seen in acute demyelinating polyradiculoneuropathy also known as Guillain Barre Syndrome." *Id.*, p. 214. On the second day of his treatment, November 12, 2010, Mr. Hinnefeld was evaluated for occupational therapy. *Id.*, p. 240. The evaluation record indicates that the active range of motion in Mr. Hinnefeld's left and right fingers was impaired. *Id.* During a muscle performance test, Mr. Hinnefeld's upper extremities were graded between 3+ and 3- out of 5. *Id.* His shoulder flexion scored 4 out of 5. *Id.* Additionally, his ability to walk unassisted and feed, groom, and dress himself was impaired. *Id.*, p. 241. The therapist indicated Mr. Hinnefeld would "need continued rehab" for all activities of daily living. *Id.* Consequently, Mr. Hinnefeld was to receive physical therapy once a day for six days, or until he was discharged from the hospital, and occupational therapy for once a day for five days, or until discharged. *Id.*, pp. 241, 243.

On November 13, 2010, the third day of his IVIG treatment, Mr. Hinnefeld reported that he felt stronger through his lower extremities and could rise onto his left

toes. Pet. Ex. 3, p. 257. His physical therapist indicated that he was "progressing well," with "no new complaints." *Id.*

Two days later, Mr. Hinnefeld expressed that he was "feeling better" and was "ready to go home." Pet. Ex. 3, p. 258. He was discharged on November 15, 2010. *Id.*, p. 260. At the time of his discharge, Mr. Hinnefeld's GBS was described as "under good control," with the weakness in his upper and lower extremities having resolved. *Id.*, p. 44. The discharging physician indicated that, after receiving a five-day treatment of IVIG, Mr. Hinnefeld "completely reverted back to normal." *Id.* Mr. Hinnefeld was recommended for outpatient physical therapy and occupational therapy. *Id.*, p. 45.

The day after his discharge, on November 16, 2010, Mr. Hinnefeld received a neurological examination to assist in developing a rehabilitation plan. Pet. Ex. 3, pp. 19, 22. He continued to suffer from limited motion, weakness, and coordination in his upper extremities. *Id.*, p. 21. The physician created a treatment plan of home exercise, neuromuscular re-education, postural training, therapeutic exercises, and fluidotherapy. *Id.*, p. 22.

On November 22, 2010, Dr. Moore evaluated Mr. Hinnefeld during a follow-up appointment. According to Dr. Moore, Mr. Hinnefeld had made a "significantly good recovery." Pet. Ex. 4, p. 2. Mr. Hinnefeld was described as having full strength, except for a "mild amount of finger abduction weakness." *Id.* Doctor Moore recommended he continue therapy, but believed he was ready to resume normal life activities. *Id.*

During a therapy session on November 23, 2010, Mr. Hinnefeld reported that he felt stronger and could again play the bass in his band. Pet. Ex. 3, p. 28. He continued to progress, making gains in strength and function. *Id.* He did not have contact with his therapist again until December 17, 2010, when she called him after he failed to attend two consecutive appointments.[7] *Id.*, p. 3. Mr. Hinnefeld reported over the phone that he was "doing well." *Id.* On December 21, 2010, he was discharged from the occupational therapy program with home instructions and directions to contact a physician if further problems occurred. *Id.*, p. 7.

The next medical record is dated August 1, 2011, approximately eight months later, when Mr. Hinnefeld was seen by Dr. Moore for a follow-up examination. Pet. Ex. 4(2), pp. 2-3.[8] Mr. Hinnefeld stated that he was "doing great" and had "slowly regained all [of his] strength." *Id.*, p. 2. Doctor Moore noted that Mr. Hinnefeld's reflexes, coordination, and strength were all normal. *Id.*, p. 3.

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[7] Mr. Hinnefeld missed a total of three appointments between November 23, 2010 and December 21, 2010. The first, scheduled for November 30, 2010, was cancelled "secondary to therapist illness." Pet. Ex. 3, p. 27. He then failed to attend appointments scheduled for December 10, 2010 and December 17, 2010. *Id.*, pp. 9, 3.

[8] Petitioner filed volume 2 of exhibit 4 on September 6, 2011. Despite labeling the exhibit as a continuation of exhibit 4, petitioner labeled the first page as page one, the second as page two, and so forth. I thus refer to this exhibit as exhibit 4(2), using the page numbers provided by petitioner.

II. The Six Month Rule.

A. Procedural History.

Petitioner filed this petition on May 20, 2011. The petition incorrectly alleged a Table injury, and did not address whether the residual effects of petitioner's GBS persisted for more than six months. Shortly thereafter, petitioner filed six exhibits of medical records pertaining to the diagnosis and treatment of his GBS. Petitioner filed no records addressing the time period between December 21, 2010, his last therapy session, and the August 1, 2011 evaluation.

After a telephonic status conference on June 8, 2011, I ordered petitioner to file an amended petition correcting his original claim of a Table injury. Order, filed June 8, 2011. Petitioner's amended petition, filed on June 10, 2011, again failed to address whether his injury had persisted for six months. *See* Amended Petition ["Am. Pet."], filed June 10, 2011. On September 6, 2011, petitioner filed additional medical records.

Another telephonic status conference was held on October 5, 2011. During the conference, petitioner's counsel stated that he believed Mr. Hinnefeld was examined by Dr. Moore in May 2011. *See* Order, filed Oct. 5, 2011. I afforded petitioner an opportunity to file these additional records, as well as any other unfiled records pertaining to the six-month timeframe between November 2010 and May 2011. Order, filed Oct. 5, 2011. However, on October 11, 2011, petitioner indicated that no further records from Dr. Moore would be filed.[9] On November 3, 2011, petitioner filed an affidavit along with his statement of completion, indicating that all relevant medical records had been filed. Less than one month later, petitioner filed a status report indicating that nothing further would be filed in the case. Petitioner's Status Report, filed December 5, 2011.

Respondent then filed a report pursuant to Vaccine Rule 4(c), contending that petitioner failed to provide sufficient evidence that the influenza vaccine causes GBS or, assuming it does, that the influenza vaccine caused petitioner's GBS. Respondent's Report ["Res. Rep."], filed Jan. 9, 2012, at 12-14. Additionally, respondent argued that petitioner's medical records failed to establish that the residual effects or complications of his GBS persisted for more than six months after onset. Res. Rep. at 14-15. Despite being afforded an opportunity to do so, petitioner has filed nothing further regarding causation or the six-month rule in this case.

[9] As discussed during the October 5, 2011 status conference and in my order of the same day, I planned on issuing an order authorizing petitioner to serve a subpoena on Dr. Moore. However, in response to an email inquiry from my law clerk regarding Dr. Moore's address needed for the order, petitioner's counsel responded "[a]ll of Dr. Moore's records have been filed." My law clerk replied indicating that petitioner's counsel was to contact chambers if he still desired authority to subpoena Dr. Moore's records. No further communication occurred.

B. Factual Determinations.

The primary factual issue is whether Mr. Hinnefeld's GBS was resolved prior to six months after the onset of his symptoms on November 9, 2010. Absent a determination that his GBS persisted beyond this time (May 9, 2011), petitioner cannot meet the requirement under § 11(c)(1)(D)(i). Thus, he would not be entitled to compensation for his injury.

I conclude that Mr. Hinnefeld did not suffer "residual effects" of GBS for more than six months. The medical records do not support that Mr. Hinnefeld experienced any adverse effects which persisted for more than six months. At the time of Mr. Hinnefeld's discharge, the treating physician indicated Mr. Hinnefeld had "completely reverted back to normal" after five days treatment. Pet. Ex. 3, p. 258. Although a post-discharge neurological examination in November 2010 revealed some residual weakness, it apparently resolved. Mr. Hinnefeld participated in only two subsequent physical therapy sessions. *Id.*, pp. 3. 9, 21. After less than one month of therapy, Mr. Hinnefeld was discharged from the program entirely. *Id.*, p. 7.

Mr. Hinnefeld was not seen again by a physician until nine months later. During Dr. Moore's examination, Mr. Hinnefeld reported that he was "doing great." Pet. Ex. 4(2), p. 2. The records indicate that Mr. Hinnefeld's strength, coordination, and reflexes were all normal. *Id.*, p. 3.

C. Applying the Facts to the Law.

Pursuant to the Act, petitioner must prove by a preponderance of the evidence that the residual effects of his injury lasted more than six months after the administration of the vaccine. § 11(c)(1)(D)(i); *see Stavridis v. Sec'y, HHS*, No. 07-261V, 2009 WL 3837479, at *3 (Fed. Cl. Spec. Mstr. Oct. 29, 2009); *Watson v. Sec'y, HHS*, No. 89-92V, 1990 WL 293420, at *1 (Cl. Ct. Spec. Mstr. Sept. 14, 1990). Petitioner's claims alone, unsupported by the medical records or by medical opinion, are insufficient. § 13(a)(1).

The medical records do not support that Mr. Hinnefeld suffered residual effects of GBS for more than six months after onset. After his final therapy appointment, on December 21, 2010, Mr. Hinnefeld reported no further health problems associated with his GBS. Doctor Moore, during his examination on August 1, 2011, indicated Mr. Hinnefeld's reflexes, coordination, and strength were all normal. Pet. Ex. 4(2), p. 3.

Moreover, petitioner failed to file an expert opinion that Mr. Hinnefeld experienced any residual effects after the successful treatment of his GBS. *See Stavridis*, 2009 WL 3837478, at *4 (requiring petitioner to file an expert report supporting the theory that a low white blood cell count was a residual effect of a hemolytic injury). Without an expert opinion or some other evidence that Mr. Hinnefeld suffered adverse effects of his GBS for more than six months, petitioner is unable to satisfy the six month requirement.

III. Conclusion.

Assuming arguendo that the influenza vaccine caused Mr. Hinnefeld's GBS, the residual effects did not persist longer than six months, a statutory requirement. The petition for compensation is therefore DENIED. In the absence for a motion for reviewed filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Special Master