In the United Stated Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(E-Filed: August 1, 2008)

No. 07-290V

TO BE PUBLISHED

TAMMY L. EDWARDS GOZA, f/k/a TAMMY L. SUMPTER,	)	
Petitioner,	)	Respondent's Motion for Judgment on the Record; Influenza Vaccine; Alleged Injury of Guillain-Barre Syndrome or CIDP; No Responsive Expert Opinion Filed
v.	)	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Anne Toale, Sarasota, FL, for petitioner.

Lisa Watts, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

This Ruling on Entitlement **SUPERCEDES** the Ruling that was filed yesterday, July 31, 2008.

On May 8, 2007, petitioner Tammy L. Edwards Goza, f/k/a Tammy L. Sumpter, through counsel, filed a petition seeking compensation under the National Vaccine Injury

[1] Pursuant to 42 U.S.C. § 300aa-12(d)(4), Rule 18(b)(2) of the Vaccine Rules of this Court, and the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), this ruling will be made available to the public unless a party objects, within fourteen days, to the disclosure of: (1) any "trade secret or commercial or financial information which is privileged and confidential;" or (2) any information contained in "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy."

Compensation Program (the Vaccine Program).[2] Petitioner claims that she developed Guillain-Barre Syndrome (GBS) or chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) as a result of the influenza vaccine she received on October 15, 1997. See Petition ¶ 2-3.[3]

Respondent filed a Rule 4(c) Report (R's Rept.) on January 7, 2008. In the Rule 4(c) Report, respondent asserted that this case was not appropriate for compensation under the Vaccine Act. Respondent stated that "petitioner ha[d] not yet demonstrated by a preponderance of the evidence that she received a covered vaccine on October 15, 1997, or that her . . . neurologic condition (to include CIDP) was caused by receipt of a covered vaccine." R's Rept. at 10. In addition, respondent challenged the filed affidavit from petitioner's treating physician, Patti M. Nemeth, M.D., Ph.D., a neurologist, as inadequate to support petitioner's cause-in-fact claim.

On February 11, 2008, petitioner's counsel filed into the record the deposition of Ms. Andrea Rau, the nurse who administered the flu vaccine at Ms. Goza's place of employment, Magnet, Inc., in October of 1997. Ms. Rau's deposition testimony, together with the sign-in sheet that recipients of the administered flu vaccination (including Ms. Goza) signed, support a finding that it is more likely than not that Ms. Goza received the influenza vaccination in October of 1997.

On March 26, 2008, petititioner's counsel filed an expert report from Dr. Ahmet Hoke. Dr. Hoke is of the opinion that petitioner developed, within two weeks of the administration of the flu vaccination, atypical GBS that turned out to be CIDP. In Dr. Hoke's opinion, the administered flu vaccine causally triggered petitioner's CIDP.

Respondent declined the opportunity to file a responsive expert opinion. Instead, on July 11, 2008, respondent filed a motion for judgment on the record. That motion is now ripe for a ruling.

I. DISCUSSION

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[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (West 1991 & Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

[3] An amended petition was filed on May 15, 2007, correcting the location of the administration of the vaccination to indicate that the vaccine was administered by Washington Internal Medicine in Washington, Missouri. Amended Petition ¶ 2-3.

A. The Factual Record

On October 15, 1997, the date that petitioner alleges that she received the influenza vaccination, petitioner was 37 years old. She had a prior history of two automobile accidents resulting in chronic neck pain, headaches, and an anxiety disorder dating back to 1990, which required prescription medication. P's Ex. 12 at 177.

According to her medical records, several weeks after receiving the flu vaccine, specifically in early to mid-November 1997, petitioner experienced the onset of weakness, tingling, and sensory loss in the upper extremities. See P's Ex. 6 at 24, 29; P's Ex. 8 at 2, 7; P's Ex. 11 at 24, 26; P's Ex. 12 at 61, 177; P's Ex. 22 at 456. Her symptoms progressed to include the lower extremities over the course of several weeks. Id.

Petitioner's medical records reflect that by December 31, 1997, petitioner had a "true proximal weakness" in the upper extremities, diminished reflexes, and EMG findings of denervation. P's Ex. 6 at 24. Petitioner presented to the Missouri Baptist Medical Center on January 6, 1998, with complaints of developing weakness and numbness in her upper extremities in mid-November 1997. Id. An admission note by her treating physician, Dr. Goldring, indicated that when he first evaluated petitioner for her complaints, he found no significant abnormality. Id. Petitioner was scheduled for an elective cervical myelogram on January 7, 1998. Id. However, due to the progressive deterioration of petitioner's condition and her fear she was becoming paralyzed, petitioner presented to the emergency room instead. Id. At that time, she gave no history of a preceding influenza vaccination. Id. Petitioner was admitted and transferred to Barnes-Jewish Hospital.

The discharge summary from her seven-day hospitalization at Barnes-Jewish Hospital in January 1998, reflects that petitioner was treated with intravenous Solu-Medrol for five days without much improvement. P's Ex. 12 at 177-79. She was also found to have a urinary tract infection, which was treated with Bactrim. Id. On discharge, petitioner continued to have severe weakness and was advised to follow-up with the neuromuscular clinic. Id.

Petitioner continued to experience neurologic problems after January 1998. A treatment note dated February 5, 1998, by Dr. Pestronk, a neurologist at the Washington University School of Medicine's Neuromuscular Division in St. Louis, Missouri, indicates that petitioner continued to experience progressive motor weakness in her upper and lower extremities. P's Ex. 8 at 7-9. Dr. Pestronk's diagnosis was lower motor neuron disease, a variant of amyotrophic lateral sclerosis ("ALS"). Id. Dr. Pestronk noted that petitioner had no family history of ALS, but that her serum would be sent for genetic testing. Id. Petitioner's needs for home health assistance, physical therapy, and a

wheelchair were also noted. Id.

On March 24, 1998, petitioner was seen at the Mayo Clinic for a second opinion. P's Ex. 11 at 21-28. A report of a neurology examination by Dr. Daube times the onset of petitioner's symptoms to the "mid fall of 1997." Her symptoms were noted to have begun as generalized headache, photophobia, tinnitus, and general anxiety as she was preparing for her wedding. Id. Petitioner reported that these symptoms were followed by upper respiratory symptoms with fever. Id.

Dr. Daube's neurologic examination revealed "severe generalized weakness and wasting with absent reflexes" and moderately severe sensory loss. Id. Dr. Daube concluded that petitioner's condition was a subacute progressive severe polyradiculopathy of indeterminate etiology. Id.

Not all of petitioner's test results were available during her follow-up evaluation with Dr. Daube three days later, on March 27, 1998. P's Ex 11 at 21. Dr. Daube advised petitioner that the initial findings "provide[d] no evidence as to the etiology of her polyradiculopathy." Id. Dr. Daube noted that he had discussed petitioner's case with Dr. Pestronk, her neurologist in St. Louis, and recommended treatment for an autoimmune disorder with consideration of intravenous steroids. Id. Dr. Daube's diagnosis continued to be "polyradiculopathy [of] indeterminate etiology." P's Ex. 2 at 66.

A note dated May 1, 1998, documents a phone call from petitioner to Dr. Daube. P's Ex. 11 at 19. Petitioner reported that after two treatments of IVIG over the past three weeks, she felt that she had "improved with better ability at lifting her left leg, right arm, and walking better." Id. The records indicate that Dr. Pestronk did not share petitioner's view of her treatment regimen and that petitioner had questions about the difference between Dr. Daube's diagnosis of polyradiculopathy and Dr. Pestronk's working diagnosis of ALS. Id.

Petitioner had a follow-up examination with Dr. Pestronk on July 9, 1998. P's Ex. 8 at 5-6. Petitioner reported significant improvement following her second course of IVIG in April 1998. Id. But in late June 1998, petitioner had a relapse of her condition, with nearly a complete loss of strength that necessitated hospitalization. Id. Dr. Pestronk recommended measuring petitioner's anti-GM1 antibodies and continued IVIG and Cytoxan treatment for lower motor neuron disease. Id.

Subsequently, in November 1998, petitioner was admitted to St. Luke's Hospital for five days. P's Ex. 2 at 57-60. She complained of a week-long history of subacute onset of neuromuscular weakness following a fall. Id. Her standing diagnosis of lower motor neuron disease was noted. Id. She was treated initially for possible Lyme disease.

Id. Following a neurologic consultation, however, she was treated with gamma globulin. Id. By the third day of her hospitalization, petitioner was able to walk and at discharge, petitioner's strength was improved and she was able to walk short distances. Id. Her diagnosis was CIDP. Id.

Petitioner's medical records reflect that her CIDP has waxed and waned with intercurrent infections since February 2000, when her recovery was considered "optimal." P's Ex. 2 at 33. According to Dr. Nemeth, petitioner's treating neurologist, petitioner currently has "mild weakness," which has been kept "under good control" with periodic treatments of IVIG. P's Ex. 30.

At issue in this case is whether petitioner's CIDP was caused by the influenza vaccination administered on October 15, 1997.

B. Legal Standard and Analysis

The Vaccine Act permits a petitioner to prove entitlement to compensation by showing that either: (1) the vaccinee suffered an injury listed on the Vaccine Injury Table within the prescribed time period, commonly referred to as a "Table" case, see § 300aa-14(a); or (2) the vaccinee suffered an injury that is not listed on the Vaccine Injury Table but is caused in fact by the received vaccination, commonly referred to as an "off-Table" case, see § 300aa-11(c)(1)(C)(ii)(I). By either method, a petitioner bears the burden of proving his claim by a preponderance of the evidence. § 300aa-13(a)(1).

In a "Table" case, a petitioner benefits from a presumption of causation. See § 300aa-14(a); 42 C.F.R. § 100.3(a). The record in this case does not support a finding that a Table injury occurred.

Accordingly, to establish entitlement to Program compensation, petitioner must prove, by a preponderance of the evidence, an "off-Table" claim, specifically, that the influenza vaccination that she received on October 15, 1997, caused her CIDP. Petitioner satisfies her burden of proof "by providing: (1) a medical theory causally connecting [her] vaccination and [her] injury; (2) a logical sequence of cause and effect showing that [her] vaccination was the reason for [his] injury; and (3) a showing of a proximate temporal relationship between [her] vaccination and injury." Althen v. Sec'y of Dept. of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In connection with her claim, Ms. Goza has filed medical records showing that she suffered a cluster of symptoms that were temporally associated with the administration of her influenza vaccination. At least one of her treating physicians, Dr. Nemeth, held the opinion that Ms. Goza's receipt of the influenza vaccination was causally connected to

the development of Ms. Goza's symptoms. Additionally, Ms. Goza has provided an expert opinion offering a medical theory causally connecting her vaccination to her claimed injury. Dr. Hoke stated in his report that:

> . . . Ms Goza had developed an atypical onset GBS that turned into a CIDP within weeks of vaccination with the influenza vaccine. Although there is a concern that she may have had a concurrent viral illness, I believe the symptoms suggestive of a viral illness were more likely to be related to common side effects of influenza vaccination.

P's Expert Report at 3. He further explained that:

> Nevertheless, even if we assume that she had an actual upper respiratory infection by chance around the time of her vaccination, the presence of the vaccine is more than likely to have exacerbated an autoimmune response and resulted in the development of the GBS/CIDP. Previous literature has clearly linked influenza vaccine to development of GBS (see Tishler and Shoenfeld 2006 for a review). The issue of two inciting events, i.e. an infection and a vaccination, synergistically triggering an autoimmune disease, has been better studied in the literature regarding transverse myelitis, a presumably autoimmune illness affecting the spinal cord (for example see references Fonseca et al 2003 and Trevisani et al 1993). In a similar line of argument, a good case-control study noted that people who reported vaccine related GBS had a higher incidence of URI symptoms preceding the neurological syndrome (Stricker etal 1994).

Id. at 2.

Respondent has declined to introduce an expert opinion to rebut Dr. Hoke's opinion. The Vaccine Act prohibits a special master from making a finding of entitlement to compensation based on the claims of petitioner alone, without substantiation by medical records or by a medical opinion. See § 300aa-13(a)(1). In this case, petitioner's claim is supported by both the filed medical records and an offered medical opinion and is not rebutted by any further submission from respondent. Under the Vaccine Act, Ms. Goza has met her burden for compensation.

II. CONCLUSION

The medical records in this case and petitioner's offered expert opinion from Dr. Dr. Ahmet Hoke are sufficient to support a finding of a causal connection between Ms. Goza's influenza vaccination and her alleged injury. Respondent has offered no expert

opinion to rebut the expert opinion offered by petitioner. Respondent's motion for judgment on the record is **GRANTED.** The undersigned finds that petitioner is entitled to compensation under the Vaccine Act.

The parties are directed to confer regarding a damages determination and **on or before Friday, August 22, 2008,** the parties shall contact the undersigned's chambers to schedule a status conference to address their progress in resolving the damages issue.

s/Patricia Campbell-Smith
Patricia Campbell-Smith
Special Master