# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS** 

No. 11-501V Filed: September 21, 2015 Reissued Redacted: October 13, 2015 Not to be Published

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M.M.F.,	*	
	*	
Petitioner,	*	
	*	
V.	*	Ruling on the Record; no proof of
	*	neuropathy after human papillomavirus
	*	("HPV" or "Gardasil") vaccination;
	*	medical records do not support
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
*****	****	

<u>Patricia L. O'Dell</u>, Montgomery, AL, for petitioner. <u>Justine E. Walters</u>, Washington, DC, for respondent.

## **MILLMAN, Special Master**

# **DECISION**<sup>1</sup>

On August 3, 2011, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that a human papillomavirus ("HPV" or "Gardasil") vaccine administered on January 22, 2009 caused her to suffer from an autonomic neuropathy and/or peripheral neuropathy, as well as preganglionic sudomotor dysfunction. In a

<sup>&</sup>lt;sup>1</sup> 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' 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. On October 5, 2015, petitioner moved to redact this decision. The undersigned grants petitioner's motion.

telephonic status conference on September 14, 2015, petitioner made a motion for a ruling on the record.

Special masters may determine whether a petitioner is entitled to compensation based upon the record. A hearing is not required. 42 U.S.C. § 300aa-12(d)(2)(D); Vaccine Rule 8(d). Based upon a review of the record as a whole, the undersigned finds that petitioner has not proven by preponderant evidence that she is entitled to compensation under the Vaccine Injury Compensation Program. 42 U.S.C. § 300aa-113(a)(1)(A).

## I. Background

Petitioner received her first Gardasil vaccination on September 5, 2006. Med. recs. Ex. 2, at 6. She received her second Gardasil vaccination on July 8, 2008. <u>Id.</u> at 10. She received her third Gardasil vaccination on January 22, 2009. <u>Id.</u>

On February 2, 2009, petitioner visited the emergency room complaining of intermittent numbness and tingling throughout her body that had been ongoing for about six months (putting onset at around early August 2008). Med. recs. Ex. 4, at 8. She also complained of shooting headaches, chest pains, and left leg pain. <u>Id.</u> During the visit, Dr. Kathleen R. Beckmann examined petitioner and noted a normal sensory and motor examination with normal symmetrical reflexes. <u>Id.</u> Petitioner ambulated freely. <u>Id.</u> Her muscle strength was normal in both the upper and lower extremities. <u>Id.</u> All other tests were also normal. <u>Id.</u> Petitioner had looked up on the internet diseases that Gardasil allegedly caused and found lupus, vasculitis, Guillain-Barré Syndrome, and "a host of other neurological disease and also death." <u>Id.</u> at 9. She called her parents that morning because she was very scared. <u>Id.</u> Petitioner had a normal neurological examination. <u>Id.</u>

On February 9, 2009, petitioner visited Dr. Gloria McGrath at the Marquette Neighborhood Health Center complaining of numbness in her left arm that had started four months earlier. Med. recs. Ex. 5, at 14. She informed the doctor that the numbness had spread and was getting worse in her arms, fingers, chest, and legs. <u>Id.</u> Again, her examination results were normal. <u>Id.</u> at 14-15.

On March 10, 2009, July 25, 2009, and December 22, 2009, petitioner was evaluated at the Medical College of Wisconsin West Clinic. Med. recs. Ex. 6, at 4. Petitioner's sensory examination, reflexes, and strength were normal. <u>Id.</u> at 2-12.

Petitioner underwent a series of tests at the Autonomic Reflex Lab. <u>Id.</u> at 39-40. Petitioner's Quantitative Sudomotor Autonomic Reflex Testing ("QSART"), Valsalva ratios, and tilt table test were all normal. <u>Id.</u> There was a slight abnormality in a Thermoregulatory Sweat Test ("TST") of petitioner's fingers and toes. <u>Id.</u> at 40. Upon looking at the test, the interpreting neurophysiologist concluded that "there is evidence of very mild and only distal preganglionic sudomotor dysfunction." <u>Id.</u>

On July 25, 2009, petitioner saw Dr. Jyothi P. Varanasi at Medical College of Wisconsin

West Clinic. <u>Id.</u> at 7. She gave a history that since August 2008, she had intermittent episodes of her whole body going numb, with numbness and tingling starting in her chest and radiating to her left arm and left leg. <u>Id.</u> Petitioner's mother brought in research articles linking Gardasil with this constellation of symptoms. <u>Id.</u> Petitioner had a history of some low blood sugars and was encouraged to increase the frequency of her meals to see if eating a snack helped alleviate her symptoms. <u>Id.</u> Petitioner was normal. <u>Id.</u> at 8. Her muscle bulk, tone, strength, and fine coordination were intact. <u>Id.</u> at 9. Her gait and balance were normal. <u>Id.</u> She had intact light touch and vibratory sensations throughout. <u>Id.</u> Her reflexes were normal. <u>Id.</u> Dr. Varanasi stated, "Much time was taken to explain the good fortune of finding no abnormalities on the work up so far .... With respect to the relationship with Gardasil, Dr. Woo and I discussed at length there is not enough support ... to maintain this claim." <u>Id.</u>

Finally, on July 23, 2015, Dr. Juan Figueroa performed a punch biopsy of petitioner's left foot, left distal leg, left mid-thigh, and left forearm to determine if petitioner has a small fiber neuropathy. Med. recs. Ex. 97, at 11. All four biopsies were normal. <u>Id.</u> at 16.

## I. Procedural History

On February 1, 2013, petitioner filed the report of Dr. Eric Gershwin, a rheumatologist and an immunologist. Ex. 13. Dr. Gershwin opined that HPV vaccine was a "substantial contributing cause of [M.M.F.] developing autonomic neuropathy." <u>Id.</u> at 4.

On November 7, 2013, respondent filed an expert report by Dr. Vinay Chaudhry, a neurologist. Ex. A. Dr. Chaudry stated petitioner does not have a peripheral neuropathy, either sensory, motor, or dysautonomic. <u>Id.</u> at 5. Moreover, a mildly abnormal Thermoregulatory Sweat Test ("TST") in distal fingers and toes is not the pattern seen in a neuropathy of a small fiber sensory or autonomic type, but could be related to the medications petitioner was taking, such as hydroxyzine HDL and acetaminophen with codeine. <u>Id.</u> at 4. Dr. Chaudhry stated this mild abnormality did not explain petitioner's complaints of left-sided pain, tingling, and headaches. <u>Id.</u>

Respondent filed an expert report by Dr. S. Michael Phillips, an immunologist, on December 9, 2013. Ex. E. He notes that petitioner's symptoms were attributed to stress and anxiety. Id. at 5. Dr. Phillips agreed with Dr. Chaudhry's conclusion, stating it is very unlikely that petitioner had a peripheral neuropathy. Id. at 6. He also stated that petitioner does not satisfy the criteria of a peripheral small fiber neuropathy. Id.

On March 10, 2014, petitioner filed Dr. Gershwin's supplemental expert report in which he states without offering any evidence that petitioner was genetically predisposed to the claimed immune reaction leading to her neuropathy. Ex. 82, at 1. Basing his opinion solely on petitioner's complaints ("if her complaints are credible"), Dr. Gershwin persists in his opinion that petitioner had a neuropathy which Gardasil vaccine caused. Id. at 3.

On June 18, 2014, respondent filed Dr. Chaudhry's supplemental expert report. Ex. FF. He states that complaints of intermittent numbness and tingling of the left arm and leg occurring several times a day for several months do not reflect neuropathic symptoms. <u>Id.</u> at 1. Moreover, a normal sensory examination, normal motor examination, and normal reflexes do not constitute signs of a neuropathy. <u>Id.</u> Shooting headaches involving the entire head are not symptomatic of a neuropathy. <u>Id.</u> Chest pain is not part of a neuropathy. <u>Id.</u> There is no evidence to support petitioner's subjective complaints of intermittent unilateral paresthesia are immune-mediated, genetically mediated, or related to Gardasil vaccine. <u>Id.</u> at 3.

This case was transferred to the undersigned on January 8, 2015, after having been initially assigned to Special Master George L. Hastings on August 3, 2011, and reassigned to Special Master Nora Beth Dorsey on January 14, 2013.

In an Order dated February 2, 2015, the undersigned stated that to support her case, petitioner would need to obtain either an expert report from Dr. Gershwin giving a basis for his opinion that Gardasil caused petitioner's alleged neuropathy, or obtain an expert opinion from a neurologist since Dr. Gershwin is a rheumatologist/immunologist, but not a neurologist.

In a telephonic status conference on September 14, 2015, petitioner's counsel explained that Dr. Gershwin is not willing to provide another supplemental report. She also noted that she is unable to find a neurologist willing to support petitioner's claim. Petitioner's counsel stated that she had spoken to petitioner and petitioner understands that it is not in her best interest to pursue this claim. Petitioner then moved for a ruling on the record.

The undersigned **GRANTS** petitioner's motion for a ruling on the record and **DISMISSES** this case for petitioners' failure to prove by a preponderance of the evidence the matters required in the petition. 42 U.S.C. \$ 300aa-13(a)(1).

#### II. Discussion

Under the statute, a petitioner may not be given an award based solely on the petitioner's claims. Rather, the petition must be supported by either medical records or the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not support the petitioner's claim, a medical opinion must be offered in support. Petitioner, however, has offered no such opinion. It is interesting to note that Dr. Gershwin bases his opinion on petitioner's claims rather than the results of extensive neurologic testing which proved to have normal results.

The fact that Dr. Gershwin believes petitioner's allegations is not sufficient for petitioner to prevail. Dr. Gershwin's opinion directly contradicts the opinions of her treating neurologists that she does not have a neuropathy, as well as every test result, including the July 23, 2015 biopsy, which confirmed she does not have a small fiber neuropathy. As the U.S. Court of Federal Claims stated in <u>Davis</u>, an expert's conclusions "are only as good as the reasons and evidence that support them." <u>Davis v. Sec'y of HHS</u>, 20 Cl. Ct. 168, 173 (1990). <u>See also</u>

<u>Perreira v. Sec'y of HHS</u>, 33 F.3d 1375, 1377 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it.") (citations omitted); <u>Dobrydnev v. Sec'y of HHS</u>, 566 Fed. Appx. 976, 984 (Fed. Cir. 2014) (finding that a special master may "reject an expert's opinion when the expert . . . assumes facts that are not supported by the record"); <u>Fehrs v. Sec'y of HHS</u>, 620 F.2d 255, 265 (Ct. Cl. 1980) (stating that an expert's opinions "can be no better than the soundness of the reasons that stand in support of them"). Here, Dr. Gershwin's opinion ignores the results of neurologic testing and treating neurologic opinion in petitioner's medical records. Therefore, his expert opinion offers no valid basis for awarding compensation to petitioner.

Additionally, the undersigned must give more weight to the opinions of petitioner's treating physicians than to those of Dr. Gershwin's, as her treating physicians were dealing with the purported illness contemporaneous to its onset and outside the concerns of litigation. <u>See Andreu v. Sec'y of HHS</u>, 569 F.3d 1367, 1375 (Fed. Cir. 2009) (citing <u>Capizzano v. Sec'y of HHS</u>, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (stating that "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.")

In the instant case, petitioner's treating physician at the Medical College of Wisconsin West Clinic decided that there was no evidence that the HPV vaccine caused any of petitioner's health concerns, stating "there were no signs or symptoms to indicate small fiber neuropathy with autonomic symptoms." Med. recs. Ex. 6, at 9. Dr. Woo and Dr. Varanasi, two of petitioner's other treating doctors, agreed with this assessment. <u>Id.</u> These opinions must be given more weight than Dr. Gershwin's expert report, as they were made by petitioner's treating physicians.

The undersigned notes that the only expert report from a neurologist in this case comes from Dr. Chaudhry who agrees with petitioner's treating physicians that petitioner does not have and never did have a neurological illness.

#### 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.<sup>2</sup>

### IT IS SO ORDERED.

Dated: <u>October 13, 2015</u>

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

<sup>&</sup>lt;sup>2</sup> Pursuant to Vaccine Rule 11(b), entry of judgment can be expedited by each party, either jointly or separately, filing a notice renouncing the right to seek review.