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

No. 12-285V
Filed: October 25, 2013
Not for Publication

MONTEZ PETRONELLI,	*	
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Petitioner,	*	
	*	Decision on the Record; Influenza Vaccine;
v.	*	Guillain-Barré Syndrome; GBS
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Ronald Homer, Esq., Conway, Homer & Chin-Caplan, P.C., Boston, MA, for petitioner.
Michael P. Milmoe, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

RULING ON ENTITLMENT[1]

Vowell, Chief Special Master:

On May 4, 2012, Montez Petronelli ["Ms. Petronelli" or "petitioner"] timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] [the "Vaccine Act" or "Program"]. The petition alleged that, as a result of her influenza vaccine on September 28, 2010, Ms. Petronelli suffers from a neurological demyelinating injury. The amended petition, filed on December 10, 2012, specified that petitioner suffers from Guillain-Barré syndrome ["GBS"].

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of a petitioner alone, unsubstantiated by medical

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims' website, in accordance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). 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. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

records or medical opinion. *See* § 13(a)(1). Petitioner has proffered both medical records and an expert medical opinion by Dr. Thomas Morgan causally linking her GBS to her influenza vaccination.

For the reasons stated herein, I find that petitioner has established entitlement to compensation.

I. Procedural History.

Between May 4, 2012 and September 4, 2012, when this case was reassigned to me, Special Master Lord conducted the initial status conference and petitioner filed exhibits 1-7 and her Statement of Completion. *See* Order, issued June 13, 2012; Notice of Intent to file on CD, filed July 10, 2012; Statement of Completion, filed July 13, 2012.

On September 13, 2012, I held a status conference with the parties. During the call, the parties expressed a desire to explore an informal resolution to this case. *See* Order, issued Sept. 13, 2012. Petitioner was ordered to file (1) medical records requested by respondent by October 15, 2012, (2) a status report when her demand was conveyed to respondent, and (3) her expert report by March 13, 2013.

Petitioner filed exhibits 8 and 9 on October 9, 2012. She transmitted her demand to respondent on November 20, 2012. Petitioner's Status Report, filed Nov. 30, 2012. Petitioner filed her affidavit and an amended petition on December 10, 2012. Although the parties continued to discuss settlement, petitioner filed her expert report on March 13, 2013.

On April 8, 2013, the parties conveyed to the court that petitioner had received a response from respondent regarding her life care plan assessment, but that she had not yet received a comprehensive response to her settlement demand and therefore it was unclear if a settlement agreement could be reached. Joint Status Report, filed Apr. 8, 2013, at 1. The parties requested a status conference to discuss future proceedings. *Id.*

On April 17, 2013, following the parties' requested status conference, I ordered respondent to file her Rule 4(c) report, accompanied by any response to petitioner's expert report she may elect to file, by no later than June 17, 2013. Order, issued Apr. 17, 2013.

After receiving extensions to her original deadline, respondent filed her Rule 4(c) report ["Res. Report"] on July 9, 2013. In the report, respondent stated that she would "not offer an expert report in this case," and that "other than [the] Rule 4(c) Report, and the attached literature, respondent will not expend further resources to defend this case." Res. Report at 9. Respondent suggested I decide entitlement based on the current case record. *Id.* Petitioner filed a responsive pleading to respondent's Rule 4(c) report on July 30, 2013.

II. Evidentiary Record.

Petitioner received an influenza vaccine on September 28, 2010. Petitioner's Exhibit ["Pet. Ex."] 2, p. 1. No medical records prior to the immunization or from the day of the immunization were filed by petitioner.

On October 21, 2010, petitioner was seen by her primary care physician, Dr. Sraboni Banerjee. According Dr. Banerjee's visit note, petitioner indicated she had been sick for six weeks, starting with a chest cold with no fever, sore throat, or cough, before progressing to a cough with nasal congestion and post nasal drainage. Petitioner indicated that her cough had started to resolve after four weeks, but then restarted during the past two weeks. Doctor Banerjee diagnosed her with sinusitis and prescribed amoxicillin. Pet. Ex. 2, pp. 38-39. At this visit, petitioner also complained of feeling very tired and numb, having tingling in her extremities, and muscle aches. Doctor Banerjee attributed her tingling to her sinusitis and conveyed to petitioner that her symptoms should improve within a couple of days. *Id.* at 39.

Petitioner had a follow-up visit for her sinusitis on October 25, 2010. Her cough was mostly resolved, but she still complained of numbness and muscle pains and indicated they had gotten worse. Pet. Ex. 2, p. 43. She expressed frustration that she was feeling tired and was unable to read or cook. *Id.* Doctor Banerjee speculated that her tiredness and general achiness were associated with the tension and stress brought on by her upcoming GRE exam. *Id.*

In the evening of October 25, 2010, petitioner fainted and was brought to the emergency room ["ER"] by her husband around midnight. She indicated she had a cough for two weeks that was almost resolved and had been experiencing worsening fatigue, numbness, and weakness. Pet. Ex. 1, p. 88. The ER physician ordered routine blood and lab tests. *Id.*, pp. 96-97. Because Dr. Banerjee had sent blood to the lab following her appointment with him, there was confusion in the lab and testing of the blood sample sent by the ER physician was delayed. *Id.*, p. 95. Petitioner elected to leave around 4:30 AM, prior to receiving her lab results, with the understanding that she would return if abnormal results were found. *Id*.

Petitioner spoke with Dr. Banerjee on October 26, 2010. She reported that since returning home from the ER she was doing worse with increased leg weakness, difficulty walking and climbing stairs, and a loss of balance. She also indicated that she was getting winded very easily and was unable to lift her arms above her head. Concerned that she might be describing symptoms of GBS, Dr. Banerjee advised her to return to the ER immediately for further evaluation. Pet. Ex. 6, p. 13.

She arrived at the Kaiser Permanente Santa Clara Medical Center ["SCMC"] around 3:39 PM and was evaluated by emergency room physician Dr. Haydn Hok Leung at 4:20 PM. Pet. Ex. 1, pp. 107-08. Ms. Petronelli relayed that she had a cough and myalgias for a couple of weeks, and that October 19, 2010 she noticed numbness in her toes which had progressively gotten worse and moved up her legs and also into

her arms. She also was experiencing shortness of breath. Pet. Ex. 1, p. 108. Petitioner was admitted to the hospital with diagnosis of possible GBS. *Id.*, p. 112.

A neurology resident at SCMC, Dr. Kelly Yeh, examined petitioner later that day. Doctor Yeh recorded that Ms. Petronelli had received a flu vaccine on September 28, 2010, and thereafter developed a cold consisting of a cough with mucous and a sore throat. Doctor Yeh also noted that during the previous week on October 19th or 21st petitioner started to develop numbness, pins and needles, and coldness in her toes. The numbness then ascended up her feet, into her legs, and up to petitioner's hands. Doctor Yeh documented that petitioner had not had any recent medical changes except for starting amoxicillin the previous week as treatment for her cold. Pet. Ex. 1, p. 120. Upon examination, Dr. Yeh observed petitioner had decreased sensation to light touch and pinprick which was worse in her toes bilaterally, but also present in her feet and legs, normalizing around petitioner's knees. Petitioner also demonstrated a decreased sensation to touch and pinprick in her hands bilaterally to her mid-proximal forearm. *Id.*, p. 121.

Doctor Yeh assessed petitioner as having "ascending numbness/paresthesisas with absent reflexes, severe back pain and tenderness of face/extremities, also with weakness primarily of hip flexors/hamstrings, suggestive of Guillain-Barre Syndrome." Pet. Ex. 1, p. 122. Doctor Yeh recommended frequent and serial pulmonary function tests, a lumbar puncture, and IVIG[3] treatment. *Id.* Doctor Jai Hee Cho, a physician at SCMC, also briefly saw and examined petitioner. Doctor Cho "agree[d] with the findings and the plan of care as documented in [Dr. Yeh's] note." However, in recounting petitioner's history of presenting illness in her consult note, Dr. Cho indicated that petitioner had a mild upper respiratory infection ["uri"] prior to receiving her influenza shot and that the symptoms worsened after the vaccination. Pet. Ex. 1, p. 123.

Petitioner's lumbar puncture showed elevated protein levels and normal white blood count and glucose, confirming the diagnosis of GBS. Pet. Ex. 1, p. 195. She received five days of IVIG treatments at SCMC before being discharged to another Kaiser Permanente facility for rehabilitation. *Id.*, pp. 229-232, 236-37. Petitioner was discharged from the rehabilitation facility on December 1, 2010. Pet. Ex. 5, pp. 6-7. She received home health care, which included physical and occupational therapy until January 24, 2011, when she was transitioned to out-patient therapy. *See* Pet. Ex. 7, pp. 7-18.

An EMG/NCV[4] study was performed in May 2011. The study showed that petitioner still had "evidence of a demyelinating sensorimotor polyneuropathy in the

[3] "IVIG" stands for intravenous immunoglobulin. Neil M. Davis, MEDICAL ABBREVIATIONS, 15th Edition, at 178 (2011).

[4] EMG (electromyography) studies look at the electrical activity within muscles and NCV (nerve conduction or electroneurography) studies examine the integrity of the peripheral nerves. Kathleen D. Pagona & Timothy J. Pagona, MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS ["MOSBY'S LABS"] at 571-77 (3d. ed. 2006). The two studies are commonly performed at the same time in patients complaining of weakness.

upper and lower extremities." Pet. Ex. 3, pp. 38-39. When compared with the study conducted in December 2010, Pet. Ex. 1, pp. 256-57, the study showed significant improvement. Pet. Ex. 3, pp. 38-39. In September 2011, petitioner was seen by neurologist Dr. Cho and reported that she still required a cane to walk through large stores, such as Costco, and could not go to parks without her wheelchair. *Id.*, p. 64. Doctor Cho noted that although the "lack of functional improvement is a concern, there is no objective evidence that there has been a relapse," and thus she was not concerned about CIDP.[5] Pet. Ex. 3, p. 65.

III. Discussion.

A. Legal Standards to Establish Entitlement to Compensation.

In order to prevail under the Program, a petitioner must prove either a "Table" injury[6] or that a vaccine listed on the Table was the cause in fact of an injury (an "off-Table" injury). Because GBS is not a Table injury for any vaccine appearing on the Vaccine Injury Table, petitioner must produce preponderant evidence that a covered vaccine is responsible for her injury.

When a petitioner alleges an off-Table injury, eligibility for compensation–the *prima facie* case–is established when the petitioner demonstrates, by a preponderance of the evidence, that: (1) she received a vaccine set forth on the Vaccine Injury Table; (2) that she received the vaccine in the United States; (3) that she sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) that the condition has persisted for more than six months.[7] To satisfy her burden of proving causation in fact, petitioner must establish each of the three *Althen* factors 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 proximate temporal relationship between vaccination and injury. *Althen v. Sec'y, HHS,* 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see de Bazan v. Sec'y, HHS*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec'y, HHS,* 100 Fed. Cl. 119, 132 (2011), *aff. per curiam*, 463 Fed. Appx. 932, 2012 WL 858402 (Fed. Cir. 2012) (specifying that each *Althen* factor must be established by preponderant evidence).

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[5] By definition, GBS is monophasic, meaning it occurs only once. In contrast, CIDP reoccurs. In initial presentation, patients with CIDP are often difficult to distinguish from patients with GBS, as the initial symptoms are very similar. However, GBS typically responds to either plasma exchange or IVIG; patients with GBS who receive steroids typically do not improve or may get worse. Patients with CIDP generally improve on steroids. A. Ropper & M. Samuels, ADAMS AND VICTOR'S PRINCIPLES OF NEUROLOGY, McGraw-Hill Companies (9th ed. 2009) at 1292-93.

[6] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3 (2011), corresponding to the vaccine received within the time frame specified.

[7] Section 13(a)(1)(A). This section provides that petitioner must demonstrate by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1)...." Section 11(c)(1) contains the four factors listed above, along with others not relevant in this case.

Once petitioner establishes each of the *Althen* factors by preponderant evidence, case, the burden of persuasion shifts and respondent must show that the alleged injury was caused by a factor unrelated to the vaccination. *See de Bazan*, 539 F.3d at 1354 (citing *Knudsen v. Sec'y*, *HHS,* 35 F.3d 543, 548 (Fed. Cir. 1994)); § 13(a)(1)(B). Respondent must demonstrate that "the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. Such a showing establishes that the factor unrelated, not the vaccination, was 'principally responsible' for the injury." *Deribeaux v. Sec'y, HHS,* 717 F.3d 1363, 1369 (Fed. Cir. 2013). Section 13(a)(2) specifies that factors unrelated do "not include any idiopathic, unexplained, unknown, hypothetical, or undocumented cause factor, injury, illness, or condition." Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280; *but see Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

By specifying petitioners' burden of proof in off-Table cases as the preponderance of the evidence, directing special masters to consider the evidence as a whole, and stating that special masters are not bound by any "diagnosis, conclusion, judgment, test result, report, or summary" contained in the record (§13(b)(1)), Congress contemplated that special masters would weigh and evaluate expert opinions in determining whether petitioners have met their burden of proof.

In weighing and evaluating expert opinions in Vaccine Act cases, the same factors the Supreme Court has considered important in determining their admissibility provide the weights and counterweights. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149-50 (1999); *Terran v. Sec'y, HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). As the Supreme Court has noted, a trial court is not required to accept the *ipse dixit* of any expert's medical or scientific opinion, because the "court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

B. Parties' Contentions Regarding Entitlement.

There is no dispute that petitioner received a covered vaccine administered in the United States. It is also clear from the medical records that approximately four weeks after receiving a flu vaccine, Ms. Petronelli was diagnosed with GBS and has experienced sequelae of GBS for longer than six months. Therefore, the only issue left to resolve is whether the influenza vaccine administered on September 28, 2010, was the cause-in-fact of petitioner's GBS.

1. Petitioner's Expert Report.

In support of petitioner's claim that her September 28, 2010 influenza vaccination caused her GBS, petitioner filed an expert report from Dr. Thomas Morgan. Doctor Morgan is a board certified neurologist who has been an assistant professor with the Department of Clinical Neuroscience at Brown University's School of Medicine since 1978. Pet. Ex. 13 at 1, 3. His report identifies a theory of causation, molecular mimicry,

and indicates that the timing of petitioner's vaccination and onset of symptoms is consistent with the immune mechanism he identified. Pet. Ex. 12 at 5 (explaining that "the influenza immunization generated an immune response that cross reacted with antigen targets shared by the normal elements of nerve fibers to cause" petitioner's GBS).

Acknowledging the discrepancy in the medical records regarding whether petitioner had an infection prior to her vaccination, which could be the cause of her GBS, Dr. Morgan asserts that the notation of a six week history of cold contained in Dr. Banerjee's October 21, 2010 consult note must be in error because petitioner would not have been administered a nasal flu vaccine at a time when she was sick with congestion and a cough. Pet. Ex. 12 at 5. He also notes that Dr. Banerjee's consult note contradicts the history provided to several physicians while petitioner was hospitalized at SCMC and the timeline of events contained in petitioner's affidavit.

Additionally, Dr. Morgan addresses petitioner's sinusitis, diagnosed by Dr. Banerjee at the October 21, 2012 visit. He remarked that if that diagnosis was proper, it came after petitioner's flu vaccine and was not the cause of her GBS. Pet. Ex. 12 at 5. Doctor Morgan distinguished upper respiratory infections from sinusitis and noted that sinusitis "is not causally associated with [GBS]." *Id.* at 6 (citing Duntz, M., *Sinus headache and nasal disease,* HEADACHES IN CLINICAL PRACTICE, 2d. at 235).

2. Respondent's Rule 4(c) Report.

Respondent declined the opportunity I afforded her to file an expert report. In response to petitioner's expert report, respondent only filed her Rule 4(c) report and three medical journal articles. In her report, respondent criticizes Dr. Morgan's report because he did "not address a number of references in the record that refer to an antecedent cold with no mucus or fever that was treated with amoxicillin connected to a vaccination and resolved by October 26, 2010." Res. Report at 7. Respondent also complains that Dr. Morgan did not specifically address the October 26, 2010 note of Dr. Cho and its reference to petitioner having an upper respiratory infection prior to her influenza vaccination. Res. Report at 7.[8]

Because two-thirds of patients diagnosed with GBS suffer from an antecedent infectious illness and some of petitioner's records, particularly Dr. Cho's, suggest that Ms. Petronelli had an infection prior to her influenza vaccination, respondent argues that "it is exceedingly *unlikely* that her GBS was caused by a flu vaccine." Res. Report at 8 (citing Haber et al., *Vaccines and Guillain-Barre Syndrome*, DRUG SAFETY, 34(4): 309-323 (2009) at 311). Respondent also questions the likelihood of vaccine causation based on the findings contained in the 2011 IOM Report. After reviewing the available epidemiologic and mechanistic evidence surrounding the influenza vaccine and GBS,

[8] Respondent indicated that "Dr. Kelly Yeh, an internst [sic], related to Dr. Cho 'that the patient had a mild URI, then got flu shot on 9/28 . . . .'" I interpret the record (Pet. Ex. 1, p. 123) as attributing the comment about Ms. Petronelli's potential URI solely to Dr. Cho. Doctor Yeh's own note concerning her evaluation of petitioner states "flu vaccine on 9/28/10, thereafter developed a cold." Pet. Ex. 1, p. 120.

the report concluded there was insufficient evidence to support a causal association between the influenza vaccine and GBS. Res. Report at 8 (citing K. Stratton, et al., ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY (2011) at 321-34).

3. Petitioner's Response to Respondent's Rule 4(c) Report.

In her response to respondent's Rule 4(c) report, petitioner highlights the applicable evidence and discusses how she has satisfied the three *Althen* prongs. She notes that her theory of causation (molecular mimicry) "has consistently been recognized as a biologically plausible mechanism for the onset of neurologically demyelinating disease, including GBS." Response at 4. Petitioner also stresses that her treating physicians linked her vaccination to her GBS, and that the timing of approximately four weeks between her vaccination and onset of symptoms is consistent with her causation theory. *See* Response at 4-7.

Petitioner argues that she has made a *prima facie case*, and that respondent has failed to meet her burden of showing a factor unrelated to petitioner's vaccination caused her GBS. Petitioner counters respondent's reliance on the 2011 IOM Report by noting its conclusion of no causal relationship between influenza vaccines and GBS was based on a requirement of scientific certainty and not the preponderant evidence standard applied in the Vaccine Program. Response at 8. Additionally, petitioner notes that the Haber article filed by respondent supports her theory of causation. Response at 7-8. Because respondent did not file an expert report and indicated she would not expend additional resources defending this case, petitioner posits that respondent will be unable to meet her burden. Response at 9.

C. Analysis.

This case presents the issue of whether an expert report satisfying each of the *Althen* prongs regarding vaccine causation of GBS can be countered successfully by medical literature alone. Under the circumstances present here, I conclude that literature alone, unexplained by an expert report, does not tip the balance back to respondent.

Petitioner's expert, Dr. Morgan is a board certified neurologist and an assistant professor at Brown University's School of Medicine. His curriculum vita (Pet. Ex. 13) demonstrates that he is qualified to opine in this case. As petitioner noted in her response, Dr. Morgan's causation theory is supported by medical literature filed by respondent. *See e.g.*, Haber, Res. Ex. A, at 312 (discussing molecular mimicry as a possible biological mechanism for GBS). Although other decisions involving this vaccine and this injury do not constitute binding authority,[9] Dr. Morgan's opinion is also buttressed by other decisions in the Vaccine Program awarding entitlement for GBS associated with an influenza vaccine. *See e.g., Figueroa v. Sec'y, HHS*, 715 F.3d 1314,

[9] *See Hanlon v. Sec'y, HHS*, 40 Fed. Cl. 625 (1998).

2013 WL 1811018 at *1 (Fed. Cir. May 1, 2013) (citing *Torday v. Sec'y, HHS*, No. 07-372V, 2009 U.S. Claims LEXIS 745 (Fed. Cl. Spec. Mstr. Dec. 10, 2009; *Griglock v. Sec'y, HHS*, 99 Fed. Cl. 373 (2011), *aff'd*, 687 F.3d 1371 (Fed. Cir. 2012); *Stewart v. Sec'y, HHS*, No. 06-777, 2011 WL 3241585 (Fed. Cl. Spec. Mstr. July 8, 2011)).

Respondent argues that it was not the influenza vaccine but petitioner's infectious illness that caused her GBS.[10] The onset of petitioner's illness is not concretely established. Some records place onset prior to her influenza vaccination and others afterwards. *Compare* Pet. Ex. 1, p. 123; Pet. Ex. 2, pp. 38-39 *with* Pet. Ex. 1, pp. 88-89, 112, 126-27; Pet. Ex. 5, pp. 6-7. Additionally, the evidence in the case record does not establish what infectious illness petitioner had. It is unclear whether petitioner was suffering from an upper respiratory infection or sinusitis; the former being a viral infection and the latter a bacterial infection and typically treated with antibiotics.[11]

Considering the facts contained in the medical records and petitioner's affidavit, the medical journal articles cited, and the sole medical expert opinion offered, I conclude that the weight of the evidence in this case favors a finding that petitioner is entitled to compensation.

IV. CONCLUSION

Based on the record before me, I find that there is preponderant evidence that petitioner's September 28, 2010 influenza vaccination was a substantial cause of her GBS and that sequelae from petitioner's GBS persisted for more than six months. I further find that respondent did not meet her burden of establishing a factor unrelated was responsible for petitioner's injury. **I therefore hold that petitioner has established the statutory requirements for entitlement.** A damages order will follow.

IT IS SO ORDERED.

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

[10] Respondent's decision not to file an expert report prevents me from engaging in a comparison of expert qualifications and the rationales behind competing causation theories.

[11] *Sinusitis Fact Sheet*, National Institute of Allergy and Infectious Diseases ["NIAID"] (January 2012) at 3, *available at* http://www.niaid.nih.gov/topics/sinusitis/Documents/sinusitis.pdf.