

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-0935V

Filed: April 15, 2016

UNPUBLISHED

BARBARA PEREZ,

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Petitioner,

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v.

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

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Entitlement; Motion for Decision on the Record; Decision Without a Hearing; Influenza (“Flu”); Guillain-Barré Syndrome (“GBS”); Special Processing Unit (“SPU”)

Diana Stadelnikas Sedar, Maglio Christopher and Toale, PA, Sarasota, FL for petitioner. Lara Ann Englund, United States Dep’t of Justice, Washington, DC, for respondent.

DECISION¹

Dorsey, Chief Special Master:

I. Introduction

On October 3, 2014, Barbara Perez (“petitioner” or “Ms. Perez”) filed a petition for compensation under the National Vaccine Compensation Program (“the Program” or the “Vaccine Act”),² alleging that she suffered Guillain-Barré syndrome (“GBS”) as a result an influenza (“flu”) vaccine she received on October 7, 2011. See Petition (“Pet.”) at 1. On October 30, 2015, petitioner filed a motion for a decision on the record (“Motion for Decision”). Respondent filed her Rule 4(c) report and a response to the Motion for Decision on November 2, 2015. After a review of all the evidence, the

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact 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 (2012).

undersigned finds that the medical records and information in the record do not support a finding that petitioner is entitled to compensation under the Vaccine Act. For the reasons discussed below, petitioner has failed to demonstrate that she is entitled to compensation.

II. Procedural History

Ms. Perez filed her petition on October 3, 2014. She filed nine sets of medical records and a Statement of Completion over the next two months. On December 17, 2015, the staff attorney assigned to this case held the initial status conference call. During the status conference, respondent's counsel stated that her client was still in the process of reviewing the medical records to make an assessment of the case. Additional time was granted for respondent to complete this process. See Order dated Dec. 17, 2015.

On June 29, 2015, respondent filed a status report stating that she did not wish to discuss settlement and proposed filing her Rule 4(c) report by August 28, 2015. Later that same day, then-Chief Special Master Vowell instead ordered petitioner to file an expert report in support of her claim so that respondent's Rule 4(c) report, when filed, would be based on a review of both petitioner's medical records and petitioner's expert report. See Order dated June 29, 2015. After being granted one extension of time to file her expert report, petitioner, on October 30, 2015, instead filed a motion for a decision on the record stating that "[a]fter further analysis of the records, science and expert consultation, Petitioner will not be filing a medical expert opinion." Motion for Decision at 1, ¶5.

On November 2, 2015, respondent filed her report pursuant to vaccine Rule 4(c) and a response to the Motion for Decision. Respondent stated that petitioner had not met her burden of proof under *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), because she did not offer a plausible medical theory or logical sequence of cause and effect linking the flu vaccination to her condition. See Respondent's Rule 4(c) Report and Response dated Nov. 2, 2015, at 6. In addition, respondent noted that none of Ms. Perez's treating physicians determined that the flu vaccine was the likely cause of her GBS and none offered a medical theory connecting the vaccines to the injury. *Id.* Finally, respondent argued that Ms. Perez had not shown an appropriate proximate temporal relationship between the vaccine and the onset of her GBS. *Id.* at 6-7. Respondent recommended that compensation be denied. *Id.* at 7.

The case is now ripe for decision on the record.

III. Factual History³

On October 7, 2011, Ms. Perez, who was 57 years-old at the time, received a flu vaccine. Pet. Ex. 1 at 1. She was employed as a head cook in a nursing home. Pet. Ex. 6. at 95. On October 26, 2011, petitioner was seen in the emergency room of a local hospital for a first degree burn on her left forearm while she was at work. *Id.* at 193. Her wound was dressed, she was prescribed Bacitracin ointment and discharged home. *Id.* at 195.

On November 9, 2011, petitioner was seen in the Emergency Department of Mercy Regional Medical Center (“Mercy”) for complaints of neck and back pain, fatigue, soreness, a cough, achiness and an “off/on” low grade fever. Pet. Ex. 7 at 106-14. She was diagnosed with acute bronchitis. *Id.* at 108. Petitioner was discharged the same day and instructed to follow-up with her primary care physician. *Id.* at 111.

On February 22, 2012, more than four months after receiving her flu vaccination, petitioner was seen at Elyria Medical Center (“EMH”) for complaints of chest pain and tingling in her legs that started at 2 p.m. earlier that day. Pet. Ex. 6 at 27. The attending physician wanted to admit Ms. Perez, but petitioner decided to go home instead. *Id.* Later that same day, Ms. Perez returned via ambulance to EMH for complaints of worsened chest pain and she was admitted for further evaluation. *Id.* Ms. Perez underwent a CT scan of her chest which was suggestive of underlying chronic obstructive pulmonary disease (“COPD”). *Id.* at 41-42. Her neurological examination was otherwise normal. *Id.* at 121.

In the medical records that record the history of petitioner’s present illness, it was noted that Ms. Perez had been experiencing chronic lower back pain for the past three months, pet. ex. 6 at 31, 95, although in other notations, her back pain was described as beginning suddenly while she was sleeping. *Id.* at 163. She also stated that she had been experiencing intermittent chest pain three to four times daily, five to seven times a week, for the last year. *Id.* at 166. Petitioner’s medical records note that she had undergone myocardial perfusion imaging in April 2011, the results of which were normal. *Id.* at 207-08. At the time of examination, Ms. Perez complained of numbness in both of her arms as well as abdominal pain. *Id.* at 95. She stated that her pain was not radiating in her legs at the time of her exam, but that it had previously. *Id.* The impression was spinal stenosis and facet joint arthropathy of the lumbar spine. *Id.* at 96. Ms. Perez was discharged on February 24, 2012. *Id.* at 93.

On February 25, 2012, petitioner was seen at Avon Emergency Department for complaints of back pain, specifically in her tailbone, for one week and lower back pain that began three months prior. Pet. Ex. 6 at 4-5. She reported that she had been discharged from EMH the day prior, after being admitted for complaints of chest pain

³ While the undersigned has considered all the evidence in this case and the record as a whole, the following is a brief summary of the medical records taken from the record in the case. This is by no means a complete recitation of all the relevant facts and evidence considered. See § 300aa-13(a) (stating that the special master should consider the “record as a whole”).

and tailbone pain, but was discharged without medication to manage her pain other than ibuprofen. *Id.* at 3. On examination, petitioner had normal strength and sensation. *Id.* at 6. She reported feeling slightly better and was discharged with instructions to follow-up with her physician. *Id.* at 8.

On February 27, 2012, petitioner was transported by ambulance from her home to the emergency room at Mercy. Pet. Ex. 9 at 4. Her husband reported to paramedics that petitioner began acting confused and weak for approximately an hour prior to their arrival. *Id.* The medical records document that petitioner had no facial droop but that she was slurring her words and acting confused. *Id.* Petitioner was admitted to Mercy for evaluation of a possible transient ischemic attack. Pet. Ex. 7 at 181-82.

On February 27, 2012, petitioner was evaluated by a neurologist, Dr. Norman Sese, who upon examining petitioner, noted that the deep tendon reflexes were absent in her knees and ankles. Pet. Ex. 7 at 39. He ordered an MRI of her brain, thoracic and cervical spine, and noted that her symptoms were highly suggestive of GBS. *Id.*; Pet. Ex. 4 at 38-39. Ms. Perez was transferred to University Hospital on February 29, 2012. Pet. Ex. 12 at 472.

On admission to University Hospital, Ms. Perez reported a history of chronic back pain, a one to two week history of altered mental status and difficulty ambulating. Pet. Ex. 12 at 472. She also stated that she had a “bad upper respiratory infection about 2 weeks ago but no recent gastrointestinal illness in the past few weeks, but is currently constipated.” *Id.* at 11. A neurological examination revealed that petitioner had unequal pupils, a mild left facial droop, and decreased temperature on the left side of her face. *Id.* at 12. Petitioner’s reflexes were diminished and the sensation was impaired in her left leg. *Id.* The results of her lumbar puncture showed elevated protein levels. *Id.* at 13. It was noted that petitioner’s symptoms were suggestive of GBS. *Id.* at 15. She underwent a five day course of IVIG therapy. *Id.* at 729.

Upon discharge on March 12, 2012, petitioner’s mental status and the strength in her lower extremities had improved. Pet. Ex. 12 at 472-73. She was transferred to Mercy’s rehabilitation facility and was instructed to follow up with her primary care physician upon discharge from rehabilitation. *Id.* at 474.

From March 12, 2012, until April 11, 2012, petitioner underwent inpatient rehabilitation at Mercy. Pet. Ex. 7 at 247-891. From April until August 29, 2012, petitioner continued her physical therapy at Mercy on an out-patient basis. Pet. Ex. 7 at 1-51. Upon discharge on August 29, 2012, it was noted that petitioner had reached a “functional plateau,” with her physical therapy, but that she was able to function at home. *Id.* at 8.

Petitioner continued to treat with Dr. Sese after her discharge from physical therapy. At her most recent visit (as noted in the records) on August 19, 2014, petitioner was able to ambulate with a walker and was taking Gabapentin and Zolof. Pet. Ex. 4 at 2-4.

IV. Analysis

a. Applicable Legal Standard

The Vaccine Act established the Program to compensate vaccine-related injuries and deaths. § 300aa-10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” *Rooks v. Sec’y of Health & Human Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. REP. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

To receive compensation under the Vaccine Act, a petitioner must prove either: (1) that she suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered a “causation-in-fact” injury, that is an injury that was actually caused by the vaccine she received. See §§ 300aa-13(a)(1)(A) and 11(c)(1); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting *Shyface*, 165 F.3d at 1352-53 (Fed. Cir. 1994)).

To establish causation in fact, a petitioner must show by a preponderance of the evidence that but for the vaccination, petitioner would not have been injured, and that the vaccination was a substantial factor in bringing about the injury. *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010); *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Proof of actual causation must be supported by a sound and reliable “medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” *Moberly*, 592 F.3d at 1321 (quoting *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548-49); see also *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)(medical theory must support actual cause). “[A] petitioner must demonstrate the reliability of any scientific or other expert evidence put forth to carry this burden Expert testimony, in particular, must have some objective scientific basis in order to be credited by the Special Master.” *Jarvis v. Sec’y of Health & Human Servs.*, 99 Fed. Cl. 47, 54-55 (2011) (citing *Moberly*, 592 F.3d at 1322; *Cedillo*, 617 F.3d at 1339; *Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)).

“The special master...may not make [] a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a)(1). Causation is determined on a case-by-case basis, with “no hard and fast per se scientific or medical rules.” *Knudsen*, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and “close calls” regarding causation must

be resolved in favor of the petitioner. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

If there is no Table Injury, petitioners must prove that the vaccine caused J.H.’s injury. To do so, they must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and the injury (“*Althen* Prong One”); (2) a logical sequence of cause and effect showing that a vaccine was the reason for his injury (“*Althen* Prong Two”); and (3) a showing of a proximate temporal relationship between the vaccine and injury (“*Althen* Prong Three”). *Althen*, 418 F.3d at 1278; § 300aa–13(a)(1) (requiring proof by a preponderance of the evidence).

b. *Althen* Prong One

Under the first prong of *Althen*, petitioner must set forth a reliable medical theory that explains how a particular vaccination can cause the injury in question. *Althen*, 418 F.3d at 1279. Scientific certainty is not required to establish causation under the Vaccine Act. *Id.* at 1280 (holding that the purpose of the Vaccine Act’s preponderance standard is “to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body”). However, a causation theory or mechanism must be supported by a sound and reliable medical or scientific explanation. *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994).

In this case, petitioner has failed to proffer a theory explaining how the flu vaccine can cause GBS more than four months after the vaccine was administered to her. Without a medical theory to explain the circumstances by which a vaccine can cause a particular injury as has been alleged in Ms. Perez’s case, there is no basis to find in petitioner’s favor. This is especially the case when, as in here, petitioner’s medical records raise questions bearing on causation. For example, in her Rule 4(c) report and response to Motion for Decision, respondent notes that not only has petitioner not proffered a plausible medical theory or logical sequence of events linking the flu vaccine to her condition, but none of her treating physicians determined that the vaccine was the likely cause of her GBS, and none offered a theory connecting the vaccine to her injuries. And importantly, petitioner has failed to set forth a theory explaining how GBS can result four months after the administration of a flu vaccine. As Ms. Perez has not offered a theory to preponderate the evidence in her favor, *Althen* prong one fails.

c. *Althen* Prong Two

The second prong of *Althen* requires petitioner to establish that the vaccine was the reason for the injury – not only a but-for cause of the injury but also a substantial factor in bringing about the injury. See *Shyface v. Sec’y of Health & Human Servs.*, 164 F.3d 1344, 1352 (Fed. Cir. 1999). Impressions from treating physicians can be probative when evaluating the second *Althen* prong, as “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.’” *Cappizzano v. Sec’y of Health & Human Servs.*, 440 F.3d. 1317, 1326 (Fed. Cir. 2006).

In this case, none of Ms. Perez’s treating physicians attributed her flu vaccination to her GBS, and thus the undersigned finds that petitioner has not provided a sufficient basis to rule in her favor on *Althen* prong two.

d. *Althen* Prong Three

Althen prong three requires Ms. Perez to demonstrate that her injury “occurred within a medically acceptable time frame.” *Pafford v. Sec’y of Health & Human Servs.*, 451 F.2d 1352, 1358 (Fed. Cir. 2006). Petitioner must establish a proximate temporal relationship, which “requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *De Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

As respondent has noted, the first symptoms of Ms. Perez’s GBS appear to have started on February 22, 2012, almost 20 weeks after her October 7, 2011 vaccinations. She has not offered any argument or expert testimony arguing otherwise. Respondent cites the IOM’s (Institute of Medicine) finding that “the expected latency between an antecedent event ... and the first symptom of GBS is mainly between 7 and 21 days. Occasional cases appear to have latencies between 22 and 42 days.” Respondent’s Exhibit A at 4. Indeed, claims where petitioners have attempted to seek compensation for similar types of claims outside of this time frame have failed. See *Schmidt v. Sec’y of Health & Human Servs.*, No. 13-382V, 2015 WL 1088225 (Fed. Cl. Spec. Mstr. Feb. 13, 2015)(12-week time gap between receipt of flu vaccine and onset of GBS was not a medically accepted temporal relation); *Aguayo v. Sec’y of Health & Human Servs.*, No. 12-563V, 2013 WL 441013, at *3 (Fed. Cl. Spec. Mstr. Jan. 15, 2013) (three and one-half months between vaccination and GBS was rejected as too long); *Corder v. Sec’y of Health & Human Servs.*, No. 08-228V, 2011 WL 2469736, at *27-*29 (Fed. Cl. Spec. Mstr. May 31, 2011) (proposed four month onset period from vaccination to GBS too long; two months is longest reasonable timeframe). Without any further support for her position, petitioner’s claim must also fail on *Althen* prong three.

V. Conclusion

For the reasons discussed above, the undersigned finds that petitioner has not established entitlement to compensation and her petition must be dismissed.

Therefore, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master