

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1177V

UNPUBLISHED

VALARIE WILLIAMS,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: January 19, 2021

Special Processing Unit (SPU);
Findings of Fact; Onset; Influenza
(Flu) Vaccine; Guillain-Barré
Syndrome (GBS)

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Adriana Ruth Teitel, U.S. Department of Justice, Washington, DC, for respondent.

DECISION DISMISSING CASE¹

On August 12, 2019, Valarie Williams filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that she received an influenza (“flu”) vaccine on September 11, 2016, and thereafter suffered Guillain-Barré syndrome (“GBS”). Petition at 1. This case was assigned to the Special Processing Unit of the Office of Special Masters.

On July 1, 2020, Petitioner was ordered to show cause why this case should not be dismissed for insufficient proof. ECF No. 20. Petitioner filed a response on August 14, 2020. ECF No. 21. For the reasons discussed below, this claim is hereby **DISMISSED**.

¹ Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claims' website because it contains a reasoned explanation for the action in this case, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** 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, I agree that the identified material fits within this definition, I 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 section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

This case was initiated on August 12, 2019 and specifically alleges a “Flu/GBS (Table Claim)”. ECF No. 1. On August 16, 2019, Petitioner was ordered to file medical records and a statement of completion by August 26, 2019. ECF No. 5.

Following two motions for extensions (ECF Nos. 7, 8), Petitioner filed medical records and a statement of completion on November 25, 2019. During the initial status conference, Respondent’s counsel raised a potential issue relating to onset, plus an intervening viral illness that could be causal. In response, Petitioner’s counsel stated there may be additional records and requested additional time to collect and submit them. ECF No. 12.

After two additional motions for extensions (ECF Nos. 13, 18) a second status conference was held on June 30, 2020. ECF No. 20. During the call, my initial reaction to the allegations and the supporting evidence was conveyed to the parties. Based on my review of the medical records, I indicated that the onset of Petitioner’s GBS was outside the *longest time* even accepted for a similar non-Table claim (and thus could hardly satisfy the Table’s onset requirements). Petitioner’s counsel indicated he was still attempting to obtain updated medical records and affidavit evidence. However, I also questioned how updated medical records would address the issues with the onset of Petitioner’s GBS. For those reasons, I directed Petitioner to respond to a show cause order why this claim should not be dismissed.³

Petitioner filed her response to the order to show cause on August 14, 2020. ECF No. 21. Petitioner reported that there were no additional medical records, but respectfully requested a ruling on entitlement based on the existing filed records.

II. Factual Background

Petitioner, a Navy reservist, received a flu vaccine on September 11, 2016. Ex. 1. There is no subsequent medical record setting forth any purported reaction to this vaccination, and no medical records at all until the end of December 2016.

On December 25, 2016, over one hundred days after her flu vaccination, Petitioner reported dizziness, lack of balance, general weakness, numbness in her legs with tingling

³ I also cautioned Petitioner’s counsel that if the response to the show cause order relied primarily on witness testimony aimed at establishing that Petitioner’s symptoms began sooner than the medical records establish, reasonable basis issues would be raised that could imperil some of the fees to which counsel would otherwise be entitled.

that began two days earlier. Ex. 2 at 231. She was given intravenous fluids and released that same day. *Id.* at 229, 232.

Petitioner was next treated on December 28, 2016 for weakness and paresthesia that reportedly started three days earlier. Ex. 2 at 218. A physical assessment showed Petitioner could not move the left side of her mouth and exhibited lower extremity weakness. She also reported “tingling in entire body.” *Id.* at 221, 218. The clinical impression at that time was moderate GBS with acute lower extremity weakness.

Petitioner was admitted to the hospital on December 28, 2016, for ascending numbness and tingling after a “mild febrile URI 1 week previous”. Ex. 5 at 145, 367. She also reported numbness in her toes that started on December 21, 2016. *Id.* at 153. The numbness had gradually moved up her legs, and she began noticing leg and arm weakness a few days thereafter. *Id.* An NCS and EMG study conducted on January 3, 2016 were suggestive of either GBS or acute inflammatory demyelinating polyneuropathy (“AIDP”). *Id.* at 152. A lumbar puncture was negative for GBS (*id.* at 53), but an EEG confirmed the diagnoses. See Ex. 4 at 13.

After a subsequent course of intravenous immunoglobulin (“IVIG”), Petitioner was admitted for inpatient rehabilitation on January 4, 2017. Ex. 5 at 367. Her initial rehabilitation evaluation occur on January 23, 2017. *Id.* at 129. The record states that she was visiting her boyfriend for Christmas and “ran in a race in which her legs started to lose function. [Petitioner] has been here in the hospital and has been diagnosed with Guillain Barre Syndrome.” *Id.* at 132.

On February 2, 2017, Petitioner was seen at ACH Fox-Redstone Arsenal to establish care with local neurology for evaluation, treatment, and follow-up. Ex. 5 at 112. Petitioner’s history states “[s]he was out of town in late December, when she began with symptoms that led to hospitalization.” *Id.* at 113.

On July 13, 2017 Petitioner was seen by Dr. David White to establish care. Ex. 3 at 5. Regarding the history of her condition, she reported on “Dec 25, 2016 she woke up and her body was paralyzed” and she was “unable to walk until March of 2017.” *Id.* The record also notes that Petitioner had a flu vaccination in September of 2016. “Shortly after that she began to feel more fatigued with less exercise tolerance. This was persistent, but fluctuating.” *Id.*

A repeat EMG and NCV study was conducted on October 16, 2017 that was “essentially normal.” Ex. 3 at 10. At that time, there was “no clear evidence for a chronic demyelinating polyneuropathy such as CIDP or recurrent AIDP.” *Id.*

The records contain numerous references that link Petitioner's GBS to her flu vaccination, but these records were created significantly after Petitioner's hospitalization, and otherwise provide little context with regard to the onset of her injury and relationship between vaccination and symptoms. See, e.g., Ex. 2 at 103 ("developed GBS after getting a Flu Vaccine"); 106 ("54 yo AD Navy Reservist who developed Guillain-Barré syndrome after flu vaccine."); 73-74 ("She is a Navy Reservist and developed GBS after getting a Flu Vaccine . . . GBS after flu shot."); 95 ("Pt was dx with Guillian [sic] Barre Syndrome following a vaccine..."). Further, these records do not clarify whether Petitioner self-reported the link between her flu vaccine and GBS, or if treaters proposed a relationship. See Ex. 6 at 13 (record from March 19, 2018 stating "Patient reports h/o GBS secondary to a flu vaccine.").

In addition to the medical records, Petitioner submitted a signed letter from Stephen E. Nelson in support of her claim. Ex. 9. Mr. Nelson stated that he has known Petitioner for over five years and is in a relationship with her. Mr. Nelson also stated that the week after she received her flu shot, Petitioner experienced weakness, and thereafter additional symptoms began such as sleeplessness and aching in her feet and legs. And the letter states that Petitioner's legs gave out around Thanksgiving of 2016. At that time, Mr. Nelson stated that he took Petitioner to Keesler AFB Hospital in Biloxi Mississippi.⁴

III. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30,

⁴ There is no record of a hospital visit in November of 2016.

1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,⁵ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, GBS is compensable if it manifests within 3-42 days (not less than three days and not more than 42 days) of the administration of an influenza vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). (Further criteria for establishing a GBS Table Injury case be found under the accompanying qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(15)).

Cases alleging a Table GBS injury have often been dismissed for failure to establish proper onset. See, e.g., *Randolph v. Sec'y of Health & Human Servs.*, No. 18-1231V, 2020 WL 542735, at *8 (Fed. Cl. Spec. Mstr. Jan. 2, 2020) (finding GBS onset at the earliest occurred 76 days post-vaccination, "well outside the 3-42-day window set by the Table for a flu-GBS claim"); *Upton v. Sec'y of Health & Human Servs.*, No. 18-1783V, 2020 WL 6146058, at *2-3 (Fed. Cl. Spec. Mstr. Sept. 24, 2020) (finding the petitioner did not establish the onset of his GBS within the 3-42 day time frame prescribed and thus did not establish a Table Injury).

IV. Finding of Fact

I make these findings after a complete review of the record, including all medical records, affidavits, and all other additional evidence and filings from the parties.

Petitioner alleges that she suffered a Table GBS injury following a flu vaccine administered on September 11, 2016. Petition at 1. However, contemporaneous medical records preponderantly establish that the initial symptoms of Petitioner's GBS did not occur until December 21st *at the earliest*. Ex. 5 at 153 (Petitioner reporting numbness in her toes began December 21, 2016). Additional records place the onset of Petitioner's symptoms even later, beginning December 25, 2016. Ex. 2 at 229

⁵ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

(reporting dizziness, lack of balance and weakness on December 25, 2016); Ex. 2 at 218 (record from December 28, 2016 reporting weakness and paresthesia that began three days earlier).

Further, Petitioner's records consistently state that her symptoms did not begin until December of 2016. See, e.g., Ex. 3 at 5 (record from July 13, 2017 stating that she woke on December 25, 2017 and her "body was paralyzed"); Ex. 5 at 122 (record from January 27, 2017 stating onset of Petitioner's GBS was December 25, 2016). Such facts not only put Petitioner's claim outside the 42-day limit for a viable Table flu-GBS claim, but outside the *longest time* accepted for a similar non-Table claim. See, e.g., *Chinea v. Sec'y of Health & Human Servs.*, No. 15-095V, 2019 WL 1873322, at *33 (Fed. Cl. Mar. 15, 2019), *review denied*, 144 Fed. Cl. 378 (2019) (finding that the onset of the petitioner's GBS occurred eleven to twelve weeks after her vaccination, which was beyond the six- to eight-week medically appropriate timeframe for the occurrence of vaccine-induced GBS); *Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (finding eight weeks (56 days) is the longest reasonable timeframe for a flu vaccine/GBS injury).

In contrast to the above, Petitioner notes that multiple medical records associate her GBS with her September 11, 2016 flu vaccine. Response to Order to Show Cause at n.1. But these include records created significantly after Petitioner's onset, and they otherwise provide little context (temporal or otherwise) with regard to the onset of her injury. See, e.g., Ex. 2 at 103 (record from June 22, 2017 stating "developed GBS *after* getting a Flu Vaccine") (emphasis added); 95 (record from July 7, 2017 stating "Pt was dx with Guillain [sic] Barre Syndrome following a vaccine..."); 73-74 (record from November 16, 2018 stating Petitioner "is a Navy Reservist and developed GBS after getting a Flu Vaccine . . . GBS after flu shot."). Further, it is unclear whether Petitioner self-reported the link between her flu vaccine and GBS. See Ex. 6 at 13 (record from March 19, 2018 stating "Patient reports h/o GBS secondary to a flu vaccine.").

The other evidence of a purportedly earlier onset are outweighed by the aforementioned onset evidence. Thus, Mr. Nelson's letter admittedly provides some general support for the conclusion that Petitioner experienced some initial reaction to the vaccine. Ex. 9. Further, certain later records also indicate that she may have had an adverse reaction to the flu vaccine, including a July 13, 2017 record from Dr. David White. See Ex. 3 at 5 (Petitioner reported shortly after a flu shot in September of 2016 she "began to feel more fatigued with less exercise tolerance. This was persistent, but fluctuating"). But it is legally proper to give contemporaneous records from the time Petitioner sought treatment for her GBS symptoms (in December 2016) greater weight. "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of

medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.” *Cucuras*, 993 F.2d at 1528.

Moreover, even if I gave Petitioner’s assertions about an earlier onset more weight, they would describe a GBS course inconsistent with what is known about the illness. GBS is in the vast majority of cases an acute and monophasic condition. It is not known to present with a slow, smoldering malaise that thereafter remains subacute for weeks or months. *Chinea*, 2019 WL 1873322, at *31. It is not preponderantly likely that Petitioner would have experienced GBS onset in the form she describes in early November, only to manifest acutely more than a month later.

Despite due opportunity, Petitioner has provided no reason for me not to conclude that the medical records are correct, and she otherwise has failed to show cause, or provide any argument or explanation in response to my Order to Show Cause, as to the onset of her GBS and why her Table claim should not be dismissed. Accordingly, I find there is not preponderant evidence to establish that Petitioner suffered the first symptom or manifestation of onset of GBS within 3 – 42 days of her flu vaccination as required by the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(D). Specifically, I find the onset of petitioner’s GBS began on December 21, 2016. I also find that the present facts could not support even a non-Table version of the claim, since an onset of more than ten weeks has never been deemed preponderantly possible. *Barone*, 2014 WL 6834557, at *13.

V. Conclusion

The evidentiary record does not support Petitioner’s contention that the flu vaccine she received in September 2016 caused her GBS in the timeframe proffered, and does not support the allegation that she suffered a Table Claim. My determination of a late-December onset is also fatal to any non-Table claim Petitioner might assert based on the same injury – meaning that the case should not go forward in any form.

Petitioner has not established entitlement to a damages award, and therefore I must **DISMISS** her claim in its entirety. **The clerk shall enter judgment accordingly.**⁶

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

⁶ If Petitioner wishes to bring a civil action, he must file a notice of election rejecting the judgment pursuant to § 21(a) “not later than 90 days after the date of the court’s final judgment.”