

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-321V

UNPUBLISHED

REBECCA RAY,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: January 13, 2021

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

David John Carney, Green & Schafle, LLC, Philadelphia, PA, for Petitioner.

Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CASE¹

On March 23, 2020, Rebecca Ray 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 a Table claim for Guillain-Barré syndrome (“GBS”), and in the alternative asserts a cause-in-fact case for GBS as her injury, as a result of her receipt of the influenza (“flu”) vaccination on October 9, 2018. Amended Petition, filed October 16, 2020 at 1, ECF No. 17. The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”).

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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). **This means the fact ruling 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).

For the reasons discussed below, I find that Petitioner's GBS Table claim must be dismissed for failure to establish onset within the 3 – 42 day time period following the administration of vaccination.

I. Relevant Procedural History

After the case's initiation, Respondent filed his counsel's informal assessment of this case in July 2020, pursuant to my Order, and identified several issues that he maintained precluded the informal resolution of this case in SPU. Most significantly, Respondent argued that Petitioner had failed to establish that she suffered the Table injury of GBS, because (a) she reported to her treating providers (as reflected in filed medical records) that onset of her symptoms occurred on December 22, 2018, and (b) this reported onset of symptoms (at least 74 days post-vaccination) is significantly longer than the 3 – 42 day period prescribed by the Table.³ Respondent's Status Report (ECF No. 13) at 2. This onset is also inconsistent with the onset of approximately one month alleged by Petitioner in her affidavit. Ex. 2.

On September 17, 2020, I issued an Order to Show Cause requiring Petitioner to file an Amended Petition if she was in fact asserting a Table case, and to further Show Cause why her Table claim should not be dismissed for the reasons discussed above. ECF No. 16. I further noted in my Order that I intended to reassign this case from SPU as I expected (based on my own initial review) that Petitioner would not be able to establish a Table claim, but I would afford her an opportunity to show why dismissal of such a claim was not appropriate. *Id.*

On October 16, 2020, Petitioner filed an Amended Petition alleging a Table claim for GBS, and in the alternative asserting a cause-in-fact case. ECF No. 17 at 1. Petitioner also filed a Status Report, in response to my Order to Show Cause, on October 16, 2020, indicating that she had no objection to this case being transferred out of SPU. ECF No. 18. But Petitioner failed to Show Cause, or otherwise explain or argue, why her Table claim should not be dismissed stating the evidence she intends to rely upon has been filed with the court. *Id.*

³ This issue was also raised, based on my separate review of the records, at the initial status conference in this case on May 6, 2020. However, I deferred to schedule further proceedings to address this issue until Respondent's counsel had an opportunity to complete his review. ECF No. 12 at 1.

I note that Respondent's Status Report also raised two additional issues in regard to this case: 1) that it is unclear whether Petitioner received the flu vaccine on October 8 or October 9, 2018, and 2) that the persistent IVIG treatment she has received is not consistent with GBS, but instead suggests she may have experienced a different injury. ECF No. 13. Respondent also raised these points in his Rule 4(c) Report. ECF No. 21. I do not find that it is necessary to resolve these issues at this time.

On January 7, 2021, Respondent filed his Rule 4(c) report. The Report asserts that the record “clearly establishes” that petitioner’s condition began more than ten weeks after vaccination (on December 22, 2018), thus well outside of the Table timeframe. ECF No. 21 at 5. Respondent further argues Petitioner has failed to prove actual causation as required under *Althen*, as she has failed to submit an expert report or other preponderant evidence in support of causation sufficient to satisfy her burden of proof. *Id.* at 6 (citing *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)).

II. Issue

At issue is whether Petitioner’s first symptom or manifestation of onset of GBS occurred within 3 – 42 days of vaccination, as set forth in the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(D).

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, 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,⁴ a petitioner must

⁴ 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).

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. Specifically, I note the following:

- On December 23, 2018, Petitioner was seen at the Emergency Department (“ED”) with a chief complaint of bilateral numbness in her hands and feet. Ex. 3 at 143. Petitioner’s medical history for this visit indicates that she was “seen in the ED because of bilateral upper and lower extremities tingling and numbness since *yesterday*.” *Id.* (emphasis added). A further history recorded that same date notes “44-year-old female presents to the Emergency Department with complaint of numbness/tingling in bilateral feet to ankle and both hands that *started yesterday*.” *Id.* at 145 (emphasis added).
- On December 24, 2018, Petitioner followed-up with an urgent care visit. Ex. 3 at 140. The history from that visit provides “44-year-old female patient presents to urgent care with complaints of paresthesia of hands and legs. Patient states that symptoms started yesterday. She was seen in the Emergency Department . . .” *Id.* Petitioner was referred to the ED for a neurologic evaluation. *Id.* at 141.

- An ED note from December 24, 2018 indicates that Petitioner presented “with numbness and tingling in her hands and feet. She states that this started Saturday when she woke up. Yesterday she went to the Emergency Department at Mercy Hospital and they did lab tests.” *Id.* at 138.
- Petitioner was seen for a consult on December 24, 2018 with a chief complaint of parenthesis, the history of Petitioner’s illness provides that on “12/22/2018, the patient developed parenthesis in her feet. They [sic] spread gradually to her hands. The next day, she noted some weakness in her legs and worse this morning, she felt like her legs were rubber. She had no symptoms referable to her vision, but she had some numbness in the center of her tongue.” Ex. 3 at 142.

In contrast to the contemporary records, Petitioner in her March 9, 2020 affidavit, avers that approximately a month after her vaccination, between early and mid-November 2018, “I started to experience numbness and tingling in my hands and wrists. During this time, I was frequently experiencing weakness in my legs that lead to my knees buckling, causing me to lose balance, which had never happened to me before.” Ex. 2 at ¶ 11. Petitioner indicates that she believed these symptoms were related to a pinched nerve, as she was actively playing volleyball at the time, so she did not report the symptoms to a medical professional. *Id.* Petitioner further asserts in her affidavit that by December 22, 2018, her symptoms began to “significantly worsen” and she had the onset of a new symptom, numbness of her tongue, which alarmed her and prompted her to seek medical attention. *Id.* at ¶14.

As is self-evident, the contemporaneous records are not consistent with Petitioner’s later account of the onset of her GBS symptoms in early to mid-November 2018. The aforementioned medical entries evidence that the onset of Petitioner’s GBS symptoms more likely than not began on December 22, 2018. “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 v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

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 be 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 22, 2018. Accordingly, **Petitioner’s Table Claim for GBS is dismissed.**

V. Scheduling Order

I will convene a status conference forthwith to discuss further proceedings in this case. However, Petitioner is advised that given my finding that the onset of Petitioner's GBS occurred on December 22, 2018 (over 70 days – or ten weeks - after her flu vaccination), Petitioner is unlikely to establish causation in this case even for a non-Table claim, since a timeframe of ten weeks has never been deemed medically acceptable for vaccine-caused GBS. As I have previously noted in another GBS claim, “other special masters have never gone beyond a two-month (meaning eight week) interval in holding that a vaccination caused a demyelinating illness.” *Barone v. Sec’y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (citing *Aguayo v. Sec’y of Health & Human Servs.*, No. 12–563V, 2013 WL 441013, at *3 (Fed. Cl. Spec. Mstr. Jan. 15, 2013); *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)). This means even a non-Table claim, not subject to the same strict requirements as a comparable Table claim, is also highly likely to prove unfruitful.

As a result, Petitioner should strongly consider seeking dismissal of what remains of her case. The Vaccine Guidelines provide guidance on how to exit the Vaccine Program.⁵

IT IS SO ORDERED.

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

⁵ The Vaccine Guidelines can be found at <http://www.uscfc.uscourts.gov/sites/default/files/Guidelines-4.24.2020.pdf> (last visited January 13, 2021).