In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1625V

UNPUBLISHED

ROY ROMERO, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: March 11, 2021 Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Guillain-Barré Syndrome (GBS)

Michael Adly Baseluos, Baseluos Law Firm, San Antonio, TX*, for petitioner.*

Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM[1]

On October 19, 2018, Roy Romero 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 alleged that he suffered acute inflammatory demyelinating polyneuropathy, a variant of Guillain-Barré Syndrome ("GBS"), as a result of an influenza ("flu") vaccine administered on October 21, 2016. Petition at 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[1] Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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 "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Although Mr. Romero did not formally allege a flu-GBS claim under the Vaccine Injury Table ("Table"), this case was assigned to SPU based upon the initial assumption that such a claim might be tenable. However, as discussed herein, the medical record best supports the conclusion that the onset of Petitioner's GBS occurred less than three days after vaccination – and thus outside the prescribed 3-42 day Table onset period for a flu-GBS injury. Because Petitioner cannot preponderantly establish all of the requirements of a presumptive flu-GBS injury, his Table claim must be dismissed (although the matter may proceed outside of SPU as a non-Table claim).

PROCEDURAL HISTORY

Petitioner initiated this case on October 19, 2018, alleging that he suffered GBS as a result of a flu vaccine administered on October 21, 2016.[3] Petition at 1. On January 27, 2020, Respondent filed a status report indicating that he intended to defend this case. ECF No. 36.

Respondent filed a Rule 4(c) Report on May 14, 2020. In it, Respondent asserted that Petitioner had not established that he suffered a presumptive flu-GBS injury as set forth in the Table, or alternatively that Petitioner's GBS was caused-in-fact by the vaccination. Res. Report at 17-18. Regarding the Table requirements, Respondent argued that Petitioner's medical records variously placed the onset of his GBS the day of vaccination, the day after vaccination, and/or two days after vaccination – all outside the 3-42 day Table onset period. *Id*. at 18. Respondent additionally contended that there was evidence Petitioner's GBS was caused by factors unrelated to the administration of the vaccine (e.g., gastrointestinal illness). *Id*.

A status conference was held with the parties on July 1, 2020. During the conference, the parties were informed that in light of the onset and alternative cause issues raised by Respondent, Petitioner's claim might not be viable, whether as a Table or non-Table, causation-in-fact claim. ECF No. 42. The parties were directed to *Rowan v. Sec'y of Health & Human Servs.,* No. 17-760V, 2020 WL 2954954 (Fed. Cl. Spec. Mstr. Apr. 28, 2020), a case in which I determined that a GBS onset sooner than three days post-vaccination was not scientifically or medically supported, given that GBS is known to be mediated by autoantibodies produced via the adaptive immune system, and this process takes longer than three days to result in symptoms.

[3] Petitioner also filed a Supplemental Petition on April 5, 2019, which incorporated and discussed medical records that were filed after the original Petition. In the Supplemental Petition, Mr. Romero also asserted that his pre-vaccination medical conditions were unrelated to the onset of his GBS. *See generally* Supplemental Petition (ECF No. 13).

At a follow-up status conference held on July 13, 2020, Petitioner's counsel stated that he had consulted with an expert who believed Petitioner's pre-vaccination pancreatitis could in fact have caused an onset *sooner* than three days due to immune system general activity. ECF No. 43. Counsel also maintained that *Rowan* could be distinguished, primarily due to the fact that the petitioner in that case was elderly (and therefore the immune process was likely to be slower). *Id*. And counsel further proposed that it was possible the symptoms Petitioner experienced within three days of his vaccination (e.g., weakness) were unrelated to GBS. *Id*.

In response, I reiterated my initial view that the Table claim did not appear viable given the record evidence suggesting an onset of sooner than three days, although I allowed that Petitioner might succeed with a *non-Table* causation-in-fact claim supported by the proposed expert opinion. *Id*. I therefore expressed the intention to transfer this case from SPU, given the time elapsed since the case was filed, the complexity of the medical issues involved, and the unlikelihood of informal resolution. *Id*.

I also indicated my expectation that the Table version of the claim warranted dismissal – although I noted that I would permit Petitioner to show cause why this should not occur. *Id*. I emphasized, however, that Petitioner should not obtain an expert report (although he could attempt to explain why the record facts supported a Table claim, and how an expert opinion would assist that showing). *Id*. After briefing, I noted that I would rule on the Table claim, and then (assuming I acted as predicted) transfer the matter for adjudication of the causation-in-fact claim. *Id*.

Petitioner filed a brief ("Br.") regarding his Table claim on September 28, 2020[4] (ECF No. 47), and Respondent opposed the Table claim's maintenance ("Opp.") on October 20, 2020. ECF No. 48. Petitioner filed a reply brief on October 21, 2020. ECF No. 49. Accordingly, this case is now ripe for a determination.

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 his 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.*

[4] Petitioner also filed an affidavit on September 27, 2020 providing a timeline of his post-vaccination symptoms. ECF No. 46.

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,[5] a petitioner must establish that he 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 he 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 a flu vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). Further criteria for establishing a GBS Table injury can be found under the accompanying Qualifications and Aids to Interpretation. 42 C.F.R. § 100.3(c)(15).

Cases alleging a flu-GBS Table 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).

[5] In summary, a petitioner must establish that he 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 his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for his injury. *See* § 11(c)(1)(A)(B)(D)(E).

ANALYSIS

After reviewing the entire record, including all medical records, affidavits, Respondent's Rule 4(c) Report,[6] and the parties' briefing, I have concluded that the onset of Petitioner's GBS occurred less than three days after vaccination and thus outside the prescribed flu-GBS Table onset period.[7] I have specifically based my finding on the following evidence:

- On October 21, 2016, Petitioner presented to David Gomez, PA-C, at Ramos Family Medical Group to establish care as a new patient. Ex. 17 at 3-5. During the appointment, Petitioner was administered a flu vaccine. *Id*. at 4.

- Five days later, on October 26, 2016, Petitioner presented to the emergency room at University Health System. Ex. 11 at 212. An intake record noted that Petitioner was recently hospitalized due to pancreatitis[8] and had been prescribed medication for diabetes, high cholesterol, hypertension, and GERD. *Id*. Petitioner indicated that, since taking the aforementioned medications, he had experienced progressive weakness with difficulty performing fine motor tasks and decreased energy. *Id*.

- Shortly thereafter on that same date, Petitioner was assessed by an emergency room physician, who noted that Petitioner had experienced numbness of his hands for five days, but that two-to-three days ago had also begun experiencing bilateral lower extremity weakness and pain. *Id*. at 210.

- A second emergency room physician recorded on October 26, 2016, that Petitioner was in his normal state of health four days prior, but reported numbness and weakness of the extremities for three days. *Id*. at 205. Petitioner was further noted to have fatigue and tingling in the bilateral lower extremities leading to weakness

[6] In his Report, Respondent identified several records that are potentially outstanding – including records associated with a medical appointment on October 25, 2016. *See, e.g.*, Res. Report at 6 n.7. Petitioner has asserted that many of the records requested by Respondent do not exist and that all relevant medical records have been filed. *See, e.g.*, Res. Report at 6; Petitioner's Amended Statement of Completion, filed December 19, 2019 (ECF No. 34). I find that the available record is sufficient to make a limited finding regarding the nonviability of Petitioner's flu-GBS Table claim.

[7] A more complete recitation of the facts can be found in the Petition, Respondent's Rule 4(c) Report, and the parties' briefing. Given the issues involved in this ruling, I have limited my discussion to the records most relevant to the onset of Petitioner's GBS.

[8] Petitioner was hospitalized from October 9 to October 11, 2016 for treatment of acute pancreatitis. *See* Ex. 15 at 3-4, 13-14.

and an inability to walk. *Id*. The assessment was "[l]ikely Guillain Barre vs. atypical ALS." *Id*. at 207.

- A third emergency room physician recorded on October 26, 2016 that Petitioner began experiencing bilateral lower extremity weakness for two-to-three days that had progressed upward toward his upper extremities. Ex. 11 at 208. Petitioner was referred for a neurology consultation. *Id*. at 209.

- Petitioner underwent a resident neurology consultation on October 26, 2016, at University Health System. *Id*. at 199. Petitioner stated that he had received a flu vaccination on Friday (October 21) and had begun experiencing weakness of the hands on Sunday (October 23). *Id*. By Monday (October 24) he began walking slowly, and he was unable to walk by Tuesday. *Id*. A "Faculty Attestation" from the attending neurologist noted that Petitioner had a flu vaccination a "few days ago and the next day noticed weakness and the following day unable to walk." *Id*. at 203.

- Petitioner underwent an EMG/NCS study on October 31, 2016. *Id*. at 152. The medical history provided indicated that Petitioner had weakness of the arms and legs since "~8 days ago" (or October 23rd). *Id*. Petitioner also stated that he received a flu vaccination two days prior to the onset of symptoms. *Id*.

- On November 1, 2016, Petitioner had a rehabilitation consultation for treatment of upper and lower extremity weakness. *Id*. at 139. Petitioner reported that he had received a flu vaccine about three days prior to the onset of his symptoms. *Id*.

- On November 11, 2016, Petitioner had an internal medicine consultation for treatment of a fever. Ex. 3 at 184-88. Petitioner reported that he had been administered a flu vaccine two days prior to the start of his weakness. *Id*. at 185.

- On September 27, 2020, Petitioner filed an affidavit providing a timeline of his symptom onset following the October 21, 2016 vaccination.[9] Ex. 21. Petitioner averred that he noticed weakness in his hands at 10 PM on October 23, 2016. *Id*. at 1. Petitioner further stated that he began experiencing difficulty using his hands and walking over the following two days. *Id*. at 1-2.

The records above provide varying dates regarding the onset of Petitioner's GBS. Nevertheless, I find that the cumulative record evidence preponderantly supports an

[9] Petitioner previously filed a timeline of his symptom onset in conjunction with his Petition (Ex. 4), which is consistent with the September 27, 2020 timeline.

onset of less than three days after vaccination. In making this determination, I find the records associated with Petitioner's October 26, 2016 neurological consultation to be especially probative. These records specifically include a day-by-day description of Petitioner's early symptoms. Indeed, the examining neurologist recorded that Petitioner received a flu vaccination on Friday, October 21, 2016, and began experiencing weakness of the hands on Sunday, October 23, 2016. Ex. 11 at 199. Petitioner was further noted to have begun walking slowly on Monday, October 24, 2016 with a complete inability to walk the following day. *Id*. In addition to being detailed and contemporaneous with the events described therein, these records comport with Petitioner's affidavit and the timeline he provided regarding his symptom onset.

There are other onset concessions made by Petitioner in this case. In his brief, Petitioner notes that after speaking to his expert, "it appears the weakness in [his] hands 54-55 hours of vaccination may represent the first objective sign of GBS/AIDP alleged to be caused by vaccination." Br. at 2. Petitioner further acknowledges that his post-vaccination symptoms do not appear to comport with the timeline prescribed in the Table. *Id*. Even so, Petitioner states that he does not concede that he cannot establish a flu-GBS Table claim because further expert input, or other evidence, might show that his initial symptoms were unrelated to the onset of GBS. *Id*. at 2-3. Petitioner therefore requests that I transfer this matter out of SPU without dismissing the flu-GBS Table claim. *Id*. at 3.

I have considered Petitioner's arguments but do not find them persuasive. Initially, as described, both Petitioner and his expert appear to admit that Petitioner's GBS symptoms began less than three days after vaccination. I further note that Petitioner's initial post-vaccination symptoms, including weakness, are consistent with GBS based on the Table's Qualifications and Aids to Interpretation and my prior experience adjudicating Program cases. *See* 42 C.F.R. § 100.3(c)(15)(ii) (listing weakness as a requirement for the diagnosis of acute inflammatory demyelinating polyneuropathy). I therefore conclude that further factual development and expert input are not needed to determine that the onset of Petitioner's GBS occurred less than three days after vaccination – outside the 3-42 day Table onset period. **Accordingly, Petitioner's Table Claim for flu-GBS is dismissed.** Because the matter no longer includes a Table claim (and otherwise cannot be decided, as discussed below, in an expedited timeframe), it is appropriate to transfer it out of SPU.

In his brief, Respondent questions the viability of Petitioner's remaining non-Table causation-in-fact claim, asserting that there may not be a reasonable basis for Petitioner to retain an expert in furtherance of it. Opp. at 2-4. Respondent specifically references the issues regarding the early onset of Petitioner's GBS, and also notes that Petitioner had a pre-vaccination history of gastrointestinal illness – a possible alternative cause.

See 42 U.S.C. § 300aa-13(a)(1)(B) (noting that compensation shall not be awarded if a preponderance of the evidence indicates the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition).

I have considered Respondent's arguments. Although Respondent raises issues that may ultimately prevent an entitlement finding in Petitioner's favor, the present record is insufficiently developed to resolve a non-Table version of this claim. Petitioner could establish, for example, through expert testimony or other persuasive evidence, that the specific circumstances of this case explain an earlier-than-usual onset, despite what is known about GBS's pathogenesis. He may also be able to rebut arguments regarding alternative cause. For these reasons, dismissal of the entire case would be premature. Rather, Petitioner should be permitted to proceed with his remaining non-Table causation-in-fact claim after this case is transferred out of SPU.

CONCLUSION

- **For the reasons described above, Petitioner's flu-GBS Table Claim is dismissed.**
- **Pursuant to Vaccine Rule 3(d), I will issue a separate order reassigning this case randomly to a Special Master.**

IT IS SO ORDERED.

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