In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 22-1269V
UNPUBLISHED

ALAN CORREIRA,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 3, 2025

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

James Vincent Lopez, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On August 27, 2021, Alan Correira 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 he received an influenza ("flu") vaccine on September 20, 2019, and thereafter suffered Guillain-Barré syndrome ("GBS") that was caused in fact by the vaccination. Amended Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed below, this claim is hereby **DISMISSED**.

[1] Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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

I. Procedural History

After the claim's initiation, Petitioner filed an amended petition with citations to the record. Amended Petition ("petition"), ECF No. 18. Respondent filed a Rule 4(c) Report opposing compensation, arguing Petitioner has not provided a medical or scientific showing that the vaccination caused his alleged GBS. Respondent's Rule 4(c) Report ("Res. Rep") ECF No. 21, at 1. Petitioner was ordered to show cause why this case should not be dismissed. ECF No. 24. The order noted that onset of Petitioner's GBS appeared to have occurred outside the longest time accepted for a non-table flu/GBS claim. *Id.*

Petitioner filed his response and additional evidence on September 12, 2023. Petitioner's Response to the Court's August 1, 2023 Show Cause Order ("Pet. Res."), ECF No. 27. Petitioner argues that he has established a prima facie case for causation. *Id.* at 22-31.

II. Fact History

a. Medical Records

Petitioner received a flu vaccine on September 20, 2019. Ex. 1 at 1. Ten days later, he underwent prostate surgery that involved nitrous oxide. Ex. 8 at 6 (noting that Petitioner had prostate surgery on October 1, 2019).

On November 23, 2019, Petitioner sought care at the emergency department. Ex. 7 at 5-8. He complained of numbness and tingling in his bilateral upper extremities that began on November 18, 2019, and "[c]onstant sensation for the past 6 days." *Id.* A physical exam was unremarkable, and he was diagnosed with bilateral upper extremity neuropathy. *Id.*

On November 26, 2019, Petitioner saw his primary care physician, Dr. Irvin, for a follow-up. Ex. 2 at 26-27. He reported numbness in his upper extremities, feet, tongue, and lips, but denied weakness. *Id.* Petitioner also stated that his symptoms had improved over the past three days, but were still present. *Id.* An examination showed normal gait, and no motor or sensory deficits. Petitioner was assessed with paresthesia of unclear etiology. *Id.*

Petitioner saw Dr. Leber, a neurologist, on November 27, 2019, for numbness in his forearms, tongue, and left foot. Ex. 8 at 6. He stated that on November 18, 2019, he woke with his hands and forearms feeling cold and somewhat numb. *Id.* He also reported

the prostate surgery on October 1, 2019, which Dr. Leber noted could cause myelopathy in patients with previous anemia. *Id.* A neurologic exam was "basically unremarkable," but he recorded a slight Bell's palsy of the left eyelid and mild absent sensation in the right foot. *Id.* at 7. Dr. Leber noted that due to the sudden onset of numbness, "one has to think of cervical myelopathy or cervical issues." *Id.* at 7-8. A subsequent MRI was unremarkable. *Id.* 15-16. Additionally, his B12 and folic acid were within normal limits. *Id.* at 10.

Petitioner returned to Dr. Leber on December 6, 2019, reporting recent onset of stumbling, slurring speech and tingling in his face and scalp. Ex. 8 at 10. Dr. Leber noted there was "no objective abnormality on examination, other than residual from previous left Bell's palsy." *Id.* He also stated he could not explain the described subjective sensory symptoms, and prescribed alprazolam for his anxiety. *Id.*

Later on December 6, 2019, Petitioner was seen at the emergency department for increased left facial droop that started that morning. Ex. 3 at 32. He was diagnosed with Bell's palsy. *Id.* at 35-36. Three days later, on December 9, 2019, Petitioner saw his primary care physician. Ex. 9 at 9. A physical and neurologic examination was unremarkable, but he was referred to a neurologist for a second opinion. *Id.* at 10.

Petitioner returned to the emergency department on December 12, 2019, complaining of numbness throughout his body, upper extremity pain, dizziness, and difficulty walking that started just prior to his arrival. Ex. 4 at 575. He showed left sided facial droop, absent bilateral reflexes, and an abnormal gait. *Id.* at 578. A lumbar puncture showed elevated protein levels. *Id.* at 752. The admitting physician noted that Petitioner "had a flu shot back in September. Question progressive [GBS] versus Lambert-Eaton syndrome." *Id.* at 403.

An addendum from December 13, 2019, states that Petitioner reported only subjective symptoms, and no objective abnormalities could be observed. But Dr. Khademi, a neurologist, could not rule out the possibility of an autoimmune neuropathy, "[i]n this case [GBS], predominantly sensory variant…." Ex. 4 at 1451. Dr. Khademi also noted that the nadir of the weakness is usually 3-4 weeks from onset. *Id.* at 1451, 416. Petitioner was discharged on December 14, 2019, with possible diagnoses including GBS and Labert-Eaton syndrome, an autoimmune neurological condition. Ex. 7 at 9-10.

A follow-up on December 16, 2019, with Dr. Irvin included a suspected diagnoses of the "predominantly sensory form" of GBS. Ex. 2 at 30-31. Petitioner saw Dr. Khademi for a second opinion on December 20, 2019. Ex. 5 at 9-10. An examination showed absent reflexes, left peripheral facial weakness, impaired gait, reduced sensation, but

normal motor strength. *Id.* He was assessed with inflammatory polyneuropathy and possible GBS. *Id.*

On December 21, 2019, Petitoiner returned to the emergency department for worsening paresthesia, and trouble breathing and swallowing. Ex. 4 at 1052. He exhibited decreased sensation in his trunk and chest, decreased grip strength, left sided facial droop, and absent reflexes. *Id.* at 1055. The differential diagnosis included GBS versus variant, a more chronic condition such as chronic demyelinating syndrome, and Eaton-Lambert syndrome. *Id.*

Petitioner saw another neurologist, Dr. Huntley, on December 21, 2019, reporting a five-week history of progressive weakness. Ex. 4 at 836. An examination showed "wildly" uncontrolled ambulation and absent reflexes. *Id.* at 837. He was assessed with paresthesia, dysphagia, a history of Bell's palsy with gait disorder. *Id.* at 837. Dr. Huntley also noted that he had "a hard time piecing this all together. The patient tells me Dr. Khademi was ordering IVIG, but it had not been set up yet…. I am wondering if he really needs IVIG." *Id.* at 837-38. Results from an EMG/NCS on December 24, 2019 were consistent with neuropathy with demyelinating and axonal components "in the family of GBS." *Id.* at 386. Dr. Huntley noted this was a "[f]ascinating case, a lot of overly but at the core [Petitioner] has [GBS]." *Id.* at 850.

Petitioner underwent a five-day course of IVIG, and was discharged on December 26, 2019. Ex. 4 at 79. Thereafter, Petitioner's symptoms improved. Ex. 2 at 37 (follow-up on December 30, 2019 stating symptoms have improved since his discharge); Ex. 9 at 12 (record from March 20, 2020, stating that Petitioner has improved approximately 80%). By May 20, 2020, he reported some residual numbness but also significant improvement to Dr. Vasquez, a neurologist. Ex. 6 at 8. Dr. Vasquez noted he had no flu-like symptoms before onset, no diarrhea, but he "did have a flu shot in September of last year." Ex. 6 at 8.

b. Affidavit Evidence

Petitioner submitted an affidavit in support of his claim on March 6, 2023. Ex. 12. Petitioner states that he received a flu vaccine on September 20, 2019. *Id.* at 1. He began experiencing numbness in his hands in November of 2019, although he could not recall the precise onset date. *Id.* Additionally, he states that he "did experience worsening symptoms for at least one week before seeking care…." *Id.*

c. Expert Report

Petitioner submitted an expert report from Dr. Norman Latov, M.D., Ph.D ("Ex. Rep.), dated July 24, 2023. Dr. Latov attended the University of Pennsylvania to complete his medical and doctorate degree. Ex. 15 at 1. He completed his residency in neurology and immunology at Columbia University and is now on the faculty at Weill Cornell Medicine. *Id.* at 3. Dr. Latov directs a peripheral neuropathy center as well as serving as a professor of neurology and neuroscience, and being an attending neurologist. *Id.,* Ex. Rep. at 2. In his clinical practice he has "devoted a substantial portion … to the evaluation, diagnosis, and treatment of patients with peripheral neuropathies including Guillain–Barré syndrome (GBS) chronic inflammatory demyelinating polyneuropathy (CIDP). *Id.*

Dr. Latov opined that that vaccines can induce autoimmune disease such as GBS through molecular mimicry or bystander activation. Ex. Rep. at 5-6. Both molecular mimicry and bystander activation have been accepted by the Institute of Medicine ("IOM")[10] as possible explanations for post-vaccination adverse events. *Id.* (citing INSTITUTE OF MEDICINE, ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY 57 (Stratton et al. eds., 2012) [hereinafter 2012 IOM Report] (Ex. 25)).[3] By Dr. Latov's description "[m]olecular mimicry occurs when there is a structural homology, in sequence or conformation, between an exogenous agent, such as a vaccine or infection, and a self or autoantigen that is subsequently targeted by the immune response. Induction of immune reactivity against the foreign agent results in cross reactivity with the self-antigen, with subsequent tissue damage and autoimmune disease." *Id*. at 6. Regarding bystander activation, he observes that the normal immune state incudes auto-reactive cells that are suppressed by immune tolerance, thereby preventing autoimmune

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[3] The Institute of Medicine (known as the National Academy of Medicine since 2015) is the medical arm of the National Academy of Sciences. The National Academy of Sciences ("NAS") was created by Congress in 1863 to be an advisor to the federal government on scientific and technical matters (*see* An Act to Incorporate the National Academy of Sciences, ch. 111, 12 Stat. 806 (1863)), and the Institute of Medicine is an offshoot of the NAS established in 1970 to provide advice concerning medical issues. When it enacted the Vaccine Act in 1986, Congress directed that the IOM conduct studies concerning potential causal relationships between vaccines and illnesses. *See* § 300aa–1. However, the IOM employs a standard for finding causation that is higher than what is required by petitioner's burden of proof. *E.g. Raymo v. Sec'y of Health & Hum. Servs.*, No. 11-654V, 2014 WL 1092274, at *21, n. 39 (Fed. Cl. Spec. Mstr. Feb. 24, 2014). Accordingly, IOM reports and findings should be approached with caution. Special Masters may rely on IOM reports as evidence, but they are not dispositive. *See, e.g., Crutchfield v. Sec'y Health & Hum. Servs.*, 125 Fed. Cl. 251, 262 (2014) (noting that "it was appropriate for the special master to consider the medical literature presented, including the IOM report" and that "the court often has relied on the findings of the Institute of Medicine."); *see also, Isaac v. Sec'y Health & Hum. Servs.,* 108 Fed. Cl. 743, 755 (2013), *aff'd,* 540 Fed. Appx. 999 (Mem.) (Fed. Cir. 2013) (affirming the special master's reliance on findings of the IOM); *Porter v. Sec'y Health & Hum. Servs.,* 663 F.3d 1242, 1252 (Fed.Cir.2011) (noting the special master's comment that "IOM reports are favored, although not dispositive, in the Vaccine Act Program," then affirming the special master's decision).

disease. Bystander activation occurs when infection or immunization stimulate the immune system in such a way as to overcome that immune tolerance. *Id.*

In petitioner's case, Dr. Latov observed, GBS most likely developed on or around November 16, 2019, or 57-59 days post vaccination. Ex. Rep. at 7. According to Dr. Latov, this is within the time period of elevated risk for developing GBS due to a vaccine. *Id.* To support this conclusion, Dr. Latov cited a study that examined incidences of GBS following a 1976 program for vaccination against the swine flu. *Id*. That study found that most post-vaccination GBS cases occurred within five weeks of vaccination, but also observed an increased risk lasting up to nine or ten weeks. L. Schonberger *et al.*, Guillain-Barré Syndrome Following Vaccination in the National Influenza Program, United States, 1976-77, 110 Am. J. Epid. 2:105-123 (1979), filed as Ex. 13.

Additionally, Dr. Latov concluded it is logical that Petitioner developed GBS as a consequence of his vaccination. Ex. Rep. at 8. And he noted that there were no other potential causes identified that could have triggered his GBS. *Id.*

III. Legal Standard

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.*

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 & Hum. 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). Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

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 establish that he suffered an injury meeting the Table criteria (*i.e.* a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. If a petitioner cannot establish a Table injury, he or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005): "(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 showing of proximate temporal relationship between vaccination and injury."

The association between the flu vaccine and GBS is well-established in the Vaccine Program. *See, e.g., Strong v. Sec'y of Health & Human Servs.*, No. 15-1108V, 2018 WL 1125666 (Fed. Cl. Spec. Mstr. Jan. 12, 2018); *Stitt v. Sec'y of Health & Human Servs.,* No. 09-653V, 2013 WL 3356791 (Fed. Cl. Spec. Mstr. May 31, 2013); *Stewart v. Sec'y of Health & Human Servs.*, No. 06-777V, 2011 WL 3241585, at *16 (Fed. Cl. Spec. Mstr. July 8, 2011); *see also Barone v. Sec'y of Health & Human Servs.,* No. 11-707V, 2014 WL 6834557 (Fed. Cl. Spec. Mstr. Nov. 12, 2014). Indeed, GBS was added in 2017 as a Table Claim for the flu vaccine (although this case does not involve such a claim). *See* 42 C.F.R. § 100.3(a). Accordingly, my resolution of Petitioner's claim does *not* turn on a finding, under *Althen* prong one, that (for purposes of adjudicating a Program claim) the flu vaccine "can cause" GBS, for that question has been thoroughly examined and answered in the affirmative.

There are nevertheless limits to the kinds of fact patterns that successfully establish that the flu vaccine "did cause" a particular petitioner's GBS under the second *Althen* prong. In most successful non-Table cases, onset of symptoms is demonstrated to have occurred *no longer than* six to eight weeks after vaccination. *See, e.g.*, *Barone*, 2014 WL 6834557, at *13 (eight weeks is the longest reasonable timeframe for a flu/GBS injury). This means up to 56 days.

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[4] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories; 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).

IV. Petitioner's GBS Onset Occurred Too Long After His Receipt of the Flu Vaccine to Satisfy the Third Althen Prong[5]

Petitioner asserts that he is entitled to compensation because he has established a *prima facie* case that his injury was caused-in-fact by the flu vaccine and has satisfied the *Althen* prongs. Pet. Res. at 23-31. The following factual findings are made after a complete and thorough review of the record, including all medical records, affidavits, and all other additional evidence and filings from the parties.[6]

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. A petitioner must offer "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." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

In this case, Petitioner's expert frames his discussion of onset in reference to a study examining an outbreak of GBS following administration of the 1976 swine flu vaccine – Schonberger, et al., (Ex. 14 at 6 (citing Schonberger). The medical literature offered in this case establishes that a reasonable timeframe for onset of GBS after vaccine administration would be no more than six to eight weeks, however. Schonberger at 105. Specifically, Schonberger indicates that most GBS cases after the flu vaccine that it evaluated occurred around 13-17 days, with their latest happening 41 days. *Id.* at 112. This is echoed by the timeframe set for the Table version of the claim (*see* 42 C.F.R. § 100.3 (2017)). (It is in fact arguably the case that *any* onsets that exceed the 3-42 day timeframe are suspect from a medical/scientific standpoint, since the onset timeframe is specifically engineered to be over-inclusive, rather than to reflect a precise framework in which a vaccine can, or cannot, cause injury).

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[5] As already noted, I do not include an extended discussion of the first *Althen* prong (which Petitioner effectively satisfied). I also do not engage in an extended *Althen* prong two analysis, given my determination that the timeframe for onset of Petitioner's GBS was too remote from vaccination to be deemed medically reasonable. *See, e.g.*, *Hunt v. Sec'y of Health & Human Servs.*, 123 Fed. Cl. 509, 524-25 (2015) (citing *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 355-56, *aff'd*, 475 F. App'x 765 (Fed. Cir. 2012)). However, I note that the record does not conclude that the flu vaccine "did cause" Petitioner's GBS. His symptoms do not reflect the manner in which GBS most commonly would progress. He initially reported no motor or sensory deficits, showed some improvements shortly after reporting numbness, and exhibited little objective abnormalities prior to December 6, 2019.

[6] Though every document is not specifically referenced in this ruling, the complete record was reviewed and considered. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.").

Here, contemporaneous medical records preponderantly establish that the initial symptoms of Petitioner's GBS did not occur before November 18, 2019, 59 days after his vaccination. Thus, when he presented to the hospital on November 23, 2019, Petitioner complained of numbness and tingling in his extremities that began on November 18, 2019, and had "[c]onstant sensation" for the past six days. Ex. 7 at 5-8. He repeated this timeline on November 27, 2019. Ex. 8 at 6. This evidence outweighs the record interpretation proposed by Dr. Latov for a slightly earlier onset (and I am not obligated to accept his *ipse dixit* on this point). Ex. 14 at 6 (arguing that Petitioner's symptoms began 57-59 days after vaccination).

Measuring from the September 20, 2019 vaccination, then, a Table version of the claim in this case could only succeed if onset had occurred on or before November 1, 2019 – which clearly did not occur. But even a causation-in-fact claim would have needed to be based on symptoms beginning no more than two weeks after – or by November 15, 2019, at the latest. This also did not occur.

These facts accordingly are inconsistent with even the *longest timeframes* (eight weeks) accepted for a similar non-Table claims recognized in reasoned Program decisions.[7] *See, e.g.*, *Barone*, 2014 WL 6834557, at *13. Petitioner's onset thus occurred far too long after vaccination to be considered "medically acceptable to infer causation-in-fact." *See de Bazan*, 539 F.3d at 1352; *De La Cruz v. Sec'y of Health & Hum. Servs.,* No. 17-783V, 2018 WL 945834, at *1 (Fed. Cl. Jan. 23, 2018) (finding onset of GBS more than two months after flu vaccination to be not compensable under either a theory of causation in fact or significant aggravation).

[7] Admittedly, other special masters have accepted a comparably-lengthy timeframe. *See, e.g.*, *Cooper v. Sec'y of Health & Hum. Servs.,* No. 18-1885V, 2024 WL 1522331, at *20 (Fed. Cl. Mar. 12, 2024) (finding 60-day onset of GBS following a vaccination allows inference of causation); *Spayde v. Sec'y of Health & Hum. Servs.*, No. 16-1499V, 2021 WL 686682, at *19 (Fed. Cl. Jan. 27, 2021). But such decisions do not control this outcome. Moreover, they either involve a different vaccine (for *Cooper,* the pneumococcal vaccine), or were based on reasoning that justified stretching the eight-week timeframe a few days, in the interests of the Program's emphasis on generosity and a desire not to apply a hard, bright-line "rule." *Spayde,* 2021 WL 686682, at *19. Of course, the proposed up-to-eight weeks timeframe *itself* already exceeds the "rule" of the Table claim for the flu vaccine, and does not itself constitute something that can be deemed accepted as a general matter. Moreover, this thinking reflects a logic whereby any onset not shown to be facially impossible (say, more than 90 days) should be deemed medically acceptable. I do not consider that kind of reasoning consistent with the science applicable to how vaccines are thought to cause GBS, and it is not demanding scientific certainty to reject it.

Conclusion

The evidentiary record does not support Petitioner's contention that his GBS began in a medically-acceptable timeframe after vaccination. Petitioner has thus not established entitlement to a damages award, and therefore I must DISMISS his claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this Decision.[8]

IT IS SO ORDERED.

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

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[8] 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."