In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-1222V

RANDY BROUETTE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 2, 2025

Jonathan Joseph Svitak, Shannon Law Group, P.C., Woodridge, IL, for Petitioner.

Rachelle Bishop, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On September 17, 2020, Randy Brouette 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 suffered Guillain-Barré syndrome ("GBS") resulting from an influenza ("flu") vaccine received on September 19, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (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 (2018).

For the reasons set forth below, I find that Petitioner has not established by preponderant evidence the onset element for a Table flu vaccine-GBS claim – and I find that the timeframe for onset was otherwise too long to be shown to be medically acceptable, even under a non-Table version of the claim. Therefore, the case is properly dismissed.

I. Relevant Procedural History

On July 19, 2021, Respondent stated that he intended to defend this case, and requested that Petitioner file medical records, including complete EMG/NCS reports with all relevant data (ECF No. 15). Petitioner requested, and received, numerous extensions of time to obtain the records (ECF Nos. 16, 17, 19, 20). Following a status conference, Petitioner obtained some records and moved to subpoena others (ECF Nos. 21-23). The motion was granted, and Petitioner was directed to file the records by June 16, 2022 (ECF No. 24). When Petitioner missed this deadline, I extended it to September 1, 2022. Scheduling Order (NON PDF), issued Aug. 25, 2022. Petitioner also missed that deadline.

I thus directed Petitioner to file the records by December 14, 2022, or to show cause why the case should not be dismissed for failure to prosecute (ECF No. 25). This deadline was extended several times (ECF Nos. 26, 28, 29). On March 24, 2023, Petitioner filed additional records as well as a status report stating that EMG records remained outstanding, despite countless attempts and receiving thousands of pages of records (ECF Nos. 32, 33). Over the following months, Petitioner filed records from his treating neurologist (ECF Nos. 38-40).

Respondent subsequently filed his Rule 4 Report, along with three expert reports (ECF Nos. 41-44). On February 27, 2024, Petitioner was directed to show cause why the case should not be dismissed for the reasons identified in Respondent's Report (ECF No. 45). On June 25, 2024, Petitioner responded (ECF No. 48).

II. Relevant Factual History

A. Medical Records

Petitioner's pre-vaccination medical history is significant for hypertension, hypercholesterolemia, diabetes, sleep apnea, gout, and vascular disease. Ex. 3. On September 19, 2017, Petitioner (then 59 years old) received a flu vaccine at the office of his primary care provider, Dr. Pranav Patel. Ex. 3 at 43. On October 24, 2017, 35 days after vaccination, he returned to Dr. Patel to follow up on labs. *Id*. at 44. He had no health complaints at this time, and there were no positive findings other than low vitamin D in his labs. *Id*. at 45. Petitioner was advised to restart a medication and return in three months for labs. *Id*.

On the morning of November 25, 2017 – now nine and a half weeks (67 days) after vaccination – an ambulance was dispatched to Petitioner's home for a possible stroke, and paramedics found Petitioner awake but non-responsive. Ex. 4 at 219. His family members reported that he had been "normal" the evening before. *Id*. at 219, 227. He was transported to Silver Cross Hospital emergency department ("ED") and admitted. *Id*. at 139, 219. In the ED, he was noted to have "complete expressive aphasia, R lower facial droop . . . [and] +right babinski."[3] *Id*. at 228.

Neurologist Dr. Nitin Nadkarni evaluated Petitioner on the date of his hospital admission (November 25th). Ex. 4 at 213. Dr. Nadkarni noted that Petitioner was having difficulty speaking and finding words. *Id*. at 214. On examination, Petitioner displayed bilateral facial weakness that was worse on the right side. *Id*. His reflexes and sensory examination were normal. *Id*. Dr. Nadkarni stated that Petitioner had experienced a left hemispheric ischemic event and ordered imaging. *Id*. at 214. A brain MRI done on the day of admission showed no evidence of acute infarct. *Id*. at 473. A speech therapist noted that Petitioner exhibited congestion and a cough, and Petitioner's relative reported that Petitioner had a head cold prior to arrival at the hospital. *Id*. at 615.

On November 26, 2017, Dr. Nadkarni noted Petitioner to have bilateral lower motor neuron facial weakness, bilateral upper extremity weakness, and distal sensory impairment. Ex. 4 at 416. Because his brain MRI showed no evidence of a brainstem stroke, Dr. Nadkarni treated Petitioner for "[e]volving GBS." *Id*. at 413, 416. IVIG was deferred due to vascular risk factors, and Petitioner was transferred to the intensive care unit and started on plasmapheresis. *Id*. He was noted to be a "poor historian" because he initially insisted that he had recently been on a particular medication, but after his spouse brought in his medications from home, he acknowledged that he had been mistaken. *Id*. at 413, 423.

On November 27, 2017, Petitioner reported his recent vaccination to Dr. Nadkarni. Ex. 4 at 412. On examination, his arm reflexes were absent, but he had normal deep tendon reflexes in his legs. *Id*. at 412-13. He exhibited bilateral facial weakness and slurred speech, and complained of numbness and tingling to both arms, but no pain. *Id*. Dr. Nadkarni treated him for "likely GBS," noting that his brain MRIs[4] had not shown abnormalities that would explain his clinical findings. *Id*.

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[3] A positive Babinski result refers to dorsiflexion of the big toe when the sole of the foot is stimulated. *Babinski reflex*, DORLAND'S ONLINE, https://www.dorlandsonline.com/dorland/definition?id=102809 (last visited Sept. 2, 2025). This reflex is normal in infants, but in adults is a sign of a lesion in the central nervous system. *Id*.

[4] Petitioner had a second brain MRI on November 26, 2017. Ex. 4 at 472. This MRI showed a mass "most consistent with meningioma" as well as white matter foci that "could be due to the demyelinating process or focal inflammatory lesions," with white matter changes of vasculitis also a consideration. *Id*.

However, a repeat brain MRI study done the evening of November 27, 2017, and compared to the November 25th MRI showed "interval development of confluent areas of gyriform cortical signal abnormality now noted involving parietal regions bilaterally most suspicious for developing ischemic abnormality especially in view of the bilateral internal carotid occlusion." *Id*. at 468-69.

The record includes an electromyography ("EMG")[5] report. Ex. 4 at 240-41. Although the EMG report lists a service date of December 11, 2017 (*id*. at 240), I find this date is almost certainly inaccurate. Because the EMG was reviewed and relied upon by Petitioner's treating physicians as early as November 28th and 30th (*id*. at 201, 355), it was more likely performed on or before November 28, 2017.[6] Ex. 4 at 240-41.

The EMG report concludes that "[t]here is electrodiagnostic evidence of polyneuropathy in upper and lower extremities," (Ex. 4 at 240), although even Petitioner's expert describes this as a likely "typographical error." Ex. 5 at 3 (stating that the EMG revealed prolongation of median motor nerve distal latency, but showed no evidence of generalized peripheral neuropathy, noting that "there appears to be a typographical error in the written impression, indicating 'evidence of polyneuropathy in UE and LE'"). The EMG findings section, which describes test results in more detail, noted prolonged right median nerve distal latency with normal motor amplitude and conduction velocity, but otherwise normal amplitudes, distal latencies, and conduction velocities for all tested nerves.[7] *Id*. Respondent notes the data from this study has never been produced despite several subpoenas. Respondent's Report, ECF No. 41, at *5 n.1. The record includes a

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[5] Electromyography records extracellular activity of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation. *Electromyography*, DORLAND'S ONLINE, https://www.dorlandsonline.com/dorland/definition?id=15854 (last visited Sept. 2, 2025).

[6] Respondent states that the EMG report was dictated on December 11, 2017. Respondent's Rule 4(c) Report, filed Sept. 20, 2023, at *5 (ECF No. 41). The report was transcribed on December 12, 2017; thus, Respondent's explanation for why the report is listed as having been performed on December 11th seems plausible.

[7] The findings section states:

> Motor conduction studies were performed of right median and right ulnar nerve, right peroneal, right tibial, left peroneal, left tibial, left median, and left ulnar nerves. Distal latency obtained from right median nerve was prolonged with normal motor amplitude and normal conduction velocity. Left peroneal, left tibial, left median, and left ulnar distal latencies were normal with normal motor amplitudes and normal conduction velocities.
>
> Sensory nerve conduction studies were performed of median and ulnar nerves and sural nerves on both sides. Sensory nerve action potential, distal latency, and conduction velocities were normal in all the sensory nerves tested.

Ex. 4 at 240.

note stating "NCV [nerve conduction velocity][8] COMPLETED 11/28/17," (Ex. 4 at 241) although Respondent states that the NCV results were not recorded. Respondent's Report, ECF No. 41, at *5.

Neurologist Dr. Bassel Kazkaz was consulted for a second opinion while Petitioner was hospitalized on November 28, 2017. Ex. 4 at 198. Dr. Kazkaz noted that Petitioner woke up the morning of November 25, 2017 throwing up and went to the bathroom. *Id*. at 199. While there, he developed bilateral hand weakness and speech disturbance, and was unable to open the door. *Id*. At the emergency room, he was severely hypertensive, unable to speak with right-sided lower facial droop, and right Babinski, a reflex which in adults may indicate central nervous system disorder. *Id*. A CT angiogram showed complete occlusion of the internal carotid arteries bilaterally up to the bifurcation within the neck. *Id*.

Petitioner was noted to have significant dysphasia, bifacial weakness, and bilateral distal upper extremity weakness. Ex. 4 at 199-200. Petitioner reported some numbness and tingling in his hands, but no weakness in his lower extremities. *Id*. On examination, Petitioner had "rather dramatic and significant bilateral distal hand weakness" and reduced but present upper and lower extremity reflexes. *Id*. at 200. Dr. Kazkaz reviewed the EMG study and data, which he stated "showed completely normal study without any evidence of conduction slowing, distal latency prolongation, conduction block, [or] F-wave latency prolongation." *Id*. at 201.

Dr. Kazkaz noted that Petitioner's third brain MRI on November 27th showed changes that were suspicious for developing ischemic abnormality. Ex. 4 at 201. Petitioner was noted to have an "unusual presentation" with significant bilateral pharyngeal and facial weakness and bilateral distal hand weakness with "sparing of lower extremities and sparing of proximal upper extremities." *Id*. Dr. Kazkaz noted Petitioner's carotid artery occlusion, and thought his presentation was most consistent with "unusual stroke syndrome" causing "Opercular syndrome." *Id*.

Dr. Kazkaz thought it was reasonable to consider a neuromuscular illness like GBS, particularly a rare bulbar-cervical-brachial variation, although "it would be unusual to have a second diagnosis on top of the primary acute stroke diagnosis, which is consistent with the whole clinical context," including the EMG, which was "completely normal." Ex. 4 at 201. He acknowledged that the EMG was performed early in Petitioner's illness course, but stated that given Petitioner's degree of weakness, he would expect to see some degree of conduction block in the nerves studied in the hands. *Id*. He added that GBS usually involves proximal muscles more than distal ones – not the opposite

[8] Nerve conduction velocity studies measure the speed at which impulses move along the largest fibers of a peripheral nerve. *Nerve conduction velocity*, DORLAND'S ONLINE, https://www.dorlandsonline.com/dorland/definition?id=117402 (last visited Sept. 2, 2025).

pattern Petitioner displayed. *Id*. He stated that a lumbar puncture could be considered to confirm Petitioner's diagnosis, although it does not appear that this test was done. *Id*.

On November 30, 2017, Petitioner saw endovascular surgical neuroradiology specialist Dr. Richard Burgess. Ex. 4 at 353. Petitioner reported that the previous Friday (November 24th) "he felt NORMAL – denies any weakness or paresthesia." *Id*. The next day, he woke up feeling normal. *Id*. He went out, and felt "weird" when he came back home. *Id*. Eventually he went to the bathroom with difficulty; once there, he vomited and was unable to get up or talk, and could not turn the doorknob with his hands. *Id*. He was found several hours later and brought to the hospital; the overall onset of symptoms "was over minutes." *Id*.

Dr. Burgess noted that Petitioner had now undergone plasmapheresis and was getting better. Ex. 4 at 354. Dr. Burgess commented on the negative EMG and lack of a lumbar puncture, and described it as a "highly unusual and difficult case that does not perfectly fit either GBS variant nor typical stroke syndromes." *Id*. at 355. Dr. Burgess thought Petitioner's risk factors, rapid symptom onset, lack of lower extremity symptoms, acute to subacute vascular occlusion, and MRI progression led to the conclusion that his clinical picture was most consistent with . . . a syndrome similar to Foix-Chavany-Marie/bilateral opercular syndrome." *Id*. The differential diagnosis included GBS with plasmapheresis induced borderzone strokes from hypotension. *Id*.

On December 1, 2017, Dr. Nadkarni examined Petitioner, finding normal leg reflexes but absent arm reflexes. Ex. 4 at 352. Dr. Nadkarni's impression was "likely GBS," noting a "very unusual presentation for bilateral parietal lobe stroke," and that the MRI findings did not correlate with clinical findings. *Id*. at 352-53. Plasmapheresis was continued. *Id*. Dr. Burgess examined Petitioner that same day. *Id.* at 335. He stated that Petitioner was improving daily, and that "[o]ne interpretation is hospitalization began with GBS but that plasmapheresis lowered [Petitioner's blood pressure] and in the setting bilateral carotid occlusion led to strokes seen on MRI." *Id*. at 335-36. He ordered that plasmapheresis be continued, with care taken to avoid hypotension. *Id*.

On December 4, 2017, Dr. Burgess noted that Petitioner's weakness was slowly improving. Ex. 4 at 271. He assessed Petitioner with bilateral carotid artery occlusion and bilateral parietal strokes that "[s]ignificantly worsened several days into admission after a couple of rounds of plasmapheresis." *Id*. at 272. He found this was most consistent with "watershed infarcts due to chronic/subacute carotid occlusion and hypotension." *Id*. However, he added, "[w]hile an opercular syndrome from stroke could result in symptoms similar to this patient's presentation . . . an unusual superposition of GBS followed by mild hypotension leading to minimally symptomatic MRI changes seems most likely." *Id*. at 272. While hospitalized, Petitioner's tested negative for GQ1b antibodies. *Id*. at 455.

On December 7, 2017, Petitioner was transferred to inpatient rehabilitation, where he remained until December 17, 2017. Ex. 4 at 141; Ex. 17 at 4. Thereafter, he continued outpatient care with Dr. Patel and Silver Cross Hospital. Exs. 4; 16.

Petitioner saw Dr. Patel on January 4, 2018, following his hospital discharge. Ex. 16 at 88. Dr. Patel noted that while hospitalized, Petitioner "was diagnosed with GBS post flu shot." *Id*. Petitioner was noted to have recovered "about 80%" from GBS, with a "slightly sloppy" gait, reduced right upper extremity strength, and lack of fine manipulation in his right hand. *Id*. at 88-89.

On November 6, 2019, Petitioner saw Dr. Patel to follow up on labs. Ex. 16 at 54. He was doing well, with no new complaints. *Id*. Dr. Patel documented a "history of Guillain-Barre induced from flu vaccination." *Id* at 55. The record does not explain why, however (and nearly two years after Petitioner's GBS diagnosis), Dr. Patel concluded that the condition was caused by vaccination.

B. Affidavit Evidence

Petitioner filed an affidavit in support of his claim. Ex. 6. He states that he was given a GBS diagnosis at Silver Cross Hospital in November 2017. *Id*. at ¶ 5. For over a year after his injury, he required assistance for dressing, eating, and personal hygiene. *Id*. at ¶ 8. He is no longer to do his professional work duties. *Id*. at ¶ 7.

III. Expert Reports

A. Petitioner's Expert Report, David M. Simpson, M.D.[9]

Petitioner submitted an expert report from David M. Simpson, M.D., Professor of Neurology and Director of Clinical Neurophysiology, Neuromuscular Division and the Neuro-AIDS Program at the Mount Sinai Medical Center. Ex. 5. Dr. Simpson reviewed Petitioner's medical records, noting that there was "significant discussion among the treating providers as to the relative contributions of a central vs peripheral nerve localization of Mr. Brouette's symptoms." *Id*. at 5. The evolution of MRI changes raised the question of stroke/opercular syndrome, but Dr. Simpson asserts that "after careful consideration by the neurologists, radiologists, and neurointerventional surgeons, it was ultimately concluded that GBS was the primary cause of Mr. Brouette's symptoms . . . . [and] the brain ischemic changes were a secondary phenomenon, likely precipitated by shifts in [blood pressure] induced by plasmapheresis." *Id*.

Dr. Simpson states that the onset of neurological symptoms approximately nine weeks after a flu vaccination is within the reported time onset of post-influenza vaccine GBS in the literature. Ex. 5 at 6. He relies on a study of GBS following a 1976 swine flu

[9] Petitioner apparently obtained the expert report before filing the petition, as it was filed along with the petition (ECF No. 1-7). As stated in the SPU Initial Order issued on March 19, 2021, experts should not be consulted without first consulting with Respondent's counsel and the court (ECF No. 11).

vaccination program, which he states demonstrates an "increased attributable risk [of GBS] . . . for the 10 weeks following [flu] vaccination." *Id*. (citing L. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 110 Am. J. Epidemiology 105, 111 (1979), filed as Ex. 12, ECF No. 1-14). He acknowledges, however, that the greatest risk period for GBS was in the first two to three weeks after vaccination. *Id*.

Dr. Simpson adds that after treatment with IVIG,[10] Petitioner had "both subjective and objective improvement in symptoms," although he continued to have residual neurological symptoms. Ex. 5 at 7. He concludes that "the sequence of events, with neurological symptoms beginning *within 9* weeks of influenza vaccination, followed by progressive neurological signs of sensory and motor neuropathy, support the diagnosis of AIDP/Guillain Barre syndrome."[11] *Id*. at 7 (emphasis added). He states that Petitioner's treating physicians documented a causal association between his vaccine and the onset of GBS, and he had a "clear response to plasmapheresis," supporting an immune-mediated pathogenesis. *Id*. He states that there is no alternative explanation – despite the evidence of a recent upper respiratory infection – and concludes that, more likely than not, the flu vaccine was causally related to the development of AIDP/GBS. *Id*.

B. Respondent's Expert Reports

1. Steven R. Messé, M.D.

Respondent filed an expert report from Steven R. Messé, M.D., a Professor of Neurology in the Division of Vascular Neurology at the University of Pennsylvania. Ex. A. Dr. Messé opined that Petitioner's November 25, 2017 hospital admission "was not related to the influenza vaccination that he received over 2 months previously on September 19, 2017." Ex. A at 4. Dr. Messé finds it "very clear" that Petitioner's sudden onset of symptoms on the day of admission "are attributable to bilateral hemispheric ischemia from his extensive vascular disease and bilateral carotid occlusions, and I think it is extraordinarily unlikely that he also had GBS." *Id*. In Dr. Messé's view, "the treatment he received for the purported GBS likely worsened the brain ischemia." *Id*.

Dr. Messé states that "[a]ll aspects of this case strongly favor stroke" as the cause of the symptoms resulting in Petitioner's hospitalization. Ex. A at 4. Dr. Messé emphasizes Petitioner's history of severe vascular disease, sudden onset of focal symptoms that indicate central nervous system cortical dysfunction, and MRI findings confirming bihemispheric stroke "which would explain all of his symptoms." *Id*. In contrast, Dr. Messé states that "there is little to support the idea that he had GBS." *Id*. Dr. Messé states that GBS typically presents with ascending and symmetrical weakness that

[10] The reference to IVIG appears to be a typo, as Petitioner was treated with plasmapheresis but not IVIG.

[11] AIDP stands for acute inflammatory demyelinating polyneuropathy, a form of GBS.

progresses over many hours or days, reaching a nadir at around two to four weeks; in contrast, Petitioner presented with sudden and dramatic central nervous system symptoms. *Id*.

Dr. Messé adds that "GBS is typically associated with findings of demyelination or axonopathy on EMG, neither of which were present on either of [Petitioner's] studies. Ex. A at 4. While there are rare variant forms of GBS that present differently, such as Miller-Fisher, in such cases "there is still a progression of symptoms over time related to peripheral nerve injury" that was not present in this case. *Id*. Instead, Petitioner had "fluctuating symptoms related to blood pressure variability," commonly seen in patients with stroke and large vessel occlusions. *Id*. Also important is that Petitioner's testing for anti-GQ1B antibodies – associated with the Miller-Fisher form of GBS – was negative. *Id*. Petitioner's bilateral arm weakness is "easily explained by the bilateral strokes seen on MRI, attributable to the bilateral carotid occlusions." *Id*. The absence of apparent infarct on the MRI taken on the day of Petitioner's admission "likely is due to the fact that he was experiencing ischemia, but the infarct may not yet have been completed." *Id*. In Dr. Messé's view, Petitioner's bilateral upper and lower face weakness, cited by Dr. Nadkarni as evidence that Petitioner had GBS, is also explained by bilateral strokes. *Id*.

Dr. Messé thinks it is "very likely that [Petitioner] did not even have GBS, and instead, his primary and only issue was bihemispheric strokes." Ex. A at 5. Dr. Messé notes that Petitioner had reflexes documented by both neurologists who saw him early in his course, and neither of two EMGs were indicative of a demyelinating polyneuropathy. *Id*. at 6. There was no monophasic progression of worsening over days and weeks, but instead a sudden onset of focal symptoms, "the hallmark of stroke." *Id*. Although Petitioner had absent reflexes in his face and arms on November 28, 2017, "[t]he MRI the day before clearly demonstrated bilateral strokes and it is well known that strokes may initially cause hyporeflexia." *Id*. Overall, Petitioner's "medical history, presentation, diagnostic testing, and subsequent clinical course are all consistent with bihemispheric strokes from bilateral carotid occlusions," and there is "no feature of this case that provides a credible argument that he also had GBS." *Id*.

2. Pria Anand, M.D.

Respondent filed an expert report from Pria Anand, M.D., Chief of the Division of Hospitalist Neurology and Assistant Professor of Neurology at the Boston University School of Medicine/Boston Medical Center. Ex. C. Dr. Anand opines that Petitioner's clinical course is not typical of a GBS diagnosis, and the timing of onset of his symptoms is not typical for GBS provoked by vaccination. Ex. C at 4-5. Moreover, in Dr. Anand's view, Petitioner's records "do not show any of the objective findings required to make a diagnosis of GBS." *Id*. at 5.

Dr. Anand explains that there are seven "Brighton criteria" for a GBS diagnosis, and of the seven, Petitioner meets just two, suggesting that he did not have GBS at even

the lowest level of diagnostic certainty. Ex. C at 5. Dr. Anand adds that Petitioner also does not meet the published criteria for the rare pharyngeal-cervical-brachial variant GBS mentioned in Dr. Kazkaz's notes. *Id*. at 5-6. In Dr. Anand's view, Petitioner's presentation is most consistent with an unusual stroke syndrome causing 'Opercular syndrome.' *Id*. at 6. Dr. Anand adds that Dr. Kazkaz and the physicians who saw Petitioner in the emergency department noted that he had a right-sided Babinski sign (Ex. 4 at 200, 228), which is a foot reflex suggesting an injury to the brain or spinal cord. *Id*. at 7. The Babinski sign is not seen in GBS patients, as GBS is an injury of the peripheral nerves and nerve roots that does not involve the brain or spinal cord. *Id*. The Babinski sign *is*, however, characteristically seen in patients with stroke causing weakness. *Id*. Furthermore, the Babinski sign is 98% specific meaning that when it is present, "the likelihood of a disorder of the brain or spinal cord is nearly guaranteed." *Id*.

Dr. Anand concludes that the hyperacute nature of Petitioner's symptoms, his examination, including a Babinski sign, and his MRI findings "are all consistent with a diagnosis of stroke causing all of his symptoms." Ex. C. at 7. While Petitioner attributes difficulty speaking to GBS, Dr. Anand states that "[t]here is no mechanism by which GBS, a disorder of the peripheral nerves and nerve roots that does not involve the brain at all, could cause stuttering or another problem of language." *Id*. However, stuttering "has been extensively reported in the literature as a presenting symptom of stroke." *Id*.

Finally, Dr. Anand states that GBS symptoms typically progress over a two week period, and symptoms that reach maximal severity within 24 hours are considered "fundamentally inconsistent with a diagnosis of GBS and should prompt a search for an alternative diagnosis." Ex. C at 8. In contrast to this typical course, Petitioner's symptoms were maximal at onset and rapidly progressed over a course of hours. *Id*. Symptoms that are maximal at onset and progress over the course of hours rather than days or weeks are not consistent with GBS and are more consistent with alternative neurologic diagnoses such as stroke. *Id*. Petitioner's symptoms improved over the course of just 11 days during his hospitalization, which is "not consistent with either the natural history of GBS or the response to treatment." *Id*.

Dr. Anand acknowledges the 1979 paper cited by Petitioner's expert as supporting the plausibility of an increased GBS risk up to ten weeks after vaccination. Ex. C at 9. However, that paper also found that the attributable risk of GBS post-vaccination declined beginning the fourth week after vaccination. *Id*. Further, more recent studies "suggest a narrower window of increased risk of up to 42 days, with the highest risk period during the 21 days following vaccination." *Id*. Dr. Anand concludes that the medical records, literature, clinical features, timing, and objective data in this case "do not support a diagnosis of GBS," and alternative etiologies such as stroke are more consistent with the time course and clinical features of Petitioner's symptoms. *Id*.

3. Stephen C. Jameson, Ph.D.

Respondent filed an expert report from Stephen C. Jameson, Ph.D., a Professor in the Center for Immunology, Masonic Cancer Center, and Department of Laboratory Medicine and Pathology at the University of Minnesota Medical School. Ex. E. He explains that, although Petitioner's negative antibody testing does not definitively rule out GBS, it does not support that diagnosis. *Id*. at 3.

Dr. Jameson explains that the time course of GBS aligns with a typical adaptive immune response by T and B lymphocytes. Ex. E at 2. Adaptive immune responses "take several days to become apparent, peak at 1-3 weeks after infection or vaccination, then gradually decline – kinetics that align with the typical progression of GBS, when an initiating cause is known." *Id*. He explains that GBS disease progression matches the typical adaptive immune response, peaking 1-2 weeks after onset, followed by a plateau for a few weeks and slow decline over months. *Id*. at 6. In Petitioner's case, "[t]hese kinetics were not evident . . . making it doubtful that these symptoms were caused by an immune response to the influenza vaccine that he received." *Id*.

Dr. Jameson notes that the onset of Petitioner's symptoms on November 25, 2017 occurred more than nine weeks after vaccination – well outside the 3-42 day range on the Table – and his symptoms rapidly progressed to a maximum over a span of a few hours. Ex. E at 6. Dr. Jameson is "unaware of a situation in which T and B cell responses to vaccines begin after a delay of more than 2 months." *Id*. Additionally, adaptive immune responses typically build in magnitude over several days or weeks, which is "inconsistent with such an acute onset and peak of symptoms" as that seen in Petitioner's case. *Id*. Thus, it is "difficult to envisage how the types of immune response that are associated with GBS can be aligned with the time course observed for Mr. Brouette's symptoms." *Id*. Dr. Jameson opines that "it is unlikely that Mr. Brouette developed GBS as a result of his influenza vaccination," explaining that "the late onset of Mr. Brouette's symptoms are inconsistent with the proposed link to his influenza vaccination." *Id*. at 7. He adds that "the characteristics and time course of Mr. Brouette's symptoms are difficult to reconcile with a typical progression of GBS at all." *Id*.

IV. Parties' Arguments

Respondent argues that the Petition, Petitioner's expert report, and multiple medical records state that his GBS symptoms began more than nine weeks after vaccination – far longer than the three to forty-two days required for a Table injury. Respondent's Report at *10 ("Resp.") (citing Pet. at 1, Ex. 4 at 199, 214; Ex. 5 at 5). Respondent adds that Petitioner "does not meet the Table criteria for any of the GBS subtypes." *Id*. at *10-11 Respondent explains:

> [P]etitioner did not have a nadir of weakness between twelve hours and twenty-eight days after onset; his symptoms were maximal at onset and he

> had a sudden presentation of dramatic central nervous system symptoms, including aphasia, facial weakness, and bilateral arm weakness. Ex. 4 at 199, 219. Second, petitioner's more likely alternative diagnosis is stroke. Petitioner had a longstanding history of vertebral artery steal syndrome and recent bilateral carotid endarterectomies due to complete occlusion, among co-morbidities that put him at a significantly increased risk for stroke. Ex. 3 at 19, 36; Ex. 4 at 199; Ex. 16 at 163-64. Petitioner initially presented to the ED with a NIHSS [National Institutes of Health Stroke Scale] of 10. Ex. 4 at 228, 230. His initial presentation also included a positive right Babinski, indicative of central nervous system dysfunction. *Id*. Brain MRI studies on November 26 and 27, 2017 showed that petitioner suffered a stroke. *Id*. at 468-69, 472. Additionally failing to support FS [Fisher Syndrome, a GBS subtype], petitioner did not have bilateral ophthalmoparesis, ataxia, an absence of limb weakness, or lack of alteration in consciousness.

Resp. at *11-12.

In addition, Respondent contends that Petitioner's EMG findings were not consistent with a GBS diagnosis. Resp. at *12 (citing Ex. 4 at 240-41). Petitioner did not undergo a lumbar puncture, and thus there are no findings of the protein level or white blood cell count in his cerebrospinal fluid that could support a GBS diagnosis. *Id*. Other testing did not indicate an autoimmune process, and GQ1b antibody testing was negative. *Id*. (citing Ex. 4 at 443, 451-55). Petitioner never reported neuropathic pain. *Id*. Thus, Respondent argues that, even setting aside the onset problem, Petitioner has not otherwise established a Table GBS claim. *Id*.

Respondent further asserts that Petitioner has not established that the flu vaccine actually caused his GBS. Resp. at *12-16. As a threshold matter, Respondent argues that Petitioner has not established the GBS diagnosis. *Id*. at *14. Furthermore, Petitioner has not provided evidence sufficient to meet his burden of proof under *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005). *Id*. Dr. Simpson merely invokes four potential mechanisms without substantive explanations, but does not apply these theories to the specifics of Petitioner's case or provide supporting medical literature. *Id*. Respondent argues that invocation of a general medical theory without more is not enough to satisfy Petitioner's burden. *Id*. (citing *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010)).

Respondent adds that Petitioner's expert "has not meaningfully evaluated and explained petitioner's stroke." Resp. at *15. Dr. Simpson states instead that Petitioner's treating providers concluded that GBS was the primary cause of Petitioner's symptoms (Ex. 5 at 5), but in Respondent's view this is not accurate, and in fact during Petitioner's hospitalization, his doctors "were divided as to whether petitioner initially presented with GBS before suffering a stroke." *Id*. at *15. Further, "neither petitioner's expert nor his

treating providers explained which symptoms or sequelae were attributed to petitioner's alleged GBS versus his known stroke." *Id*. And "none of petitioner's treating providers at Silver Cross Hospital attributed petitioner's presentation to his flu vaccination." *Id*. Only Dr. Patel, Petitioner's internist, referenced that Petitioner's GBS was "induced from flu vaccination," well after Petitioner's hospitalization and without a supporting rationale. *Id*. (citing Ex. 16 at 55). Additionally, viral or bacterial infection is a common cause of GBS, and Petitioner had a head cold with congestion and cough at the time of onset. Ex. 4 at 615. This infection was closer in time to Petitioner's alleged GBS onset than the flu vaccination, preponderating against Petitioner's claim. Resp. at *15.

Finally, Respondent argues that Petitioner "has not shown that nine weeks and four days is a medically reasonable temporal onset." Resp. at *16. Petitioner's lone support of a 1979 article (Ex. 5 at 5-6, citing Ex. 12) is insufficient to overcome the numerous cases stating that a GBS onset more than eight weeks after vaccination is not temporally reasonable. Resp. at *16. Thus, Respondent argues that Petitioner's causation in fact claim fails as well.

Petitioner acknowledges that the onset of his symptoms occurred 67 days after vaccination. Petitioner's Response to Order to Show Cause, filed June 25, 2024, at *5 (ECF No. 48) ("Pet."). However, he argues that Dr. Simpson's expert report "is sufficient to show that Mr. Brouette's onset of GBS occurred within a medically reasonable time period after his flu vaccination." Pet. at *4. He asserts that Dr. Simpson's opinion "should be enough," and that I should "see and accept that science and medicine show the Table dates are not sufficiently updated to reflect a more modern analysis such as that undertaken by Dr. Simpson." *Id*. at *5.

Petitioner adds that there is ample evidence that his symptoms were caused by GBS rather than the alternative cause of stroke offered by Respondent. Pet. at *2. Petitioner argues that his expert's opinion is supported by the conclusions of his treating physicians, noting that two of his neurologists found that GBS was most consistent with his clinical course and his likely primary diagnosis. *Id*. at *2-3. Although one of Petitioner's treating neurologists, Dr. Kazkaz, thought Petitioner's clinical picture was most consistent with a stroke, Dr. Kazkaz's involvement in Petitioner's care was limited to a neurology consult and second opinion just three days into Petitioner's hospitalization. *Id*. at *4. By contrast, Petitioner's other two neurologists, Dr. Nadkarni and Dr. Burgess, treated him throughout his admission and concluded that he most likely suffered GBS. *Id*.

V. Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on his claim if he has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth

in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). If a petitioner meets the requirements for a Table Injury, causation is presumed.

If, however, the vaccinee alleges an injury that either is not listed in the Table or did not occur within the prescribed time frame, the petitioner must prove by preponderant evidence that the vaccine actually caused the alleged injury. Section 11(c)(1)(C)(ii) and (iii); Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen*, 418 F.3d at 1279-80 (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)).

To establish an off-Table injury, a petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999) (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit later reiterated these requirements in *Althen*, explaining that a petitioner is required

> to show by preponderant evidence that the vaccination brought about her injury by providing: (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 a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278. All three prongs of *Althen* must be satisfied. *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). "Medical records, in general, warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). 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 "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.*

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 to the Table in 2017 for the flu vaccine, although this case does not meet the Table onset timeframe and thus is analyzed as an off-Table 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). And even onsets longer than six weeks are reasonably questioned, with special masters looking for something about a claimant's specific health that would make a slower onset medically acceptable.

Analysis

The record reflects – and Petitioner acknowledges – that onset of his symptoms occurred 67 days after vaccination. This facially does not meet the Table's 3-42 day timeframe. Thus, the matter in dispute is whether Petitioner has established that, more likely than not, his condition was caused by vaccination. I find that he has not, since symptoms beginning 67 days after vaccination is simply too late to be credibly associated with vaccination. Thus, Petitioner cannot demonstrate a "medically acceptable" temporal relationship between the vaccine and his condition, as required by the third *Althen* prong. *Althen*, 418 F.3d at 1278.

Typically, non-Table cases alleging onset of GBS more than six to eight weeks after receipt of any vaccine have been unsuccessful.[12] *See Chinea v. Sec'y of Health &*

[12] I recognize that other special masters have accepted timeframes that were slightly shorter. *See, e.g.*, *Cooper v. Sec'y of Health & Human Servs*., No. 18-1885V, 2024 WL 1522331, at *20 (Fed. Cl. Spec. Mstr. Mar. 12, 2024) (ruling the petitioner was entitled to compensation where the onset of symptoms occurred 60 days after vaccination). *Spayde v. Sec'y of Health & Human Servs*., No. 16-1499V, 2021 WL 686682 at *18-19 (Fed. Cl. Spec. Mstr. Jan. 27, 2021) (finding claimant entitled to compensation where symptoms

Human Servs., No. 15-095V, 2019 WL 1873322, at *29 (Fed. Cl. Spec. Mstr. Mar. 15, 2019) ("I am aware of no published Vaccine Program decisions that have found a timeframe longer than two months to be medically acceptable"), *mot. for rev. denied*, 144 Fed. Cl. 378 (2019); *see also Kindle v. Sec'y of Health & Human Servs*., No. 20-1423V, 2025 WL 603690, at *8 (Fed. Cl. Spec. Mstr. Jan. 21, 2025) (dismissing GBS claim where symptoms began 65 days after vaccination, stating that "a nine-week onset (coupled with symptoms that have not convincingly been demonstrated to be GBS-specific) is simply too remote from the date of vaccination to reasonably associate the two"), *mot. for rev. denied*, -- Fed. Cl. --, No. 20-1423V, 2025 WL 2251738 (July 17, 2025); *Ray v. Sec'y of Health & Human Servs*., No. 20-321V, 2021 WL 778435 (Fed. Cl. Spec. Mstr. Jan. 13, 2021) (dismissing Table GBS claim based on finding that onset of symptoms occurred over 70 days after vaccination).

Here, the record is devoid of evidence that Petitioner experienced any kind of post-vaccination reaction, or concerning symptoms within eight weeks of vaccination. Rather, he experienced his first possibly-neurologic symptoms *over nine* weeks after vaccination. To find on this record that such a timeframe is medically acceptable is to rely on a kind of *post hoc ergo propter hoc* reasoning that the Program rejects.

The onset insufficiencies in this case are compounded by the uncertainty as to whether Petitioner even suffered from GBS. And the record reflects that Petitioner had an upper respiratory infection soon before the onset of his symptoms, representing an alternative explanation for his condition – one occurring closer in time to onset than vaccination. *See Chinea*, 2019 WL 1873322, at *28 ("two-thirds of GBS cases follow an antecedent infection (typically an upper respiratory or gastrointestinal infection) beginning a few weeks prior to symptom onset"); *Rupert v. Sec'y of Health & Human Servs*., No. 10-160V, 2014 WL 785256 (Fed. Cl. Spec. Mstr. Feb. 3, 2014 (dismissing GBS claim because preponderant evidence established that claimant's GBS was caused not by vaccination but by an unrelated factor, an antecedent upper respiratory infection).

In support of his claim, Petitioner offers an expert report from Dr. Simpson. However, Dr. Simpson posits that Petitioner's symptoms began *within* nine weeks of vaccination – while the record reflects that his first symptoms occurred *over* nine weeks after vaccination – nine weeks and four days. With the onset of Petitioner's symptoms *already* at the outside edge of the single study Dr. Simpson relies on to support his opinion, this factual discrepancy takes on significance, and somewhat undermines Dr. Simpson's analysis.

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began between 49 and 60 days after vaccination). But these cases involve other factual differences, and are not binding precedent in any event. By contrast, a decision dismissing a GBS claim asserting an onset of 65 days after vaccination was recently upheld. *Kindle v. Sec'y of Health & Human Servs.,* No. 20-1423V, 2025 WL 603690, at *8 (Fed. Cl. Spec. Mstr. Jan. 21, 2025), *mot. for rev. denied,* -- Fed. Cl. --, No. 20-1423V, 2025 WL 2251738 (July 17, 2025).

Furthermore, Dr. Simpson ignores an alternative explanation for Petitioner's GBS, a recent upper respiratory infection – a known potential GBS trigger. And though Dr. Simpson's report suggests that Petitioner's treating physicians were in agreement that his primary condition was GBS, I find the record less clear on that matter.

Taking all of these concerns into account, I find that Petitioner has not demonstrated by preponderant evidence that he suffered GBS caused by his flu vaccination.

Conclusion

Petitioner has failed to preponderantly establish that his condition meets the requirements for a Table GBS or off Table claim. Accordingly, this case is DISMISSED for insufficient evidence. The Clerk of Court shall enter judgment accordingly.[13]

IT IS SO ORDERED.

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

[13] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.