

**In the United States Court of Federal Claims**  
**OFFICE OF SPECIAL MASTERS**  
**No. 19-1913V**

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AUDREY CLAPP,

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Filed: October 27, 2023

Petitioner,

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v.

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SECRETARY OF HEALTH AND

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HUMAN SERVICES,

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Respondent.

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

*Jennifer Shah*, U.S. Department of Justice, Washington, DC, for Respondent.

**ENTITLEMENT DECISION**<sup>1</sup>

On December 18, 2019, Audrey Clapp filed a petition seeking compensation under the National Vaccine Injury Compensation Program (“Vaccine Program”).<sup>2</sup> Petitioner alleges she developed Guillain-Barré syndrome (“GBS”) due to receipt of an influenza (“flu”) vaccine on December 3, 2017. Petition (ECF No. 1) at 1. The matter was originally assigned to the Special Processing Unit (“SPU”), but it was determined that certain fact disputes did not render the claim appropriate for expedited determination, and I transferred the matter to my docket for resolution.

An entitlement hearing was held on January 19, 2023. Now, after review of the medical records, trial testimony, and briefs, I deny entitlement.

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<sup>1</sup> Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

<sup>2</sup> The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) (“Vaccine Act” or “the Act”). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

## I. Factual Background

### *Pre-Vaccination Health Issues*

Petitioner Audrey Clapp was 60 years old when she received the flu vaccine at issue in 2017. Ex. 1 at 135. Her pre-vaccination medical history included type II diabetes mellitus, diagnosed in 1982. Ex. 4 at 2. She also suffered from muscle pain and swelling, irritable bowel syndrome, high blood pressure, high cholesterol, and depression. *Id.*

Ms. Clapp's diabetes and other issues sometimes went untreated, often due to financial difficulties. For example, during a 2015 hospitalization, she reported not having taken her insulin for over a year. Ex. 3 at 640; *see also* Ex. 4 at 32 (not taking cholesterol or hypertension medications), 26 (not taking Gabapentin for several months for financial reasons), and 52 (provider noting Petitioner had "been very noncompliant with all medications"). As a result, her diabetes was sometimes characterized by providers as uncontrolled. *See* Ex. 3 at 641. And her A1C levels<sup>3</sup> were measured to be abnormally high at many treatment visits. *See* Ex. 4 at 207 (A1C of 13.7 in April 2017), *Id.* at 205 (A1C of 12.6 in November 2016).

Petitioner had other periodic medical episodes in the years before her vaccination, often involving neuropathic symptoms. In September 2015, for example, she exhibited "patchy" loss of sensation in both legs during a hospital admission. Ex. 3 at 640. In May 2016, she went to an emergency room for pain and burning in her right leg. *Id.* at 584, 591. In November 2016, she reported to a primary care physician that she had a "needle sensation" in her arms and legs. Ex. 4 at 26. In March 2017, she reported "crawling and painful sensations in [her] hands and feet. *Id.* at 32. In April 2017, she reported tingling sensations and sharp pain all over her body, that felt like she was being "shot at." *Id.* at 39. And she presented with similar complaints in July 2017. *See Id.* at 46. By that point she had stopped working due to being unable to stand for hours at a time. *Id.*

Petitioner also frequently sought treatment for mental health concerns. In July 2017, she was seen for anxiety, depression, and insomnia. Ex. 4 at 46. Similar concerns were reported at an October 2017 treater visit. *Id.* at 55. Petitioner remained on anxiety medication due to her mental issues. *Id.* And in November 2017, Ms. Clapp was seen for anxiety, depression, and suicidal thoughts. Ex. 4 at 60. The treater who saw her was concerned enough to make an immediate referral to a behavioral health clinic, in order to personally ensure that Petitioner would obtain

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<sup>3</sup> A1C is "a measurement of glycated haemoglobin as a surrogate for average daily glucose levels." Eva Feldman et al., *Diabetic Neuropathy*, 5 Nat Rev Dis Primers 42 (2019), filed as Ex. C, Tab 1 (ECF No. 43).

relevant medical care that same day. *Id.* at 64. She expressed the willingness to try an alternative antidepressant, which she was then prescribed. Ex. 4 at 60 and 64.

#### *Context of December 2017 Vaccination*

On December 3, 2017, Petitioner received a flu vaccine in her left deltoid while hospitalized at Roane Medical Center in Harriman, TN. Ex. 1 at 135. She had been admitted to the hospital the day before, after blacking out and falling on a set of stairs while carrying a cup of hot tea, sustaining burns. *Id.* at 22. Petitioner reported that she was not sure why she had blacked out, and had not experienced symptoms such as chest pain, palpitations, or shortness of breath before the incident. *Id.* at 45. However, she did note that she had been having worsening difficulty with ambulation and balance over time, and often needed to hold onto something to steady herself. *Id.* She also reported several falls in the preceding weeks. *Id.* A brain MRI showed fronto-parietal atrophy and microvascular changes. *Id.* at 4.

Later in the morning after receiving the vaccine, Petitioner complained of dizziness, weakness, and pain during a physical therapy evaluation. Ex. 1 at 181. The therapist noted that Petitioner displayed substantial deficits in strength in her lower bilateral extremities. *Id.*; *see also* Tr. at 126–27. She required a walker for her ataxic gait. *Id.* at 180–81. Petitioner was discharged the next day. Her discharge summary included diagnoses of syncope, hypertension, diabetes, burns, and lower lumbar and tailbone pain as a result of her fall. Ex. 1 at 4. Her provider stated that no further workup was necessary, but she would need to see a neurologist for evaluation if she had more syncopal episodes. *Id.* at 5.

About three weeks later, during the week of Christmas 2017, Petitioner (in her affidavit) reports having experienced numbness, weakness, and tingling in her lower extremities. Ex. 2 at 3. She had difficulty walking and required a cane to support herself. *Id.* She did not at this time seek medical assistance, however. *Id.*

#### *Onset of Neurologic Symptoms in Winter 2018*

Petitioner was admitted to the University of Tennessee Medical Center (“UTMC”) in Knoxville, TN on January 22, 2018. She presented with complaints of weakness, tremors, and difficulty walking. Ex. 3 at 2418. She specifically reported to an internist that she had experienced progressively worsening symptoms over the past three weeks (meaning they began at the start of that new year). *Id.* at 2429. The internist noted upon examination that she displayed “decreased sensation to various extremities, however has fairly severe neuropathy at baseline [.]” *Id.* His assessment expressed “some concern for possible neuromuscular disorder.” *Id.* at 2430. Petitioner did not at this time mention her December 2017 hospitalization to the UTMC treaters, however, or inform them of the neurologic-like symptoms the record reveals she had been experiencing prior

to January.

Petitioner was evaluated by a neurologist at the time of her admission. This examination showed bilateral leg weakness, shaking, and poor balance, and deficient knee and ankle reflexes. Ex. 3 at 2469. The neurologist concluded that Petitioner likely had an essential tremor, with no signs of Parkinson’s or myelopathy, and ordered a lumbar puncture to rule out GBS. *Id.* The results of the lumbar puncture showed elevated protein in the cerebrospinal fluid, a concern for GBS. *Id.* at 2468. Petitioner was subsequently treated with a five-day course of intravenous immunoglobulin (IVIG), which improved her condition but did not fully resolve her symptoms. *Id.* at 2432–33. She continued to experience substantial weakness and gait disturbance, but refused a skilled nursing placement. *Id.* at 140. She was discharged on January 30, 2018. *Id.* at 2432–33.

Petitioner thereafter saw multiple providers for worsening tremors, sleep disturbance, and other symptoms. Ex. 4 at 74–80. One noted that Petitioner displayed “tremor in hands, mouth, and head that were attributed to Guillain Barre due to flu shot, but only by elimination of Parkinson’s and other causes.” *Id.* at 87. This provider also noted that Ms. Clapp’s tremor worsened in association with her increased dose of the new antidepressant medication, and discontinued it for this reason. *Id.* at 87, 91.

#### *Further Medical Treatment in 2018*

Two months later, Petitioner was again admitted to UTMC on March 13, 2018. She now reported weakness, nerve pain, shaking, gait instability, and falling, plus nerve pain running up the right side of her body to her head. Ex. 3 at 2096, 2104, 2107. She displayed slurred speech, and exams showed greater weakness on the right side than the left, with decreased sensation to touch in the extremities. *Id.* at 2097, 2132. Although notes from this treatment encounter record “acute worsening of Guillain-Barre symptoms,” the relevant treater also speculated that Petitioner might “actually have a chronic inflammatory demyelinating polyneuropathy (CIDP) as opposed to an AIDP/Guillian-Barre syndrome.” *Id.* at 2132. Petitioner received a three-day course of IVIG, which again improved her symptoms. *Id.* at 2110.

Petitioner continued to seek treatment for tremors, falling, pain, tingling, and weakness for the remainder of 2018—although her ongoing symptoms proved inconsistent with GBS or any comparable neuropathy. For example, on September 27, 2018, she visited a neurologist’s office for worsening of the same symptoms, but was observed to display “variable effort to strength testing” and “giveway weakness.”<sup>4</sup> Ex. 5 at 11, 12. The neurologist also noted a “stocking” pattern

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<sup>4</sup> The term “giveway weakness” was explained at trial in connection with a discussion of psychiatric issues relating to neuromuscular disorders during his testimony. Respondent’s expert defined “functional weakness” to mean “that the arms and legs and the nervous system apparatus is intact but the patient is not doing it, usually implied for psychiatric reasons.” Giveway weakness, “in the context of testing strength could sometimes be seen with pain, but usually when it’s described that way, it means the patient gives a decent effort when you first test their strength but

of sensory loss, which is characteristic of diabetic neuropathy. *Id.*, Tr. At 48, 62. In addition, in connection with this visit her treaters ordered an electromyography (“EMG”) test to check for the presence of demyelinating disease. *Id.* at 12–13. The results indicated severe polyneuropathy, absence of the lower extremity sensory nerve action potentials, and severe asymmetric axonal motor changes, but no indication of lumbosacral plexopathy, myopathy, or radiculopathy. *Id.* at 15–16. In evaluating these results, the provider opined that “the polyneuropathy changes present cannot be differentiated from those that would be present with Guillain-Barre syndrome versus diabetes.” *Id.* at 16.

The following month, Petitioner had back surgery at UTMC to remove and replace L4-5 hardware that had been previously implanted. Ex. 3 at 1547. Two days after discharge, Petitioner presented to the UTMC emergency department, complaining of one week of generalized weakness and fatigue, headache, shaking all over, and occasional slurred speech, adding that symptoms worsened with movement. *Id.* at 1540–41. Emergency room physician Dr. Rawad Massouh examined Petitioner, noting that her history included “suspected” GBS, but that after her March 2018 re-admission her ongoing symptoms had begun to be viewed as more likely reflecting CIDP. *Id.* at 1542. She demonstrated normal strength and reflexes, and tremulousness with movement upon physical examination, and Dr. Massouh’s impression was “CIDP flare up.” *Id.* at 1541–42.

On October 9, 2018, Dr. Li Hua performed a neurology consult. Ex. 3 at 1566. Dr. Hua noted that Petitioner had a reported history of AIDP and had undergone a recent, but inconclusive, EMG that could be consistent with diabetic neuropathy. *Id.* An exam revealed mild weakness in the legs, decreased sensation in the legs, and trace to absent reflexes. *Id.* at 1567. An MRI/MRA (magnetic resonance angiogram) was negative other than non-acute ischemic changes. *Id.* The impression was near syncope or side-effects from pain medication, or less likely a transient ischemic attack or mini-stroke. *Id.* Dr. Hua concluded that Petitioner’s symptoms were “not likely due to recent [GBS].,” and recommended no further workup. *Id.*

Petitioner was again admitted to UTMC on December 22, 2018, after fainting while washing dishes and waking up on the floor. Ex. 3 at 1276. She reported worsening tremors and progressive weakness to providers, plus diarrhea, nausea, and a stomach “bug,” resulting in decreased oral intake. *Id.* When examined, Petitioner displayed diminished reflexes and decreased sensation on her right side, but 4/5 strength in her extremities. *Id.* at 1279. Her doctor concluded that her recent illness and dehydration was the cause of her episode. *Id.* She also underwent a neurologic evaluation at this time. *Id.* at 1290. That treater concluded that Petitioner suffered from “mixed sensorimotor polyneuropathy and autonomic neuropathy is possible,” but did not recommend treatment beyond rehydration and treatment of a UTI. *Id.*

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then will have a sudden collapse in effort. This is not what happens with an organic disorder of nerve and muscle where the effort output is more consistent. And if there’s fatigue, it would be a much more gradual, continuous process and not a sudden giving way.” Tr. at 122–123.

### *Medical Concerns in 2019 and Beyond*

Petitioner had several recurrences of symptoms over the next two years, with some hospital admissions. *See, e.g.*, Ex. 32 at 829 (admission to UTMC on September 19, 2019). She exhibited periodic episodes of increased tremors and weakness, among other symptoms. *See* Ex. 20 at 20 (March 2019 appointment at UTMC for ongoing tremors and “burning and tingling in hands and feet”), *Id.* at 8 (March 2020 appointment at UTMC for worsening neuropathy, balance, and tremors), *Id.* at 4 (September 2020 appointment at UTMC reporting difficulty with daily activities due to tremor). Providers have noted her previous GBS diagnosis along with her history of diabetic neuropathy. *See* Ex. 20 at 9 (March 2020 visit recording history of diabetic neuropathy) *Id.* at 12 (March 2019 visit recording history of diabetic peripheral neuropathy), *Id.* at 4 (September 2020 visit recording history of diabetic neuropathy) Ex. 38 at 901 (September 2020 neurology consultation noting prior GBS diagnosis). But it is evident in the record (from treater discussions of Petitioner’s overall history) that GBS, or something like it, may not *continue* to constitute an accurate assessment of her illness. As one neurologist stated in September 2020, “[i]t is difficult to sustain an additional diagnosis of Guillain-Barre in this patient with longstanding history of diabetes and cervical [lumbar] radiculopathy.” *Id.*

## **II. Expert Testimony**

### *A. Petitioner’s Expert – Justin Willer, M.D.*

Dr. Willer prepared two expert reports for this matter, and testified for the Petitioner. He opined that the flu vaccine had caused Petitioner to experience GBS. *See generally* Report, dated Mar. 7, 2022 (ECF No. 34-1) (“Willer First Rep.”); Report, dated July 26, 2022 (ECF No. 40-1) (“Willer Second Rep.”).

Dr. Willer received his undergraduate degree from Columbia College of Columbia University and his medical degree from the University of Health Sciences/The Chicago Medical School. Curriculum Vitae, filed March 7, 2022 (ECF No. 34-2) (“Willer CV”) at 1. Beginning in 1995, he has held hospital appointments at University Hospital, Long Island College Hospital, Maimonides Hospital Medical Center, and Kings County Medical Center, but he has not treated pediatric patients since 2000. *Id.* He has also held academic appointments as a Neuromuscular Consultant and Assistant Professor of Clinical Neurology at the State University of New York, HSC at Brooklyn. *Id.* He is licensed to practice medicine in New York, New Jersey, and Florida, and is board certified by the American Board of Psychiatry and Neurology, with added qualifications in clinical neurophysiology, and the American Board of Electrodiagnostic Medicine. *Id.*

Dr. Willer did not deem Petitioner’s pre-vaccination health issues to be related to what came later. He acknowledged that she had lower back issues, and confirmed when questioned that

she had been properly diagnosed with diabetes. Tr. at 15. He also took note of her previous December 2017 hospitalization after passing out on the stairs, but stated that though she had been diagnosed with syncope at the time, “there’s really no way of knowing exactly what happened because there was no witness,” and therefore that the nature of this incident could not be accurately linked to Petitioner’s subsequent issues *Id.* at 16. Without a witness, the description of the episode from the patient herself was likely to be “extremely inaccurate.” *Id.*

Otherwise, Dr. Willer opined, Petitioner’s hospital records in connection with the December falling accident revealed no symptoms or signs indicative of the onset of GBS. Tr. at 16. He did not deem this event to be caused by syncope. *Id.* at 40. An MRI performed shortly after the episode showed that Petitioner had likely experienced two cerebellar strokes at some point, which Dr. Willer pointed to as the better explanation. *Id.* And he characterized notes stating that she had displayed on exam “4 out of 5 strength symmetric in the upper and lower extremities” during her December 2<sup>nd</sup> hospital admission as “bogus” to a “reasonable medical certainty.” *Id.* at 69–70. This strength rating, Dr. Willer maintained, was only “what the examiner thought she had, which was most likely artifactual,” and was not reflective of “real quadriparesis.” *Id.*

Dr. Willer overall accepted the Petitioner’s GBS diagnosis. He deemed it to have ample evidentiary support, pointing to Petitioner’s episodes of progressive weakness, loss of reflexes, response to IVIG, and lingering symptoms of ataxia, dysesthesias, and tremor. Tr. at 10. Her onset, he opined, began during the week of Christmas 2017, when she experienced numbness, progressive weakness (which admissions records reflected), and tingling in her lower legs. *Id.* at 17. Her worsening back pain and lower extremity weakness were also consistent with the onset of GBS, which can present with either ascending paralysis starting in the legs, or descending paralysis starting in the arms. *Id.* at 19; M. Dimachkie et al., *Acquired Immune Demyelinating Neuropathies*, 20 *Continuum: Lifelong Learning and Neurology* 1241, 1260 (2014), filed as Ex. P44(a), (ECF No. 34-3) (“Dimachkie”).

Petitioner’s subsequent symptoms, as experienced during the January 2018 hospitalization, were in Dr. Willer’s view also consistent with GBS—but not with diabetic neuropathy. First, Petitioner displayed diminished reflexes upon initial examination which later became areflexic. Tr. at 20. This would be “diagnostic of Guillain-Barré syndrome as that’s the only thing that would produce a sudden areflexia,” whereas diabetic neuropathy would more likely feature consistently diminished but present reflexes. *Id.* Second, the improvement in her reflexes following administration of IVIG “pretty much establishes that it has to be [GBS].” *Id.* at 21. In fact, Dr. Willer proposed, IVIG would have “no effect” for treatment of a diabetic neuropathy. *Id.* at 22.<sup>5</sup>

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<sup>5</sup> Later, Dr. Willer denied that IVIG has a substantial placebo effect, and dismissed studies that suggest this could be the case. Tr. at 58. He emphasized his overall view that GBS would not be consistently treated with IVIG if its effect was “mostly placebo.” *Id.*

Her eight-day hospitalization, he added, was “a little quick, but not out of the range” for someone with GBS. *Id.* at 23.

Dr. Willer admitted that the history that Petitioner gave to providers during this January 2018 hospital admission omitted significant facts about the episodes of weakness, balance difficulties, dizziness, and mental health issues she had experienced in the month prior. Tr. at 85–86. But he opined that this was the fault of her providers for not thoroughly questioning the Petitioner about her medical history. *Id.* at 87. At the same time, Dr. Willer acknowledged that episodes both before and after Petitioner’s vaccination seemed to reflect similar complaints, and struggled to demonstrate how this was not the case. *Id.* at 95 (disputing use of the word “similar” in characterizing the two sets of reported symptoms from December 2017 and January 2018).

Dr. Willer also deemed Petitioner’s later symptoms in 2018 to reflect ongoing, GBS-associated sequelae. He characterized her March 2018 hospitalization as the product of “Guillain-Barré syndrome TRF, or treatment-related fluctuation.” Tr. at 26. This, Dr. Willer maintained, typically takes place within eight weeks of the first GBS “attack,” which was in fact around the time this second round of symptoms began. *Id.*; L. Ruts et al., *Distinguishing Acute-Onset CIDP from Fluctuating Guillain-Barre Syndrome, A Prospective Study*, 74 *Neurology* 1680, 1686 (2010) filed as Ex. P44(j), (ECF No. 35-2). A GBS TRF can be hard to differentiate from acute onset CIDP. *Id.* Because the Petitioner had experienced a sudden deterioration in strength and walking ability over three to four days, and had already been diagnosed with GBS, Dr. Willer concluded that this was another GBS incident rather than evidence that something else explained her presentation. *Id.* at 28. Additionally, he considered Petitioner’s response to IVIG administered at this time to confirm the earlier GBS diagnosis. She again was responding favorably to the treatment, and therefore again corroborated the diagnosis’s accuracy. *Id.* at 29. Dr. Willer admitted that some of the numbness in her legs could also have been due to diabetic neuropathy, but that did not wholly account for her presentation and ongoing symptoms. *Id.* at 29–30.

More evidence of GBS sequelae, Dr. Willer maintained, could be seen in the records of medical treatment received by Petitioner between May and September 2018, since she continued in this timeframe to experience weakness, numbness, and some ambulatory issues. Tr. at 30. At worst, these symptoms could reflect a combination of Petitioner’s diabetes and the post-vaccination GBS she had experienced. *Id.* at 31. A patient’s recovery time from GBS can depend on a number of factors, including their health at onset and how much intensive physical therapy they undergo in treatment. *Id.* at 32. Petitioner’s diabetes might actually have exacerbated her GBS symptoms, including worse spinal arthritis, compressive neuropathy, and small fiber neuropathy. *Id.* at 42. Dr. Willer did, however, seem to concede that prior poor management of Petitioner’s diabetes (which medical science had suggested demands prompt action in controlling blood sugar

levels, before the harm they cause sets in and becomes irreversible) could have created circumstances that could not later be reversed by further blood sugar level reductions. *Id.*<sup>6</sup>

Dr. Willer challenged the view of Respondent’s expert, Dr. Lancaster, that there was an overarching similarity between Petitioner’s pre- and post-vaccination status. He particularly took issue with the argument that many of Petitioner’s reported symptoms might reflect a conversion disorder-style psychologic issue. Tr. at 39. In fact, Petitioner’s very GBS could *itself* be responsible for psychological issues, rather than vice-versa. *Id.* He also denied that variable efforts Petitioner displayed during some exams undermined her GBS diagnosis (even if they might suggest the existence of conversion disorder). *Id.* at 33–34 (“[w]hen someone is not giving a complete effort, you can’t really tell how weak they might be”); J Stone et al., *Function Weakness and Sensory Disturbance*, 73 J. Neurology Neurosurg. Psychiatry 241, 245 (2002) filed as Ex. P44(m) (ECF No. 35-5).

Nevertheless, Dr. Willer agreed that conversion disorder could be the result of several psychological risk factors, including anxiety, depression, stress, and PTSD—and Petitioner’s medical history revealed she possessed these risk factors pre-vaccination. Tr. at 39, 58–59, 62–67; Voon et al., *Emotional Stimuli and Motor Conversion Disorder*, 133 Brain 1526, 1536 (2010) filed as Ex. P44(k), (ECF No. 35-3). He also agreed that symptoms of conversion disorder may include weakness, gait disturbances, tremor, dizziness, stuttering, and events resembling seizures, stroke, and syncope—all of which Petitioner had displayed at various times. Tr. at 60, 67–70. And he did not dispute that many of Petitioner’s recurrent complaints, from the second half of 2018 onward, could not be considered GBS-related. *Id.* at 90–91.

Dr. Willer concluded by opining that Petitioner’s GBS onset occurred in the required 42-day window for a Table claim. She had experienced onset, he maintained, around three to four weeks after her December 3, 2017 vaccination. Tr. at 44. And he denied the record revealed any alternative explanation for her injury. *Id.*

B. *Respondent’s Expert – Eric Lancaster, M.D.*

Dr. Lancaster prepared two expert reports for this matter, and testified for Respondent. *See* Report, dated May 31, 2022, filed as Ex. A-B (ECF No. 36-1) (“Lancaster First Rep.”); Report, dated Dec. 1, 2022, filed as Ex. C, Tab 1 (ECF No. 43-2) (“Lancaster Second Rep.”). Dr. Lancaster disagreed with Dr. Willer’s conclusion that Petitioner developed GBS after receiving the flu vaccine. Tr. at 105. Rather, he opined that the record presented numerous more likely diagnoses,

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<sup>6</sup> Dr. Willer also disputed the proper conclusions to be drawn from the EMG testing Petitioner received in September 2018, maintaining variously that it could both confirm a radiculopathy but also might not detect one. Tr. at 37.

such as diabetes, symptoms attributable to mental health issues, and/or cervical and lumbar radiculopathy. *Id.*

Dr. Lancaster received his medical and doctorate degree from the University of Maryland School of Medicine. Curriculum Vitae, filed as Ex. B (ECF No. 36-2) (“Lancaster CV”) at 1. Thereafter, he completed his internship, neurology residency, neuromuscular fellowship, and neuromuscular research fellowship at the University of Pennsylvania. *Id.* Since 2013, he has been an Assistant Professor of Neurology at the University of Pennsylvania. *Id.* Dr. Lancaster is board certified in neurology, neuromuscular medicine, and electrodiagnostic medicine. *Id.* He has written over 30 peer-reviewed publications, with most of his recent publications focusing on autoimmune neurological disorders and their mechanisms. *Id.*

GBS, Dr. Lancaster explained, has a number of characteristic features. Tr. at 130. Most cases of GBS will reach their symptoms nadir within four weeks of onset, and although there is a “gray area” between four and six weeks, “many of the diagnostic criteria sort of frown on or don’t allow beyond four weeks.” *Id.* at 133. Weakness caused by GBS should be “consistently reproducible” at any physical exam, although the degree of weakness can change over the course of hours or days with a “very rapid progressive course.” Tr. at 131. Recovery after onset should not be especially rapid, he added, so that “if someone is acutely very weak on day 1 and they are back to normal on day 2 or day 3 or even day 5, I would very much question whether or not Guillain-Barre Syndrome could be the answer.” *Id.* Dr. Lancaster also denied that tremor was a common GBS symptom or feature, deeming it a “distinctly unusual way for GBS to present,” and thus a factor that would weigh “somewhat against [GBS] being the correct diagnosis.” Tr. at 133.

Petitioner’s overall history was not, in Dr. Lancaster’s reading, supportive of a GBS diagnosis. Tr. at 143. Ample pre-vaccination records (as outlined above) revealed issues that seemed likely connected to her post-vaccination health. *Id.* at 148. Complaints of weakness, gait instability, and tremors were consistent in both doctor’s appointments and evaluations during hospital admissions pre and post-vaccination. *Id.* at 147. Although there was some variation, “...these were some of the recurrent themes that occurred in all of these events.” *Id.* Thus, Dr. Lancaster generally concluded that “all of this was present before she was vaccinated, and it kept going after she was vaccinated.” *Id.* at 148.

Specific occurrences in Petitioner’s treatment history were, Dr. Lancaster maintained, supportive of his conclusion. In December 2017, for example, Petitioner had displayed increasing difficulty with balance and standing. Tr. at 106. She began to have distinct episodes in which she experienced tremors and significant muscle weakness, which would come on rapidly and then quickly return to baseline. *Id.* at 107–08. This history, however, was not later shared with Petitioner’s treaters in January 2018 (calling into question the validity of a GBS diagnosis that did not take such factors into account). *Id.* at 140–141. Indeed, the timeline this information would

have established was “simply too long” to be consistent with GBS. *Id.* at 141. Ultimately, Petitioner’s doctors were “lacking important information about what happened to the patient before.” *Id.* at 140.

Then there was Petitioner’s December 2017 hospitalization (at which time she actually received the vaccination at issue). Besides not reflecting GBS (as discussed above), Dr. Lancaster also disputed the contention that Petitioner’s December 2nd admission to UTMC was caused by a stroke. *Tr.* at 129. He pointed out that the brain MRI performed at that time explicitly found no evidence of an acute stroke, despite its value as “very good sensitive test” to confirm stroke. *Id.* This, coupled with the months of progressive symptoms Petitioner experienced leading up to the admission suggested “to a high degree of certainty” that a stroke was not the cause of her December 2017 hospitalization. *Id.* Dr. Willer, Dr. Lancaster proposed, had unsuccessfully distinguished this event as unrelated in Petitioner’s overall health course.

Dr. Lancaster then discussed Petitioner’s doctor’s visits and hospital admissions from January 2018 onward, concluding that they were not supportive of a GBS diagnosis either. He reiterated his observation of evidence of symptoms “attacks” both before and after vaccination. This medical history information (which Petitioner failed to provide to treaters in the context of her January 2018 hospitalization) was particularly inconsistent with the acute timeframe in which GBS was known to progress, with Dr. Lancaster arguing that “if they were aware of the two months of symptoms preceding her [earlier] hospitalization [on] December 2, 2017, her doctors might well have come to a different conclusion about what was happening.” *Tr.* at 134. However, Dr. Lancaster admitted that based on what treaters knew or observed from her January 2018 presentation, GBS was reasonably included in the diagnostic differential, even if in retrospect he considered it incorrect based on a more comprehensive and holistic understanding of Petitioner’s history. *Id.* at 161, 164.

In addition, Petitioner’s exam results varied—for example, resulting in different reflex level observations—in a manner consistent with GBS. *Tr.* at 142. And the findings of elevated CSF proteins (which Dr. Lancaster accepted as accurate) had less diagnostic significance when dealing with a patient with a history of diabetes, like Ms. Clapp. *Id.* at 134, 143. Although an elevated CSF protein is an indicator of GBS, a patient with diabetes may have elevated CSF protein at any given time, diminishing the diagnostic value of the finding. *Id.* at 135.

More evidence that the GBS diagnosis was erroneous could be seen from Petitioner’s subsequent treatment history. During her March 13<sup>th</sup> admission to UTMC, for example, Petitioner presented with tremors, diffuse pain, inability to function and stuttering, while her reflexes were “less than average but not necessarily pathological.” *Tr.* at 145. This, Dr. Lancaster maintained, would “not be at all what you would expect from someone with active Guillain-Barré leading them to return to the hospital.” *Id.* He also pointed out notes indicating a functional overlay, which he

interpreted as a suspicion of conversion disorder. *Id.* at 146. Petitioner’s stuttering was likely of particular concern for conversion disorder, as “the speech and stuttering issue would not be part of Guillain-Barré in this context.” *Id.*

Dr Lancaster also did not find Petitioner’s improvement after treatment with IVIG to corroborate the GBS diagnosis. He did not take issue with why treaters might utilize IVIG, given the need to “err on the side of acting in the patient’s best interest,” and agreed overall that IVIG is an effective GBS treatment. Tr. at 146; *see also Id.* at 135. However, in Dr. Lancaster’s understanding IVIG can also have a placebo effect. *Id.* at 136. In studies of CIDP treatment with which he had familiarity (but have not been filed in this case), patients treated with IVIG for an extended period of time who believe they are dependent on the drug for good health are sometimes switched over to a new brand of IVIG, with a portion of patients given a placebo instead, and “...a surprising number of the placebo patients do not have any worsening.” *Id.* at 136.

In fact, Dr. Lancaster noted, patients may be started on IVIG treatments *before* doctors have fully confirmed GBS to be the proper diagnostic explanation for a patient’s condition. Tr. at 137. Because IVIG must be given to GBS patients soon after the condition is suspected for them to benefit, and has a low risk of side effects, doctors may opt to start such treatments right away—and Dr. Lancaster was aware of “multiple cases” where patients that are initially suspected to have GBS are later diagnosed with other conditions such as vitamin deficiency neuropathies, paraneoplastic cancer disorders, or chronic autoimmune neuropathies such as CIDP. *Id.* at 137–38. Petitioner also improved rapidly at different points with and without IVIG treatment, further undermining the conclusion that the treatment’s efficacy supported the GBS diagnosis. *Id.* at 144.

Dr. Lancaster interpreted Petitioner’s overall record to support an alternative diagnosis: diabetic neuropathy. In fact, he opined, “[i]t would actually be a bit surprising for a woman her age who has had diabetes since the 1980’s and who has poorly controlled diabetes to not have neuropathy.” Tr. at 112. Diabetic neuropathy generally presents with numbness, pain, burning, and abnormal sensations that start in the feet. *Id.* at 111. From there, the loss of sensation progresses—“So it appears as if something is coming up the toes, up the foot, up the ankle, up the legs and then eventually the fingertips, the thighs, moving up the hands.” *Id.* at 112. Diabetic neuropathy is generally a clinical diagnosis, and thus does not require an EMG for confirmation. *Id.* at 113. *See also* Eva Feldman et al., *Diabetic Neuropathy*, 5 Nat Rev Dis Primers 42 (2019) filed as Ex. C, Tab 1 (ECF No. 43)

The foot pain that Petitioner initially described to treaters would be a common indicator for a diabetic neuropathy. Tr. at 112. If Petitioner’s symptoms had been caused by lumbar spine issues, by contrast, she would have presented with “lightning bolt-type pains out of the back” rather than pain starting in the feet. *Id.* But diabetic neuropathy could also be difficult to distinguish from GBS. In a patient with no nervous system issues at baseline, weakness and loss of reflexes

could be a sign of GBS. *Id.* at 114. However, in a patient with existing neuropathy due to diabetes, it would be harder to separate, meaning “you would need to have more convincing other forms of evidence to be sure.” *Id.* at 115.

Another possible explanation for at least some of Petitioner’s symptoms, Dr. Lancaster maintained, would be conversion disorder (brought on by her preexisting anxiety and other mental health issues), in which symptoms mimic GBS but have a psychological origin. Tr. at 109. In so arguing, Dr. Lancaster pointed to Petitioner’s pre-vaccination treatment visit on November 22, 2017, at which time she reported worsening depression and anxiety, suicidal thoughts, and shaking. *Id.* at 117. He emphasized that the “warm handoff” for immediate mental health care that the treater carried out at that time revealed the extent to which Petitioner’s presentation was deemed urgent. *Id.* at 118. In addition, “she was found to have a tremor that eventually was thought by her treating neurology team to be functional, could be a manifestation of conversion disorder.” *Id.* at 119.<sup>7</sup>

### III. Procedural History

This matter was initially assigned to SPU. (ECF No. 1). Respondent then filed the Rule 4(c) Report on September 22, 2021. (ECF No. 32). The matter was transferred out of SPU to my docket that same month. Notice, dated Sept. 23, 2021. After the filing of the previously-discussed expert reports, I scheduled the matter for hearing in January 2023. With post-hearing briefs filed in April 2023, the matter is now ripe for adjudication.

### IV. Applicable Legal Standards

#### A. *Petitioner’s Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); see also *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).<sup>8</sup>

<sup>7</sup> Dr. Lancaster also speculated that Petitioner’s mental health might have been impacted by the stress of losing her job, and moving from an independent living situation to a living situation with a friend that was less than ideal. *Id.* at 110.

<sup>8</sup> Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec’y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d* 104 F. App’x. 712 (Fed. Cir. 2004); see also *Spooner v. Sec’y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at \*7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

In this case, Petitioner does not formally assert a Table claim (although as discussed below the claim is best analyzed in that manner).

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec’y of Health and Hum. 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.”

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden

placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory’s scientific or medical *plausibility*. See *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec’y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (“[h]owever, in the past we have made clear that simply identifying a ‘plausible’ theory of causation is insufficient for a petitioner to meet her burden of proof.” (citing *Moberly*, 592 F.3d at 1322)); see also *Howard v. Sec’y of Health & Hum. Servs.*, 2023 WL 4117370, at \*4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *appeal docketed*, No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* “addresses the petitioner’s overall burden of proving causation-in-fact under the Vaccine Act” by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary

evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec’y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at \*17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

#### B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider “all [ ] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, “[m]edical records, in general, warrant consideration as trustworthy evidence.” *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec’y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical

records was rational and consistent with applicable law”), *aff’d*, *Rickett v. Sec’y of Health & Hum. Servs.*, 468 F. App’x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec’y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at \*2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec’y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff’d*, 993 F.2d at 1525 (Fed. Cir. 1993) (“[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter’s symptoms”).

Accordingly, if the medical records are clear, consistent, and complete, then 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). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also* *Murphy v. Sec’y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den’d*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, the Federal Circuit has also noted that there is no formal “presumption” that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec’y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at \*19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez*, 2013 WL 1880825, at \*3 (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the

accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

### C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the factors for analyzing the reliability of testimony are:

(1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g., Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to

determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at \*17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

#### D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at \*5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

## ANALYSIS

### I. Guillain-Barré Syndrome

GBS is an acute, monophasic form of inflammatory demyelinating polyneuropathy. Dimachkie at 1. It is a rapidly progressing and ascending motor neuron paralysis, frequently seen after infection (*Dorland's Illustrated Medical Dictionary* (33d ed. 2020) (“*Dorland's*”) at 1802)—although the flu vaccine *is* associated with it as well—and it is typically monophasic. Dimachkie at 1. Weakness and numbness typically progress over two to four weeks. *Id.* GBS begins with paresthesia of the feet, and progresses to flaccid paralysis of the lower limbs, ascending upwards through the body. *Dorland's* at 1802. Essential elements of GBS include progressive weakness in more than one limb, and either hyporeflexia or areflexia. Dimachkie at 6. Other symptoms supporting a diagnosis of GBS include a disease progression of less than four weeks, symmetric weakness, sensory symptoms, cranial nerve involvement, autonomic dysfunction, CSF protein elevation, electrophysiologic features of demyelination, and recovery after its monophasic course. *Id.* Symptoms casting doubt on a GBS diagnosis include evidence of marked asymmetry in weakness, onset with or persistence of bladder/bowel dysfunction, and polymorphonuclear leukocytes in the CSF. *Id.*

To prove GBS caused by the flu vaccine, a petitioner may rely on a Table claim, and thus need not demonstrate causation. He must, however, establish that he *did* experience GBS, with onset within 3-42 days of vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). Here, there is no dispute that Petitioner received the flu vaccine, and her GBS (assuming the accuracy of the diagnosis) began in late December 2017-early January 2018, and thus would have begun within the 3-42 day timeframe. This leaves only the question of whether Petitioner herein likely *did* experience GBS.

### II. Petitioner has Not Carried her Burden of Proof

In this case, as in others, determination of the proper diagnosis is critical to the claim's resolution. *Broekelschen*, 618 F.3d at 1347. Petitioner's causation claim centers on the contention that she experienced GBS—she does not allege a different injury.<sup>9</sup> Petition, filed December 18, 2019 (ECF No. 1). In fact, she *only* alleges that injury. Petitioner's Pre-Hearing Submission at 14 (ECF No. 45); Post-Hearing Submission, dated April 18, 2023 (ECF No. 51) (“Post-Hearing Brief”), at 53 (invoking Table timeframe). The claim therefore succeeds or fails on the issue of diagnosis.

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<sup>9</sup> Petitioner thus does not allege CIDP as her injury – and in fact the record is not consistent with that peripheral neuropathy, even though treaters speculated CIDP was possible in the spring of 2018, and her recurrence of GBS/neurologic-like symptoms for much of 2018 could be consistent with that alternative diagnosis.

Here, as amply established by Dr. Lancaster’s opinion and persuasive interpretation of the medical record, it has not been preponderantly demonstrated that Petitioner likely experienced GBS. Her overarching disease course *pre-dated* vaccination (meaning the vaccine could not explain her symptoms, regardless of how the injury is characterized); she was hospitalized at the time of vaccination for symptoms that overlap with what she experienced in January 2018; and later on, she experienced additional symptoms inconsistent with GBS, but rationally explained equally by either ongoing diabetes or reflective of a conversion disorder (the psychologic bases for which were evident in November 2017).

In addition, even though GBS was reasonably suspected in January 2018 (albeit based on an incomplete record), later treaters disputed the diagnosis, or felt Petitioner’s overall presentation was more consistent with diabetic neuropathy or conversion disorder. *See, for example*, Ex. 3 at 1567 (neurologist’s notes stating that Petitioner’s symptoms were “not likely due to recent [GBS]”); Ex. 38 at 901 (neurologist’s statement in 2020 that “[i]t is difficult to sustain an additional diagnosis of Guillain-Barre in this patient with longstanding history of diabetes and cervical [lumbar] radiculopathy.”). The course of Petitioner’s symptoms—when evaluated from December 2017 (the hospitalization event, and time of the relevant vaccination) through the end of 2018—is ultimately not consistent with GBS as commonly understood. The diagnosis cannot be viewed independent of Petitioner’s total health history—and once it is placed in context, it loses explanatory heft.

Dr. Willer’s opinion to the contrary was far less persuasive, and did not reasonably account for Petitioner’s complete medical history. Rather, too often he attempted to explain away evidence contrary to a GBS diagnosis, or struggled to provide alternative explanations that were unconvincing—denying, for example, that Petitioner’s December 2017 presentation (syncope and neurologic-like symptoms) might have had some association with her January 2018 hospitalization, re-defining its cause as a stroke, or maintaining that (absent eyewitness recollection of the cause of Petitioner’s fall) no one could ever “know” what had then occurred. He similarly did not persuasively frame Petitioner’s second round of post-vaccination symptoms (in March 2018) as caused by treatment fluctuation (a conclusion not proposed by contemporaneous treaters). In fact, it would be inconsistent with GBS for a relapse of neuropathic symptoms to occur six weeks after initial treatment—especially given Petitioner’s contention that her symptoms first manifested in early January. If the diagnosis were correct, she would have still been suffering from primary GBS more than eight weeks post-*onset*, far exceeding GBS’s expected acute course.<sup>10</sup>

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<sup>10</sup> This timeframe, which describes the progression of GBS from onset to nadir, is not the same as the timeframe for onset *after* a trigger, like infection or vaccination. Thus, although a Program Table claim can succeed as long as GBS *first* manifests up to 42 days (or six weeks) after vaccination, its *subsequent* course would not continue on for more than four weeks from onset in the majority of cases.

None of this is to say that there was no evidence supporting the proposed diagnosis. On the contrary, there was (and hence the parties required a hearing and the use of experts in this case to resolve the matter). Certainly GBS was (as Dr. Lancaster conceded) reasonably *suspected* in January 2018, based on Petitioner’s presentation (albeit without consideration of her hospitalization the immediate month before). Some of Petitioner’s presenting symptoms were consistent with it, and certain testing results were supportive. Even the later September 2018 EMG allowed both for GBS *and* a diabetic neuropathy as explanatory possibilities. Also, the efficacy of the IVIG treatments Petitioner received provides some additional evidence of a possible immune-mediated illness (although I do not discount Respondent’s points about the limits of relying on response to IVIG to substantiate a GBS diagnosis). Petitioner can similarly point to treater views supporting the diagnosis, at least early on—but treater views are never sacrosanct,<sup>11</sup> and here those initial views were not tempered by or inclusive of consideration of Petitioner’s full medical history. But the totality of proof, when Petitioner’s history is considered *both pre and post-vaccination*, along with her ongoing issues months after the January 2018 hospitalization and later treater views that clearly were informed by the overall record, is unsupportive of GBS as Petitioner’s likely injury.

Petitioner’s various pre and post-hearing briefs make much of the fact that Respondent has not “proven” an alternative cause, or even waived the chance to so attempt, leaving only the vaccine as possibly causal. Post-Hearing Brief at 57. But I do not find on this record that the burden ever shifted to Respondent to do so. *See* Section 13(a)(1)(B); *Cedillo*, 617 F.3d at 1338 (after a claimant successfully establishes a prima facie case of causation, “the burden then shifts to the government to prove alternative causation by a preponderance of the evidence”); *see also* . *Doe v. Sec’y of Health & Hum. Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010) (“[petitioner] never established a prima facie case, so the burden (and attendant restrictions on what ‘factors unrelated’ the government could argue) never shifted”). While Petitioners are not obligated to “disprove” alternative explanations for an alleged injury as a component of their initial case, special masters *reasonably consider the entire record* when evaluating whether an initial showing as to any issue—including diagnosis—has preponderant support. They do not “hold” evidence that undermines the claim for some later stage of analysis. *Stone v. Sec’y of Health & Hum. Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012) (“...no evidence should be embargoed from the special master’s consideration simply because it is also relevant to another inquiry under the statute”).

Here, the overall record does not preponderate in favor of the GBS proposed diagnosis. That determination reasonably takes into account Petitioner’s pre-vaccination history (which Dr. Willer unpersuasively distinguished) as well as her later issues, and their high explanatory relevance. When the scope of Petitioner’s overall health history is fully evaluated, her January 2018 incident and related treatment (along with initial treater hunches about diagnostic

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<sup>11</sup> *Snyder*, 88 Fed. Cl. at 746 n.67 (2009)

explanations) no longer looks as much like GBS as it was first thought to be. I have reasonably reached that conclusion without determining what the most likely alternative explanation would be.<sup>12</sup>

### CONCLUSION

Based on the entire record in this case, I find that Petitioner has not preponderantly established her claim, and therefore its dismissal is warranted. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.<sup>13</sup>

**IT IS SO ORDERED.**

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

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<sup>12</sup> In fact, I cannot on this record ultimately determine *what* is the most likely explanation for Petitioner's January 2018 hospitalization, despite Dr. Lancaster's speculated causes. Rather, I find only that the injury is *not likely* GBS.

<sup>13</sup> Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.