In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 20, 2026

ANNETTE DANIELLE LUCERO,	*	
Petitioner,	*	No. 20-1789V
v.	*	Special Master Young
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Renee Ja Gentry, The Law Office of Renne J. Gentry, Washington, DC, for Petitioner.
Mary Eileen Holmes, United States Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On December 7, 2020, Annette Danielle Lucero ("Petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program").[2] Pet., ECF No. 1. Petitioner alleged that she received an influenza ("flu") vaccination on November 21, 2018, and "thereafter suffered a Table Injury known as Guillain-Barré Syndrome ("GBS"),[3] and

[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 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

[3] GBS is a "rapidly progressive ascending motor neuron paralysis." *Guillain-Barré Syndrome*, DORLAND'S MED. DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=110689 (last visited Feb. 17, 2026) (hereinafter "DORLAND'S"). "It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face; other characteristics include slight fever, bulbar palsy, absent or lessened tendon reflexes, and increased protein in the cerebrospinal fluid without a corresponding increase in cells." *Id.*

Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"),[4] which were caused-in-fact by the vaccination."[5] *Id.* at Preamble. Petitioner later added a significant aggravation claim in her motion for a ruling on the record but did not file an amended petition. Pet'r's Mot. at 2, ECF No. 40.

A careful analysis and weighing of all the evidence and testimony presented in this case in accordance with the applicable legal standards,[6] reveals that Petitioner has failed to provide preponderant evidence that the flu vaccine she received on November 21, 2018, caused her to develop GBS or CIDP or significantly aggravate her GBS or CIDP. Accordingly, Petitioner is not entitled to an award of compensation.

I. Procedural History

Petitioner filed her petition, an affidavit, and medical records on December 7, 2020. Pet.; Pet'r's Exs. 1–6, ECF No. 1. Petitioner filed additional medical records on December 17, 2020, and August 24, 2021. Pet'r's Ex. 7, ECF No. 7; Pet'r's Ex. 8, ECF No. 18. On November 1, 2021, Respondent filed his Rule 4(c) report arguing against compensation. Resp't's Rept., ECF No. 20.

On July 13, 2022, Petitioner filed an expert report from Salvatore Napoli, M.D. Pet'r's Ex. 9, ECF No. 26. On October 24, 2022, Respondent filed an expert report from Peter Donofrio, M.D. Resp't's Ex. A, ECF No. 28. On February 3, 2023, Petitioner filed a supplemental report from Dr. Napoli. Pet'r's Ex. 23, ECF No. 34. On April 19, 2023, Respondent filed a supplemental report from Dr. Donofrio. Resp't's Ex. C, ECF No. 33.

The parties agreed to resolve entitlement with a ruling on the record. ECF No. 38. On April 12, 2024, Petitioner filed a motion for a ruling on the record. Pet'r's Mot. In her motion, and for the first time, Petitioner alleged an alternative significant aggravation claim for her GBS.[7] *Id.* at 2.

---

[4] CIDP is a "slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves, usually with elevated protein in the cerebrospinal fluid." *Chronic Inflammatory Demyelinating Polyneuropathy*, DORLAND'S. "It occurs most commonly in young adults, particularly males, and is related to [GBS]. Presenting symptoms often include tingling or numbness of the digits, weakness of the limbs, hyporeflexia or areflexia, fatigue, and abnormal sensations." *Id.*

[5] In Petitioner's motion for a ruling on the record, after acknowledging that Respondent alleged Petitioner fails to meet the Table requirements, Petitioner chose to move forward with only a causation-in-fact claim. Pet'r's Mot., at 1–2, 8. ECF No. 40. Petitioner's motion for a ruling on the record "asks for a finding that [Petitioner's] GBS was caused by her vaccination. In the alternative, "should the special master find that her symptoms began prior to her vaccination, that [Petitioner's] GBS was significantly aggravated by her [flu] vaccination." *Id.* at 2.

[6] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

[7] Petitioner did not file an amended petition.

Respondent filed a response on July 11, 2024, and Petitioner filed a reply on August 1, 2024. Resp't's Response, ECF No. 43; Pet'r's Reply, ECF No. 44. This matter is now ripe for consideration.

II. Factual Background

A. Medical History

1. Pre-Vaccination and Vaccination Records

Petitioner was born March 28, 1964, with a past medical history that included hypertension, post-menopausal treatment with hormone replacement therapy, sleep apnea, anxiety, and a Hepatitis B infection in the 1970s. Pet'r's Ex. 2 at 6, 584.

On April 26, 2018, Petitioner had a telehealth visit with Amena Syed, M.D., for sleep apnea. Pet'r's Ex. 2 at 26. She reported feeling fatigued during the day. *Id.* She had symptoms of restless legs, with an onset in the "last few months." *Id.* at 27. She was diagnosed with restless leg syndrome, but no treatment was prescribed for that condition. *Id.* at 29. On August 7, 2018, Petitioner underwent a home sleep study, which revealed mild obstructive sleep apnea. *Id.* at 34.

On November 21, 2018, the date of the subject vaccination, Petitioner saw Nurse Practitioner ("NP") Christina Farrell at her primary care provider's ("PCP's") office for palpitations and "neurological muscle weakness." Pet'r's Ex. 2 at 40. The history stated Petitioner presented with concerns of palpitations and "muscle fatigue with feeling as though muscles giving out that started [six to eight] weeks ago and ha[d] been increasing in frequency." *Id.* at 41. It was noted that Petitioner had a lot of stress and changes in her life at this time and was recently diagnosed with sleep apnea, although she had not followed through with getting a mouth device for treatment. *Id.* A review of systems revealed additional complaints of congestion, postnasal drip, and a runny nose. *Id.* Petitioner also had "intermittent" weakness in both hands, both arms, and both legs. *Id.* She denied any numbness. *Id.* On examination, she had an inflamed throat and mucus membranes. *Id.* A neurological examination showed she had normal strength. *Id.* at 42. Her bloodwork and electrocardiogram ("EKG") were normal. *Id.* at 42–44. She was diagnosed with allergic rhinitis, palpitations, and vitamin D deficiency. *Id.* at 40.

At that same November 21, 2018 visit, Petitioner received an intramuscular quadrivalent flu vaccination. Pet'r's Ex. 2 at 40, 45.

2. Post-Vaccination Records

Nine days later, on November 30, 2018, Petitioner saw Dr. Trixy Franke at her PCP office for a follow-up for "progressive muscular weakness." Pet'r's Ex. 2 at 47. Petitioner reported "gradual generalized symmetric weakness" for the past six months, which was "most noticeable in past [two] months." *Id.* She reported having a "weaker grip," causing her to drop things easily and could no longer turn the ignition in her car with one hand. *Id.* She also complained of difficulty getting out of chairs, using the zipper on pants, shampooing, toileting, and working light switches. *Id.* She was stumbling more frequently. *Id.* She reported paresthesia in her face and hands. *Id.* at

48. Examination revealed normal reflexes and strength. *Id.* at 49. Dr. Franke's assessment was "weakness" and "numbness and tingling of skin." *Id.* She remarked that there was an "[u]ncertain etiology" for Petitioner's "progressive muscle weakness with associated paresthesia." *Id.* She did not suspect GBS. *Id.* ("Doubt [amyotrophic lateral sclerosis ("ALS")] or GBS."). She ordered magnetic resonance imaging ("MRIs") of the brain and cervical spine. *Id.*

On December 4, 2018, Petitioner called Dr. Franke to report that her weakness had worsened since her last visit and was now severe in all four extremities. Pet'r's Ex. 2 at 52–53. Dr. Franke advised her to go to the emergency department ("ED") if she had difficulty eating or breathing. *Id.* at 53. Two days later, Petitioner called back, saying she felt "extremely weak" and asked her husband to take her to the ED. *Id.* at 55.

On December 6, 2018, Petitioner presented to the Sunnyside Hospital ("Sunnyside") ED where she saw Dr. Eric Roth. Pet'r's Ex. 2 at 59. Petitioner reported that she had been experiencing "gradually worsening global weakness over [six] months," which had seemingly become more rapid in the past two weeks, more prominently in her arms. *Id.* Dr. Roth noted that Petitioner had a flu shot two weeks prior. *Id.* Petitioner reported difficulty completing activities of daily living ("ADLs"); for example, she stated she could not button her pants or brush her teeth. *Id.* at 60. She stated that she had been working 70 to 80 hours per week, caring for her ailing parents, and experiencing stress at her new job. *Id.* Dr. Roth noted Petitioner had decreased reflexes in both arms. *Id.* His differential diagnosis included multiple sclerosis ("MS"), GBS, myasthenia gravis, and central cord syndrome. *Id.* He noted: "It seems that rate of progression of her symptoms has accelerated since she got a flu vaccination so GBS is a possibility." *Id.* at 59. Petitioner was admitted to the hospital. *Id.* at 73–75.

Early on December 7, 2018, Petitioner was examined by hospitalist Dr. Karen Piper. Pet'r's Ex. 2 at 64. Petitioner again reported that her symptoms began six months earlier and had rapidly worsened in the past two weeks. *Id.* History also noted that Petitioner "[g]ot [f]lu shot [two] weeks ago but was being seen at the time in Urgent Care for muscle fatigue for [six to eight] weeks prior and palpitations." *Id.* On examination, she was observed to use her elbows to push herself to a sitting position. *Id.* at 68. Her hand grip was weak, with 3/5 strength bilaterally, and leg raise strength was assessed at 5-/5. *Id.* Dr. Piper assessed progressive quadriplegia, worse in the upper extremities than the lower extremities. *Id.* at 70. She recommended a neurohospitalist consultation. *Id.*

The same day, Petitioner saw neurohospitalist Dr. Tajbibi Becker. Pet'r's Ex. 2 at 82. For the first time, she reported a history of a prior upper respiratory infection ("URI"). *Id.* According to the history provided to Dr. Becker,

> [Petitioner] began feeling mild generalized nonspecific weakness about [six] months ago, had some stressors, recently started a new job. She and her husband travel[led] to the East Coast in early November, they did travel outdoors [though] they do not remember any tick bites but are concerned about that. About [three] weeks ago she had a mild [URI]. She developed arm greater than leg weakness and was seen around Thanksgiving for evaluation, at the time received a flu shot which she felt accelerated her progressive weakness to the point that she began falling

> down in the past few days. She denie[d] diarrheal illness. Arms [were] particularly weak and recently there [were] some paresthesias but only in her hands. She note[d] palpitations. She denie[d] constipation or bulbar symptoms. She [] had some mental fogginess but [] attributed this to stress. She specifically remember[ed] having brisk reflexes but [was] areflexic today.

Id. A lumbar puncture revealed an elevated protein level and white blood count ("WBC"), as well as albuminocytologic dissociation. *Id.* at 69, 74. A workup assessing potential infectious causes was negative. *Id.* at 74. Dr. Becker's differential diagnosis included GBS. *Id.* at 82. The plan was to start intravenous immunoglobulin ("IVIG") treatment. *Id.*

Petitioner was discharged from the hospital on December 10, 2018. Pet'r's Ex. 2 at 73. The discharge summary noted that Petitioner reported "intermittent subacute numbness and functional difficulty related to grip strength" over the preceding six months. *Id.* at 74. Her rapidly progressive weakness of the extremities had developed "over the antecedent [three] weeks (and possibly [two] months prior)." *Id.* "She described an antecedent URI but no other recent illnesses. She had received a flu vaccine [two] weeks prior to admission." *Id.* Her MRIs were not suggestive of a demyelinating disease. *Id.* A three-day course of IVIG had "markedly" improved her symptoms. *Id.* Her diagnosis at discharge was acute inflammatory demyelinating polyneuropathy ("AIDP")/GBS. *Id.* at 73–74. The plan was to discharge Petitioner back to her PCP and outpatient rehab therapies. *Id.* at 74. She was instructed to seek further imaging/studies and a neurology referral "if symptoms suggestive of [a] chronic/relapsing process occur[red]." *Id.* It was anticipated Petitioner would "return to prior level of function." *Id.* at 73.

On December 13, 2018, Petitioner began outpatient physical therapy. Pet'r's Ex. 2 at 127. Petitioner told the therapist that her weakness began about two months before her hospitalization. *Id.* She reported that she then had a flu shot "and [the] weakness got worse." *Id.*

On January 9, 2019, Petitioner reported to her physical therapist that she was "having some decrease in her function over the last few days." Pet'r's Ex. 2 at 140. The next day, she presented to the Sunnyside ED complaining of progressively worsening weakness over the past four days. *Id.* at 149. She reported that she had a head cold after her discharge from the hospital in December. *Id.* Dr. Julia Bullick wrote, "[r]ecurrence of symptoms of [GBS], also consider[ed] natural course of disease though [Petitioner's] symptoms seem[ed] markedly worsened compared to two weeks ago. Less likely CIDP given acute nature of course." *Id.* at 150. Petitioner was again admitted and given two further IVIG treatments. *Id.* at 162. Her diagnosis remained GBS. *Id.* at 161. She was discharged on January 12, 2019. *Id.*

On January 22, 2019, Petitioner saw neurologist Benjamin Koo. Pet'r's Ex. 2 at 198. Petitioner reported that her symptoms began "around Thanksgiving" and "progressed quickly after the flu vaccine." *Id.* Dr. Koo conducted an electromyography/nerve conduction study ("EMG/NCS"), which revealed "electrodiagnostic evidence for a subacute, demyelinating sensory-motor polyneuropathy with sparing of the sural sensory response characteristic of [GBS]." *Id.* at 202.

Petitioner again presented to the Sunnyside ED on February 3, 2019, for progressively "increasing weakness" over the past week. Pet'r's Ex. 2 at 217. History noted Petitioner had a "history of admission for [GBS] 12/6/[20]19 after a flu shot with recurrence on 1/10/2019." *Id.* at 217; *id.* at 223 (GBS "seems to be recurrently relapsing – [December 2018, January 2019,] and now [February 2019]."). Dr. Jason Miller admitted her for further IVIG treatment, and she was given two doses of IVIG as an inpatient. *Id.* at 219. She was discharged on February 6, 2019, with a diagnosis of "generalized weakness" and "[p]ossible exacerbation of [GBS]." *Id.* at 225. Dr. Koo commented that it was "[u]nclear whether this [was] a true exacerbation/CIDP or subjective malaise." *Id.* The plan was to continue periodic IVIG treatments on an outpatient basis. *Id.*

On February 21, 2019, Dr. Koo performed a repeat EMG/NCS. Pet'r's Ex. 2 at 275. He concluded that there was "electrodiagnostic evidence for a primary demyelinating polyneuropathy as can be seen in CIDP. Infusion center was called to arrange IVIG 2 gm/kg every [three] weeks." *Id.*

Petitioner continued with biweekly IVIG treatments throughout February and March 2019. *See* Pet'r's Ex. 2 at 326. On March 27, 2019, she had a follow-up appointment with Dr. Koo. *Id.* at 325. For the first time, her diagnosis was CIDP rather than GBS. *Id.* Petitioner reported that the IVIG treatment effects were wearing off "within less than a week" and that she was noticing progression of weakness. *Id.* at 326. An examination revealed diminished reflexes and weakness in all four limbs. *Id.* at 327–28. Dr. Koo's plan was to increase the weekly IVIG dose, and if that failed to stabilize her symptoms, to start long-term steroids and/or plasma exchange therapy. *Id.* at 325. He also planned to perform additional lab tests. *Id.* On April 5, 2019, rheumatologist Brian Greenberg consulted on Petitioner's case due to "abnormal labs" suggesting Sjogren's disorder. *Id.* at 358. He conducted a workup, which did not identify any other diagnoses. *See id.* at 457.

After Petitioner suffered several blood clots from the IVIG infusions, Dr. Koo decided to start her on a trial of rituximab on June 17, 2019, while temporarily continuing the IVIG with the addition of warfarin to prevent clots. Pet'r's Ex. 2 at 499, 540. She was advised to take a pneumonia vaccination prior to beginning the rituximab treatments, but she declined to do so "based on [her] [f]lu vaccine reaction experience in November 2018." *Id.* at 521.

On June 28, 2019, Petitioner sought a second opinion from neurologist S. Pius Wei. Pet'r's Ex. 5 at 9. She stated that her symptoms began in mid-November including weakness, fatigued, and feeling "run-down." *Id.* at 10. She received a flu shot during the ED evaluation and over "[t]he next few days, started to feel worse and worse." *Id.* On examination, Dr. Wei observed decreased reflexes but normal strength. *Id.* at 11. Dr. Wei's assessment was CIDP. *Id.* at 9. He noted her CSF findings were compatible with AIDP/CIDP. *Id.* Dr. Wei agreed with Dr. Koo's assessment and plan, including "escalation to Rituximab if needed rather than plasmapheresis, doubtful that plasmapheresis would be less thrombotic than IVIG." *Id.* at 9.

Petitioner saw Dr. Koo for a follow-up appointment on September 4, 2019. Pet'r's Ex. 2 at 709. Her diagnosis remained CIDP. *Id.* Because Petitioner had suffered recurrent thrombotic episodes while on IVIG even with anticoagulant treatment, the IVIG had been discontinued. *Id.* Since then, her weakness had worsened. *Id.* at 710. Treatment with prednisone had not provided any benefit. *Id.* at 709. Although Petitioner had been given one rituximab treatment, "the efficacy

[would] not be known for a few months." *Id.* "To stabilize her symptoms," Dr. Koo's plan was for Petitioner to start plasmapheresis while waiting for the rituximab to work. *Id.*

On September 7, 2019, Petitioner presented to the Sunnyside ED after she experienced worsening weakness to the point where she was "completely unable to walk with her walker." Pet'r's Ex. 2 at 746. She could not use her arms to text or use her iPad. *Id.* Petitioner was admitted for plasmapheresis with an assessment of CIDP. *Id.* at 758. On September 19, 2019, she was discharged with a diagnosis of CIDP and sent to a rehabilitation facility to continue plasmapheresis and rehabilitative therapies. *Id.* at 759. On September 27, 2019, Petitioner was discharged from the rehabilitation facility. *Id.* at 1021. She continued on plasmapheresis on a twice-weekly basis, along with prednisone treatment. *Id.* at 1114.

As of June 2020, Petitioner continued with a regimen of plasmapheresis. Pet'r's Ex. 2 at 1424. On September 4, 2020, Dr. Koo reduced the frequency of plasmapheresis from twice to once weekly. Pet'r's Ex. 7 at 202–03. At an office visit on August 2, 2021, Dr. Koo noted Petitioner's condition was stable. Pet'r's Ex. 8 at 145.

B. Petitioner's Affidavit

In her affidavit filed on December 7, 2020, Petitioner explained that prior to the flu vaccine she received on November 21, 2018, she was "in good health and suffering from no medical conditions relevant to [her] petition other than general malaise." Pet'r's Ex. 3 at ¶ 3. On November 27, 2018, she "began experiencing limb weakness and loss of dexterity." *Id.* at ¶ 4.

She recalled consulting with her PCP on November 30, December 5, and December 6, 2018. Pet'r's Ex. 3 at ¶ 5. And on December 6, 2018, January 10, 2019, and February 3, 2019, she was hospitalized. *Id.* at ¶ 6. She averred she was formally diagnosed with GBS on December 6, 2018, after a lumbar puncture. *Id.* On January 22, 2019, Petitioner underwent an EMG "and the results indicated [CIDP]". *Id.* at ¶ 7.

As of the date of this affidavit, Petitioner continued to suffer from the effects of her CIDP. Pet'r's Ex. 3 at ¶ 10. She is unable to fully function in daily activities. *Id.* at ¶ 11. Petitioner believed the flu vaccine on November 21, 2018, "caused [her] GBS and CIDP." *Id.* at ¶ 12.

III. Experts

A. Expert Qualifications

1. Petitioner's Expert, Dr. Salvatore Napoli, M.D.

Petitioner did not file Dr. Napoli's curriculum vitae. However, Dr. Napoli did list his qualifications in his first expert report. Dr. Napoli is a board-certified neurologist who has practiced medicine for the last 10 years. Pet'r's Ex. 9 at 1. He received his M.D. from Albany Medical College and subsequently completed a neurology residency at Albany Medical Center Hospital and a clinical neuroimmunology fellowship at the Partners Harvard Multiple Sclerosis Center at Brigham and Women's Hospital. *Id.* at 2–3. In the last five years, he has seen and treated

approximately 10 to 40 patients with CIDP, GBS, "and other autoimmune peripheral nerve disorders." *Id.* at 2. Dr. Napoli has published articles focused on the neuroimmunology component of central nervous system ("CNS") disorders. *Id.*

2. Respondent's Expert, Dr. Peter Donofrio, M.D.

Dr. Donofrio is a board-certified neurologist. Resp't's Ex. A at 1. He received his M.D. from the Ohio State University School of Medicine and subsequently completed an internal medicine residency, a neurology residency, and a neuromuscular fellowship. Resp't's Ex. B at 1–2. He was a practicing physician for 47 years before retiring. Resp't's Ex. A at 1. During that time, he evaluated and treated patients with GBS, CIDP, "and the related condition of Miller Fisher Syndrome."[8] *Id.* Dr. Donofrio is a Professor Emeritus of Neurology at Vanderbilt University. *Id.*; Resp't's Ex. B at 2. Currently, he is the Vice President of the Board of Directors of the GBS/CIDP Foundation. Resp't's Ex. A at 1. Dr. Donofrio has authored or co-authored numerous publications. Resp't's Ex. B at 15–34.

B. Expert Reports

1. Dr. Napoli's First Report

In his first expert report, Dr. Napoli referred to Petitioner's diagnosis as GBS and CIDP. *See* Pet'r's Ex. 9 at 5–6. He opined Petitioner's "[flu] vaccine triggered [Petitioner's] symptoms and development of [GBS] and CIDP." *Id.* at 6. Dr. Napoli explained vaccines are meant to stimulate an immune response. *Id.* at 4. "If the antigen present on the vaccine shares any homologies with host antigen, then immune response will be directed at both the injected antigens and host antigen leading to an autoimmune response." *Id.* He stated this is called molecular mimicry and "is a well-known response in immunology." *Id.* For support of this contention, he generally cited articles on autoimmunity. *Id.* (citing Pet'r's Ex. 11;[9] Pet'r's Ex. 13;[10] Pet'r's Ex. 14;[11] Pet'r's Ex. 15).[12]

Dr. Napoli then cited literature addressing vaccination and GBS. Schonberger et al.[13] reported an increased risk of GBS following the A/New Jersey flu vaccination within a five-week

[8] Miller Fisher Syndrome is a variant of GBS "characterized by areflexia, ataxia, and ophthalmoplegia." *Fisher Syndrome*, DORLAND'S.
[9] Arnon Dov Cohen & Yehuda Shoenfeld, *Vaccine-Induced Autoimmunity*, 9 J. AUTOIMMUNITY 699 (1996).
[10] S. Lee & M.C. Levin, *Molecular Mimicry in Neurological Disease: What is the Evidence?*, 65 CELLULAR & MOLECULAR LIFE SCIS. 1161 (2008).
[11] Dimitrios Karussis & Panayiota Petrou, *The Spectrum of Post-Vaccination Inflammatory CNS Demyelinating Syndromes*, 13 AUTOIMMUNITY REVS. 215 (2014).
[12] Kai W. Wucherpfennig & Jack L. Strominger, *Molecular Mimicry in T Cell-Mediated Autoimmunity: Viral Peptides Activate Human T Cell Clones Specific for Myelin Basic Protein*, 80 CELL 695 (1995).
[13] Lawrence B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976–1977*, 110 AM. J. EPIDEMIOLOGY 105 (1979).

period post vaccination. Pet'r's Ex. 16 at 1. Langmuir et al.[14] reported an increased risk for GBS within 42 days (primarily within the second and third weeks) of the 1976 swine flu vaccination. Pet'r's Ex. 17 at 1. Haber et al.[15] reviewed "evidence for a possible causal association between vaccination and GBS" including case reports. Pet'r's Ex. 18 at 2. The authors discussed case reports that reached "inconclusive results on the association between [flu] vaccine and GBS," and found "with rare exceptions, causal associations between vaccines and GBS have not been substantiated." *Id.* at 5, 11. Dr. Napoli also cited case reports of GBS following the pneumococcal vaccine. Pet'r's Ex. 9 at 4–5 (citing Pet'r's Ex. 19;[16] Pet'r's Ex. 20;[17] Pet'r's Ex. 21).[18]

In Dr. Napoli's opinion, "there was a logical sequence of cause and effect between the vaccine and [Petitioner's] GBS." Pet'r's Ex 9. at 5. He explained that Petitioner received the flu vaccination on November 21, 2018, and within nine days, "experienced symptoms of limb weakness and loss of dexterity." *Id.* "Within two weeks, she developed worsening limb weakness and decrease in mobility" requiring hospitalization with IVIG treatment. *Id.* Relying on Schonberger et al. and Langmuir et al., Dr. Napoli opined "[t]his is an appropriate timeline for neurologic injury secondary to vaccine as it falls within the realm of a [five- to six-]week period following vaccination." *Id.* (citing Pet'r's Exs. 16–17). He concluded, "the onset of [Petitioner's] symptoms began within one to two weeks of her receipt of the vaccine which is a medically accepted time frame that falls within the realm of causation." *Id.*

2. Dr. Donofrio's First Report

Dr. Donofrio began by commenting that although Dr. Napoli used GBS and CIDP interchangeably, GBS and CIDP "are two different illnesses with different evolutions, manifestations, disease behavior, and response to treatment." Resp't's Ex. A at 6.

GBS is a monophasic illness. Resp't's Ex. A at 6 (citing Resp't's Ex. A, Tab 1;[19] Resp't's Ex. A, Tab 2).[20] "Patients with GBS do not typically have a recurrence and would not be expected to have multiple exacerbations months to years after the initial event." *Id.* at 7. Unlike GBS, CIDP is not a monophasic illness. *Id.* Dr. Donofrio opined that "CIDP is not the long term consequence of GBS. CIDP is a separate illness which shares some clinical features . . . with GBS." *Id.* He believed it to be a misconception to refer to CIDP as the chronic form of GBS. *Id.* "GBS and CIDP are separate diseases and GBS does not evolve into CIDP." *Id.* at 8. He stated CIDP is a "chronic polyradiculoneuropathy that can manifest as a chronic progressive illness." *Id.* at 7 (citing Resp't's

[14] Alexander D. Langmuir et al., *An Epidemiologic and Clinical Evaluation of Guillain-Barré Syndrome Reported in Association with the Administration of Swine Influenza Vaccines*, 119 AM. J. EPIDEMIOLOGY 841 (1984).
[15] Penina Haber et al., *Vaccines and Guillain-Barré Syndrome,* 32 DRUG SAFETY 309 (2009).
[16] H. E. Khatib et al., *Case Report: Guillain-Barré Syndrome With Pneumococcus – A New Association in Pediatrics*, 11 IDCASES 36 (2017).
[17] Nidhi Ravishankar, *Guillain-Barre Syndrome Following PCV Vaccine*, 2 CLINICS IN SURGERY 1413 (2017).
[18] Hung Fu Tseng et al., *Pneumococcal Conjugate Vaccine Safety in Elderly Adults*, 5 OPEN FORUM INFECTIOUS DISEASES 1 (2018).
[19] Arthur K. Asbury & David R. Cornblath, *Assessment of Current Diagnostic Criteria for Guillain-Barré Syndrome*, 27 ANNALS NEUROLOGY s21 (1990).
[20] Hugh J. Willison et al., *Guillain-Barré Syndrome*, 388 LANCET 717 (2016).

Ex. A, Tab 3;[21] Resp't's Ex. A, Tab 4;[22] Resp't's Ex. A, Tab 5).[23] Citing Ruts et al.,[24] he explained that 15% of cases of CIDP have an acute onset. *Id.* (citing Resp't's Ex. A, Tab 6). Consequently, the initial diagnosis is often GBS and is later changed to CIDP. *Id.* "If CIDP presents acutely, it may appear to resemble GBS, but its subsequent behavior as a disease will be CIDP." *Id.* at 8.

Dr. Donofrio filed studies that address the relationship between GBS and CIDP. In Willison et al., the authors noted that in patients that are initially diagnosed with GBS based on a rapidly progressive course but then "subsequently have further progression exceeding [four] weeks, CIDP should be considered instead of GBS." Resp't's Ex. A, Tab 2 at 8. These cases are indicative of the "5% of patients initially diagnosed with [GBS that] were eventually found to have acute onset [CIDP]." *Id.* This consideration is especially prudent, according to the authors in cases wherein patients "have three or more periods with clinical deterioration, or when there is a new deterioration after [eight] weeks from onset of weakness." *Id.*

The Ruts et al. study specifically aimed "to provide criteria that can help to distinguish between GBS-[treatment related fluctuations ("TRFs")] and [acute ("A")-CIDP] in the early phase of disease." Resp't's Ex. A, Tab 6 at 1. Acknowledging the difficulty in differentiation because they share "many symptoms and signs in the acute phase of disease," the authors identified the time to reach nadir of symptoms as the main factor clinicians consider. *Id.* They continued that the timeframe for GBS is within four weeks and more than two months for CIDP. *Id.* However, they cautioned that a significant number of patients, eight to 16%, do not fit neatly within one presentation. *Id.* at 2. Indeed, they noted it may be very difficult to distinguish between a GBS-TRF patient's secondary deterioration and a second episode of weakness in an A-CIDP patient. *Id.* These patients would need a repeated IVIG course or "a long-term maintenance treatment with steroids, IVIG, or plasma exchange with or without immunosuppressive agents." *Id.* The authors compared 16 GBS-TRF patients to eight A-CIDP patients in a prospective longitudinal study over the course of one year. *Id.* Within the study population, "5% of the patients initially diagnosed with GBS were revealed to have A-CIDP." *Id.* at 5. All A-CIDP patients had nadir within four weeks; "however, active disease exceeded [eight] weeks." *Id.* Conversely, none of the GBS-TRF group "deteriorated after eight weeks," or had more than two TRFs. *Id.* Additionally, "[t]he median time to reach nadir, first exacerbation, and second exacerbation was significantly longer in the A-CIDP group compared to the GBS-TRF group." *Id.* Some A-CIPD patients were able "to walk independently at nadir of the different deteriorations," compared to none of the GBS-TRF patients. *Id.* Also, some GBS-TRF patients "needed artificial ventilation at nadir of the different deteriorations, compared to none of the A-CIDP patients." *Id.* In summary, the authors opined:

---

[21] Peter James Dyck et al., *Chronic Inflammatory Polyradiculoneuropathy*, 50 MAYO CLINIC PROCEEDINGS 621 (1975).

[22] Joint Task Force of the EFNS and the PNS, *European Federation of Neurological Societies/Peripheral Nerve Society Guideline on Management of Chronic Inflammatory Demyelinating Polyradiculoneuropathy: Report of a Joint Task Force of the European Federation of Neurological Societies and the Peripheral Nerve Society- First Revision*, 15 J. PERIPHERAL NERVOUS SYS. 1 (2010).

[23] Marinos C. Dalakas, *Advances in the Diagnosis, Pathogenesis and Treatment of CIDP*, 7 NATURE REVS. NEUROLOGY 507 (2011).

[24] L. Ruts et al., *Distinguishing Acute-Onset CIDP From Fluctuating Guillain-Barré Syndrome*, 74 NEUROLOGY 1680 (2010).

> Patients with A-CIDP generally are less severely disabled compared to patients with GBS-TRF. Patients remaining able to walk independently at nadir of different deteriorations, having no cranial dysfunction, and showing electrophysiologic features likely to be compatible with CIDP are more likely to have A-CIDP.

Id. at 6; *see also* Resp't's Ex. A, Tab 4 at 2 (In patients with prominent sensory symptoms, acute-onset CIDP is likely in a patient initially diagnosed with GBS if deterioration continues for more than two months from onset or if more than three treatment-related fluctuations occur.).

The Dalakas paper described CIDP in practical terms as "the chronic counterpart of [GBS] owing to various electrophysiological, histological and immune similarities. CIDP differs from GBS, however, by its time course, mode of evolution, prognosis and responsiveness to steroids." Resp't's Ex. A, Tab 5 at 1. CIDP is chronic, but the author described it as "often monophasic with stepwise progression; . . . [and] relapsing with spontaneous remissions, necessitating periodic evaluation of the usefulness of continued immunotherapy." *Id.* at 2. The article further discussed differences between GBS and CIDP. *Id.* Most notably, that "CIDP symptoms do not usually reach [nadir] until at least [two] months from disease onset; by contrast, GBS evolves over less than [four] weeks." *Id.* The author noted however, some patients that present with "subacute onset and a monophasic course that falls between the time frame of the two diseases." *Id.* Still others "experience a more acute onset and peak symptoms within [six to eight] weeks of onset, resembling GBS." *Id.*

Dr. Donofrio believed "CIDP is the best explanation for Petitioner's illness as she experienced the initial bout of weakness and [four] relapses on January 10, 2019, February 3, 2019, February 20, 2019, and September 7, 2019." Resp't's Ex. A at 7. CIDP was listed as the diagnosis as early as February 2019. *Id.* (citing Pet'r's Ex. 2 at 225). He noted that the terms GBS and CIDP were used "imprecisely" in the medical records but that "the forms of treatment prescribed are clearly those used in CIDP rather than GBS." *Id.* at 9. Specifically, Petitioner's treatment with IVIG, subcutaneous immunoglobulin, plasma exchange, corticosteroids, and rituximab are supportive of a CIDP diagnosis over GBS. *Id.* at 7. For further support of his opinion regarding diagnosis, Dr. Donofrio commented on Petitioner's complaints of malaise and fatigue. *Id.* He cited Boukhris et al.[25] for the position that fatigue can be a presenting symptom of CIDP. *Id.* (citing Resp't's Ex. C, Tab 3). Given, Petitioner's presentation to her PCP on November 21, 2018 (the day of her flu vaccination), Dr. Donofrio opined her CIDP began "well before" vaccination since she complained on that date of neurologic muscle weakness for the past six to eight weeks and had generalized malaise dating back to April 2018. *Id.* (citing Pet'r's Ex. 2 at 26, 40, 47). Thus, relying on medical records, he opined the date of onset of her CIDP was in April 2018. *Id.*

[25] S. Boukhris et al., *Pain as the Presenting Symptom of Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)*, 254 J. NEUROLOGICAL SCIS. 33 (2007). Pursuant to his references, Dr. Donofrio intended to cite S. Boukhris et al., *Fatigue as the Main Presenting Symptom of CIDP: a Study of 11 Cases*, 10 J. PERIPHERAL NERVOUS SYSTEM 329 (2005). However, that article was not filed, the 2007 Boukhris et al. article was. Boukhris et al. 2007 found that pain was the most common presenting symptom of CIDP but noted two cases with fatigue as a presenting symptom. Resp't's Ex. C, Tab 3 at 1. Boukhris et al. 2007 cited the Boukhris et al. 2005 article.

Further, Dr. Donofrio believed CIDP is the correct diagnosis because 16-32% of patients have an antecedent infection preceding onset. Resp't's Ex. A at 7 (citing Resp't's Ex. A, Tab 12).[26] While he opined the onset of her CIDP was April 2018, he asserted her URI around November 21, 2018, exacerbated her condition. *Id.* He believed the medical records documented Petitioner had a URI "close to the time of her flu vaccination" including a physical examination on November 21, 2018, finding "basal mucous edema, rhinorrhea, and erythema of the posterior oral pharynx." *Id.* at 7–8. "The features of an URI would corroborate with her admission of having a mild upper respiratory tract infection about [three] weeks before admission, when seen by the neurologist on December 8, 2018." *Id.* at 8 (citing Pet'r's Ex. 2 at 89). The discharge summary from "her December 6 through 10, 2018 admission [] describe[d] an antecedent upper respiratory tract infection." *Id.* (citing Pet'r's Ex. 2 at 73). Additionally, Dr. Donofrio noted that Petitioner had "another URI that precipitated another exacerbation of CIDP" on January 18, 2019. *Id.* He concluded that Petitioner's CIDP, which started in April 2018, worsened after her URI. *Id.* at 7. He opined, the "worsening of CIDP after a[] URI in November 2018 is a much more plausible causal relationship than a vaccination for which there is very little supportive data in CIDP." *Id.* at 8.

Dr. Donofrio did not think the medical or scientific literature "demonstrate[s] the probability of a causal relationship between CIDP and prior vaccinations, including the flu vaccination." Resp't's Ex. A at 8. He referenced several case reports of CIDP developing after vaccination but distinguished them from the present case, because they involved a different vaccine, the patient also had lupus, and/or the two-day onset is "an interval so short that it precludes attributing the onset of the illness to an immune response." *Id.* (citing Resp't's Ex. A, Tab 7 (CIDP arising in a patient with lupus after rubella vaccination);[27] Resp't's Ex. A, Tab 8 (CIDP arising two days after flu vaccination);[28] Resp't's Ex. A, Tab 9 (same)).[29] However, he focused on the 2012 IOM report in which the authors stated that "[n]o studies were identified in the literature for the committee to evaluate the risk of [CIDP] after the administration of the [flu] vaccine," and "the committee assesse[d] the mechanistic evidence regarding an association between [flu] vaccine and CIDP as weak based on two cases." *Id.* (quoting Resp't's Ex. A, Tab 10 at 1).[30] Dr. Donofrio commented that the "report of a few patients developing CIDP after any vaccination does not prove a cause and effect relationship as the CIDP may have occurred purely by chance." *Id.* (citing Resp't's Ex. A, Tab 10).

Dr. Donofrio took issue with the literature Dr. Napoli filed to support his position as "none of them discuss CIDP." Resp't's Ex. A at 8. He specifically pointed out that Haber et al. reported

---

[26] Thomas H. Brannagan III, *Current Diagnosis of CIDP: The Need for Biomarkers*, 16 J. PERIPHERAL NERVOUS SYS. 3 (2011).

[27] P.G. Sanz et al., *Chronic Inflammatory Demyelinating Polyradiculoneuropathy in a Patient with Systemic Lupus Erythematosus and Good Outcome with Rituximab Treatment*, RHEUMATOLOGY INT'L (2011).

[28] J.M. Brostoff et al., *Post-Influenza Vaccine Chronic Inflammatory Demyelinating Polyneuropathy*, 37 AGE AND AGEING 229 (2008).

[29] Praful Kelkar, *Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) With Rapid Progression After Influenza Vaccination: A Report of Three Cases*, 8 J. CLINICAL NEUROMUSCULAR DISEASE 20 (2006).

[30] Inst. of Med., *Adverse Events Associated with Childhood Vaccines: Evidence Causality* (Kathleen Stratton et al. eds., 2012).

a "negative relationship between vaccinations and GBS." *Id.* (emphasis omitted) (citing Pet'r's Ex. 18). Dr. Donofrio also pointed out that Dr. Napoli failed to mention Petitioner's URI that preceded her weakness and January 18, 2019 CIDP exacerbation, as well as her weakness and malaise that started in April 2018. *Id.* at 8–9.

In sum, Dr. Donofrio opined that Petitioner's correct diagnosis is CIDP, not GBS (or AIDP). Resp't's Ex. A at 9. At the time Petitioner received her vaccination on November 21, 2018, she also had a URI. *Id.* "The behavior of [P]etitioner's illness is consistent with the initial presentation of CIDP and four exacerbations." *Id.* He believed her fatigue, dating back to April 2018, "could be explained by pre-existing CIDP." *Id.* Thus, "[t]he presence of those symptoms as a likely harbinger of CIDP makes moot the flu vaccination [as a cause] and any diagnosis of GBS." *Id.* "Because there is no evidence that CIDP can be caused by flu vaccination, it follows that the [P]etitioner's flu vaccination was not a more-likely-than-not cause of her CIDP or exacerbations thereof, and her episodes of weakness did not occur in a medically acceptable timeframe to infer vaccine causation." *Id.*

3. Dr. Napoli's Second Report

Dr. Napoli filed a supplemental report "strongly disagree[ing] with Dr. Donofrio's assessment." Pet'r's Ex. 23 at 1. First, as to diagnosis, Dr. Napoli wrote that while Petitioner was in the "acute setting with acute symptoms, she was described as having [GBS] which was a completely reasonable and appropriate hypothesis and diagnosis in that setting." *Id.* He explained that it was as Petitioner's "symptoms evolved, with relapses and progression over a period of time, that it was considered CIDP." *Id.* He opined, "[t]he difference between the two diagnoses involves timing and progression, which the specialists at the time would not have known about. However, . . . the underlying pathology is the same: demyelinating neuropathy. If anything, the diagnosis of CIDP bears out the seriousness of her condition." *Id.*

Next, Dr. Napoli opined that the "timeline of onset of symptoms strongly suggest that the vaccine was the true etiology" rather than a URI. Pet'r's Ex. 23 at 1. He stated the vaccine "was given within days of the onset of symptoms" and the "potential" URI was three weeks prior to onset. *Id.* Therefore, the "onset of [Petitioner's] neurologic symptoms fits the timeline of vaccine administration more so than a possible [URI] that occurred [one] month prior." *Id.*

Finally, he believed that "to suggest that symptoms of malaise and fatigue in April 2018 were the initial harbinger of onset of CIDP symptoms is extremely hypothetical." Pet'r's Ex. 23 at 1. Dr. Napoli did not find documentation, such as neurologic examination or electrodiagnostic data, to support Dr. Donofrio's conclusion. *Id.* Further, Dr. Napoli wrote that "symptoms of malaise and weakness are common in the general population and can mean anything. There is no specific data to suggest those symptoms were anything close to being CIDP." *Id.*

4. Dr. Donofrio's Second Report

Dr. Donofrio agreed with Dr. Napoli that "in the initial acute setting with acute symptoms, it might have been appropriate to render the diagnosis [GBS]." Resp't's Ex. C at 1. "[B]ut the eventual diagnosis was CIDP, and the initial presentation subsequently was categorized as the

acute form of CIDP. A patient cannot have both GBS and CIDP, as these are distinct conditions." *Id.* Thus, he maintained that the correct diagnosis for Petitioner is CIDP. *Id.* He added that "the arguments for and against flu vaccine causation in GBS would not apply to CIDP." *Id.* at 2.

Dr. Donofrio then pointed out that Dr. Napoli did not state his rationale for the opinion that the timeline is more appropriate for a vaccine-related etiology than the URI. Resp't's Ex. C at 1. He explained that "the neurologic literature does not bear out the relationship between flu vaccination and GBS after the swine flu epidemic of 1976-77, much less a theoretical causal link between flu vaccination and CIDP." *Id.* As mentioned in his first report, there are "very few cases of CIDP [] preceded by a flu vaccination," whereas 16-32% of patients with CIDP have an antecedent infection preceding onset. *Id.* "The timeline is better suited for a[URI] to lead to CIDP than the vaccine. This belief is supported by the medical literature as cited [in his reports] and the lack of literature supporting a relationship to vaccination." *Id.* Furthermore, Dr. Donofrio again emphasized that Petitioner "complained of weakness on the day of the vaccination which would eliminate any consideration of the vaccine causing the weakness." *Id.*

Dr. Donofrio recognized that although Dr. Napoli pointed out "the absence of documented weakness, numbness, neurologic deficits, or electrodiagnostic data in [P]etitioner, [Dr. Napoli did] not offer any alternative medical or neurologic explanation for the symptoms of malaise and fatigue." Resp't's Ex. C at 2. Dr. Donofrio believed that "symptoms of malaise and fatigue are important and can be used as clues to the onset of an illness" and thus asserted that "these pre-vaccination symptoms indicate [P]etitioner was developing CIDP." *Id.* (citing Resp't's Ex. C, Tab 3). In his clinical experience, Dr. Donofrio finds

> it is unlikely a patient would have one condition causing significant malaise and fatigue/weakness in the weeks and months before the vaccination, and then develop a totally different condition causing similar symptoms after the vaccination. In the practice of medicine, one illness that can explain all or most of a patient's symptoms and signs is most likely to be correct (the concept of Occam's Razor).

Id.

Ultimately, Dr. Donofrio maintained that Petitioner "developed CIDP months before the vaccination, or the URI caused her to develop CIDP around the time of vaccination." Resp't's Ex. C at 2.

IV. Applicable Legal Standards

A. Standard of Adjudication—Burden of Proof

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of Health & Hum. Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

B. Standard of Adjudication—Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). 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).

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1325, 1326 (Fed. Cir. 2006) (citing *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005)). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Capizzano*, 440 F.3d at 1326. This is because "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.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.* There is no presumption that medical records are accurate and complete as to all the patient's physical conditions. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that "[b]ecause a reasonable fact finder could conclude that [Petitioner's] testimony [wa]s not inconsistent with her medical records . . . it was not arbitrary and capricious for the special master to credit [Petitioner's] testimony" over her medical records).

Where there are inconsistencies, special masters are within their discretion to award contemporaneous medical records greater weight than later conflicting testimony. *See Cucuras,* 993 F.2d at 1528 (holding that the special master's reliance on contemporaneous medical records over conflicting oral testimony given after the fact was not arbitrary or capricious); *see also Burns*, 3 F.3d at 417 (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master"). Indeed, the Court of Federal Claims has outlined four potential 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. *LaLonde v. Sec'y of Health & Hum. Servs.,* 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

Despite the weight afforded to medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. *Valenzuela v. Sec'y of Health & Hum. Servs.*, No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Hum. Servs.*, No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) ("[Section 13(b)(2)] must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them." (emphasis omitted)).

C. Standards for Adjudication—Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); *Capizzano*, 440 F.3d at 1319–20. While the petition initially asserted a Table claim and causation-in-fact claim, Petitioner's motion for a ruling on the record narrowed her assertions to only causation-in-fact. Pet'r's Mot. at 1–2. Therefore, Petitioner must prove a vaccine she received caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(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.

A petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). 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 548–49. A petitioner is not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano,* 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is unnecessary. *Althen*, 418 F.3d at 1278–81; *see also Moberly*, 592 F.3d at 1322. Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1325. However, Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor.

§ 13(a)(1). Furthermore, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. *See Waterman v. Sec'y of Health & Hum. Servs.*, 123 Fed. Cl. 564, 573–74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. *Moberly*, 592 F.3d at 1322; *see also de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322.

Next, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). In particular, Petitioner must prove 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)); *see also Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. *Shyface*, 165 F.3d at 1351. The special master in *Pafford* noted petitioners "must prove [] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." 2004 WL 1717359, at *4 (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.,* 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted).

Lastly, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. For example, if a petitioner's theory involves a process that takes several days to develop after vaccination, an injury that occurred within a day of vaccination would not be temporally consistent with that theory. Conversely, if the theory is one that anticipates a rapid development of a reaction post-vaccination, the development of the alleged injury weeks or months post-vaccination would not be consistent with that theory. *See de Bazan*, 539 F.3d at 1352. Causation-in-fact cannot be inferred from temporal proximity alone. *See Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) ("[w]ithout more, [a] proximate temporal relationship will not support a finding of causation").

In determining whether Petitioner is entitled to compensation, the special master shall consider all materials in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in her favor. *See Moberly*, 592 F.3d at 1325–26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of

the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); *Althen*, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor). A petitioner who satisfies her burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

D. Standards for Adjudication—Alternative Causation

A petitioner who satisfies all three prongs of the *Althen* test (or all six prongs of the *Loving* test) has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). Where a petitioner demonstrates by a preponderance of the evidence that she suffered an injury caused by vaccination, the government must not merely prove the existence of an alternative cause, but that such an alternative actually caused the injury. *Knudsen,* 35 F.3d at 549. Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" § 13(a)(2); *see also Doe*, 601 F.3d 1349 (opining that an idiopathic diagnosis cannot be a "factor unrelated," as it is idiopathic).

"Regardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case." *Flores v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 157, 162-63 (2014); *see also Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); *de Bazan*, 539 F.3d at 1353 ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); *Pafford*, 451 F.3d at 1358–59("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

IV. Discussion

A. Diagnosis

In cases where the diagnosis is contested, "special masters may find whether a preponderance of evidence supports any proposed diagnosis before evaluating whether a vaccine caused that illness." *Hibbard v. Sec'y of Health & Hum. Servs*, No. 07–446V, 2011 WL 1766033, at *6 (Fed. Cl. Spec. Mstr. April 12, 2011) (citing *Broekelschen v. Sec'y of Health & Hum. Servs.,* 618 F.3d 1339, 1345–46 (Fed. Cir. 2010)). In this case, diagnosis is in dispute, so it is appropriate to address it first.

Petitioner asserts that her diagnosis is GBS, "which has since evolved into its chronic form," CIDP. Pet'r's Reply at 1. Respondent, through his expert, argues "GBS and CIDP are distinct conditions, and it is a 'misconception' to characterize CIDP as the chronic form of GBS." Resp't's Response at 11 (quoting Resp't's Ex. A at 6–7).

Dr. Napoli's opinions on GBS and CIDP are contradictory in that he acknowledged the diseases are different but continued to refer to them as one. He stated the difference between the two diseases is timing and progression and opined that Petitioner's diagnosis of GBS was "completely reasonable and appropriate" in that acute setting. Pet'r's Ex. 23 at 1. However, as Petitioner's "symptoms evolved with relapses and progression over time, [] it was considered CIDP." *Id.* Thus, it seems Dr. Napoli acknowledged the change in diagnosis from GBS to CIDP.

While Dr. Donofrio asserted that CIDP is not the chronic form of GBS, the Dalakas paper described CIDP in practical terms as "the chronic counterpart of [GBS]." Resp't's Ex. A, Tab 5 at 1. Importantly, the paper further described GBS and CIDP as distinct diseases and pointed out differences between the two, including timing and progression. *See id.* at 2 ("CIDP symptoms do not usually reach [nadir] until at least [two] months from disease onset; by contrast, GBS evolves over less than [four] weeks."). Further, the Ruts et al. article, in distinguishing GBS from CIDP, noted that none of the GBS patients studied continued to deteriorate after eight weeks. Conversely all of the A-CIDP patients studied had nadir within four weeks, despite active disease continuing beyond eight weeks. And Willison et al. noted that in patients initially diagnosed with GBS based on a rapidly progressive course, CIDP should be considered where there is "further progression exceeding [four] weeks." Resp't's Ex. A, Tab 2 at 8.

While the two diseases may overlap, the literature provides preponderant evidence that they are distinct, and Dr. Napoli acknowledged differences between the two. In fact, the only similarity Dr. Napoli made between GBS and CIDP was "the underlying pathology" as a "demyelinating neuropathy." Pet'r's Ex. 23 at 1. He did not explain this any further or provide any citations on this point.

While a neurological condition may initially present as GBS, the subsequent disease course may ultimately reveal that CIDP is more applicable; thus, as is the case here, the proper diagnosis is no longer GBS. The medical providers who examined and diagnosed Petitioner provided a detailed record of such evolution of Petitioner's condition. On December 6, 2018, Petitioner presented to the ED reporting difficulties with ADLs and the rapid worsening of gradual weakness. Petitioner was admitted to the hospital with a differential diagnosis of GBS. During her December 7, 2018 hospitalization, Dr. Becker evaluated Petitioner and maintained a differential diagnosis of GBS, starting her on a three-day-course of IVIG that "markedly" improved her symptoms. Pet'r's Ex. 2 at 73. The hospital discharge summary included that Petitioner reported "intermittent subacute numbness" over the preceding six months and that her rapidly progressive weakness of the extremities had developed "over the antecedent [three] weeks (and possibly [two] months prior)." *Id.* at 74. The discharge diagnosis was AIDP/GBS, but she was instructed to seek further neurology evaluation "if symptoms suggestive of [a] chronic/relapsing process occur[red]." *Id.* at 74.

On January 10, 2019, Petitioner returned to the ED with worsening weakness over the past four days. Dr. Bullick wrote, "[r]ecurrence of symptoms of [GBS], also consider[ed] natural course of disease though [Petitioner's] symptoms seem[ed] markedly worsened compared to two weeks ago. Less likely CIDP given acute nature of course." Pet'r's Ex. 2 at 150. Petitioner was again admitted and given two further IVIG treatments. *Id.* at 162. Her diagnosis remained GBS, and a January 22, 2019 EMG/NCS supported that assessment. *Id.* at 161.

Petitioner returned to the ED on February 3, 2019, for increasing weakness. History noted Petitioner had a "history of admission for [GBS] 12/6/[20]19 after a flu shot with recurrence on 1/10/2019." Pet'r's Ex. 2 at 217, 223 (GBS "seems to be recurrently relapsing – [December 2018, January 2019,] and now [February 2019]."). Dr. Miller admitted her for further IVIG treatment, and she was given two doses of IVIG. *Id.* at 219. She was discharged with a diagnosis of "generalized weakness" and "[p]ossible exacerbation of [GBS]." *Id.* at 225. Dr. Koo commented that it was "[u]nclear" whether this was indicative of a GBS exacerbation, "CIDP[,] or subjective malaise." *Id.*

This was the first indication in the medical record that reflects the clinical presentation transition from GBS to CIDP. A repeat EMG/NCS performed on February 21, 2019 showed "primary demyelinating polyneuropathy as can be seen in CIDP." Pet'r's Ex. 2 at 275. A note from Petitioner's March 27, 2019 visit with neurologist Dr. Koo, listed Petitioner's diagnosis as CIDP, rather than GBS. On June 28, 2019, Petitioner sought a second opinion from neurologist Dr. Wei, whose assessment was also CIDP. He specifically noted Petitioner's CSF findings were compatible with CIDP. On September 7, 2019, Petitioner returned to the ED for worsening weakness and the inability to walk. The diagnosis at admission and discharge was CIDP. Indeed, the documented progression of Petitioner's disease course in the medical records and arrival of her treaters to the ultimate diagnosis of CIDP after extensive treatment and continued testing (including the EMG/NCS consistent with CIDP), is the most persuasive evidence that Petitioner suffered from CIDP.

Both Drs. Napoli and Donofrio agreed that based on Petitioner's initial presentation, GBS was the correct diagnosis at that time. However, the medical records show Petitioner's condition worsened and had approximately four recurrences, also described as exacerbations, flares, or relapses. Importantly, the physicians noted her condition was "recurrently relapsing." Pet'r's Ex. 2 at 223. This characterization, according to the filed literature, is contrary to the definition of GBS. *See* Resp't's Ex. A, Tab 2 at 2 (GBS is a "monophasic disease course (<1 month) . . . usually without relapse."). Consistent with that literature, Dr. Donofrio opined that "[p]atients with GBS do not typically have a recurrence and would not be expected to have multiple exacerbations months to years after the initial event, as the [P]etitioner did." Resp't's Ex. A at 7. Conversely, the medical records accurately document a disease consistent with the description of CIDP. The Dalakas paper described CIDP as chronic but "often monophasic with stepwise progression; . . . [and] relapsing with spontaneous remissions, necessitating periodic evaluation of the usefulness of continued immunotherapy." Resp't's Ex. A, Tab 5 at 2. Dr. Napoli did not address the inconsistencies between his asserted GBS diagnosis and Petitioner's presentation in the context of this literature.

Dr. Donofrio offered medical literature that explained how and why CIDP is often initially diagnosed as GBS and subsequently changed to CIDP. For example, Willison et al. warned that in patients initially diagnosed with GBS based on a rapidly progressive course but then "subsequently have further progression exceeding [four] weeks, CIDP should be considered instead of GBS." Resp't's Ex. A, Tab 2 at 8. This is consistent with Petitioner's initial hospitalization, during which the discharge diagnosis was AIDP/GBS, but Petitioner was instructed to seek further neurology evaluation "if symptoms suggestive of chronic/relapsing process occur[red]." Pet'r's Ex. 2 at 74. Willison et al. noted that these types of cases are indicative of the "5% of patients initially diagnosed with [GBS that] were eventually found to have acute onset [CIDP]." Resp't's Ex. A, Tab 2 at 8. This consideration is especially prudent in cases wherein patients "have three or more periods with clinical deterioration, or when there is a new deterioration after [eight] weeks from onset of weakness." *Id.* After the first hospitalization, Petitioner had further progression and three subsequent hospitalizations over the span of nine months.

Dr. Donofrio also argued that Petitioner's response to the IVIG courses was consistent with CIDP. Petitioner had continuous success with IVIG that wore off within one week of treatment. Dr. Napoli did not address Dr. Donofrio's arguments about the successful IVIG treatment; he merely stated his strong disagreement with Dr. Donofrio's comments on diagnosis generally. However, without explanation or supporting authority, his conflicting opinion is not as persuasive.

After consideration of all of the evidence, including but not limited to Petitioner's medical history, filed medical literature, and expert reports, I find that Petitioner has not presented preponderant evidence that she has GBS. The record contains preponderant evidence that Petitioner has CIDP.

B. Causation

1. *Althen* Prong One

From the outset, Petitioner only presented evidence of causation as it relates to GBS and did not file any medical literature related to CIDP. Dr. Napoli also did not present any opinions on causation as it relates specifically to CIDP. Because I found preponderant evidence that CIDP is the relevant diagnosis, a causation theory that is presented solely in the context of GBS is not applicable to CIDP without further explanation. It follows that Petitioner cannot prove causation by a preponderance of the evidence.

I will note that Petitioner presented preponderant evidence of a sound and reliable medical theory that could connect the flu vaccination to GBS pursuant to *Althen* prong one. But Petitioner has not alleged that this causation theory is applicable to CIDP, and she has not alleged a CIDP injury with a different causation theory given the differences between the conditions that have been detailed in this Decision. Indeed, Petitioner has not presented preponderant evidence of a causation theory for any chronic demyelinating disease. Therefore, Petitioner has failed to present preponderant evidence that her causation theory for flu vaccine-caused GBS is applicable or analogous to her CIDP diagnosis, and accordingly, does not meet her burden pursuant to *Althen* prong one.

2. *Althen* Prong Two

A successful argument pursuant to *Althen* prong two is heavily dependent on a reliable causation theory. Petitioner's inability to meet her burden demonstrating how the flu vaccine can cause CIDP effectively precludes her from being able to show that her symptoms were actually caused by the vaccine according to said theory. Moreover, Dr. Napoli did not analyze Petitioner's clinical presentation (even as GBS) in the context of his theory. This alone hinders any meaningful discussion on prong two.

In considering the reliability of a petitioner's evidence of a prima facie case, the special master may consider alternative causes for a petitioner's condition that are reasonably raised in the record, even if the respondent does not pursue a formal alternative cause argument. *Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010). Thus, in weighing a petitioner's case-in-chief, a special master may consider evidence that the petitioner's alleged injury could have been caused by alternative causes. *Id.*

While Petitioner received the flu vaccine on November 21, 2018, she also had a URI on November 21, 2018. In addition to the "neurological muscle weakness" complaints that day, she also reported congestion, postnasal drip, and a runny nose. Pet'r's Ex. 2 at 40–41. The discharge summary from her December 2018 hospitalization also noted an antecedent URI. In fact, Petitioner's treaters do not definitively identify whether the cause of Petitioner's CIDP is her URI or flu vaccine. Dr. Donofrio asserted that Petitioner's URI caused her CIDP or worsening of her CIDP.[31] He reasoned there are "very few cases of CIDP [] preceded by a flu vaccination," whereas 16-32% of patients with CIDP have an antecedent infection preceding onset. Resp't's Ex. C at 1. Dr. Donofrio also asserted that the timeline is better suited for URI causation, although he did not provide specific literature supporting this assertion. In rebuttal, Dr. Napoli argued that the onset of Petitioner's neurologic symptoms fit the timeline of vaccine causation (within days) more so than a URI causation (described as three weeks and one month). He also did not provide further explanation for his contention. Ultimately, their unsupported conclusions are not preponderant evidence of actual causation for either the URI or the flu vaccine in Petitioner's case. Petitioner did not provide preponderant evidence of a logical sequence of cause and effect between Petitioner's vaccination and her CIDP. Therefore, I find that Petitioner has failed to satisfy *Althen* prong two.

3. Althen Prong Three

Petitioner asserts her "symptoms began just [six] days after vaccination, and she experienced near-debilitating symptoms as early as [nine] days after vaccination." Pet'r's Mot. at 21. Dr. Napoli opined this is "an appropriate timeline for neurologic injury secondary to vaccine as it falls within the realm of a [five- to six-]week period following vaccination." Pet'r's Ex. 9 at 5. Whereas Dr. Donofrio opined Petitioner's CIDP began "well before" vaccination since she complained of neurologic muscle weakness for the past six to eight weeks on November 21, 2018

[31] Because I find below that there is preponderant evidence that Petitioner's onset was pre vaccination, and Petitioner failed to present a significant aggravation claim, I only discuss Dr. Donofrio's opinions regarding the URI causing Petitioner's CIDP, not worsening her CIDP.

(the day of her flu vaccination) and had generalized malaise dating back to April 2018. Resp't's Ex. A at 7.

The medical records indicate Petitioner had symptoms of fatigue and malaise as early as April 2018. But beyond the April 2018 visit, which was focused on fatigue and restless leg syndrome, there are no records indicating Petitioner sought medical treatment for fatigue or malaise until November 2018. Additionally, there was no medical literature filed that indicates fatigue and malaise alone, months prior to the onset of other symptoms, are early harbingers of the disease.

However, it cannot be ignored that on the day of vaccination, Petitioner complained of "neurological muscle weakness" for the past six to eight weeks that was increasing in frequency. Pet'r's Ex. 2 at 40. Several post-vaccination medical records also indicate Petitioner had progressive weakness before the date of vaccination. *See, e.g.*, Pet'r's Ex. 2 at 47 (November 30, 2018 notes indicating "gradual generalized symmetric weakness" for the past six months, which was most noticeable in the previous two months), 59 (December 6, 2018 notes indicating she was experiencing "gradually worsening global weakness over [six] months," which had seemingly become more rapid in the past two weeks), 64 (December 7, 2018 notes indicating Petitioner's symptoms began six months earlier and rapidly worsened in the past two weeks). Thus, Petitioner consistently reported that her weakness began at several weeks to months prior to vaccination. Although a neurologic examination on the date of vaccination was normal, pursuant the medical literature, these symptoms ("muscle fatigue with feeling as though muscles giving out" and intermittent weakness in legs, arms, and hands) are indicative of CIDP. *See* Pet'r's Ex. 2 at 41; Resp't's Ex. A, Tab 12. Dr. Napoli was not able to explain how Petitioner's weakness prior to vaccination was unrelated to her ultimate diagnosis of CIDP.

Accordingly, Petitioner has not presented preponderant evidence that her symptoms began post vaccination. While Petitioner asserts symptom onset was approximately one week post vaccination, the complaints of progressive weakness on the day of vaccination cannot be ignored. Her assertions are further undercut by the medical literature filed by Respondent, characterizing CIDP as progressive muscle weakness. Although as Dr. Napoli pointed out, there was no documented neurologic deficits or electrodiagnostic data suggestive of GBS or CIDP prior to vaccination, the progressive nature of the disease may explain why Petitioner did not seek medical attention until she did. Petitioner made it clear that she had endured symptoms for several days and sought medical counsel only after her condition continued to worsen. Because Petitioner did not provide preponderant evidence that her symptoms began post vaccination, she is unable to establish an appropriate temporal relationship between her vaccination and the development of her alleged injury. Accordingly, Petitioner fails to prove *Althen* prong three.

C. Significant Aggravation Claim

In her motion for a ruling on the record, Petitioner, for the first time, asserted in the alternative that Petitioner's GBS was significantly aggravated by the flu vaccine. Pet'r's Mot. at 2. Additional analysis is required to determine whether Petitioner's vaccination significantly aggravated her pre-existing injury. The elements of an off-Table significant aggravation case are set forth in *Loving*. *See Loving*, 86 Fed. Cl. at 142–44; *see also W.C. v. Sec'y of Health & Hum.*

Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). The *Loving* court combined the *Althen* test with a test from *Whitecotton v. Sec'y of Health & Hum. Servs.* 17 F.3d 374 (Fed. Cir. 1994), *rev'd sub nom.*, *Shalala v. Whitecotton*, 514 U.S. 268 (1995) (concerning on-Table significant aggravation cases). The resultant test has six components, which are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

As stated above, I found Petitioner did not present preponderant evidence that she has GBS. Accordingly, evaluating a significant aggravation claim for GBS is moot. Notwithstanding that finding, Petitioner did not present any evidence of a medical theory connecting the flu vaccine to significantly aggravated GBS *or* CIDP. The medical literature cited for *Althen* prong one, showing a sound and reliable medical theory connecting the flu vaccine to GBS, does not contemplate the significant aggravation of preexisting GBS, only new onset causation. Importantly, Dr. Napoli never opined on the significant aggravation of Petitioner's condition and in fact denied that Petitioner's prior weakness was related to her current condition. *See* Pet'r's Ex. 23 at 1. Moreover, Dr. Napoli did not opine on the appropriate timeframe for significantly aggravating GBS post vaccination. Therefore, Petitioner is unable to meet her burden pursuant to *Loving*.

V. Conclusion

After a careful review of the record, Petitioner has failed to provide preponderant evidence that her November 21, 2018 flu vaccine caused or significantly aggravated her GBS or CIDP. Accordingly, Petitioner's claim is **DENIED**. Absent a timely motion for review, the Clerk is directed to enter judgment dismissing this case for insufficient proof in accordance with Vaccine Rule 11(a). [32]

IT IS SO ORDERED.

s/Herbrina D. S Young
Herbrina D. S. Young
Special Master

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