In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 11, 2026

CANDY LARUE,	*	
Petitioner,	*	No. 19-1135V
v.	*	Special Master Young
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

John L. DeFazio, Viola Cummings and Lindsay, LLP, Niagara Falls, NY, for Petitioner.
Alex Saxe, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On August 5, 2019, Candy LaRue ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018). Pet., ECF No. 1. Petitioner alleged she developed chronic inflammatory demyelinating polyneuropathy ("CIDP")[2] as the result of an influenza ("flu") vaccine she received on August 22, 2016. *Id.* at 1. Respondent argued against compensation, asserting that Petitioner could not establish a causation-in-fact claim by a preponderance of the evidence. Resp't's Rep. at 14, ECF No. 25.

A careful analysis and weighing of all the evidence presented in this case in accordance with the applicable legal standards[3] reveals that Petitioner has failed to provide preponderant

[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] 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." *Chronic Inflammatory Demyelinating Polyneuropathy*, DORLAND'S MED. DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/ definition?id=99346 (hereinafter, "DORLAND'S").

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the Ruling 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

evidence that the flu vaccine she received on August 22, 2016, caused her to suffer from CIDP. Accordingly, Petitioner is not entitled to an award of compensation.

I. Procedural History

Petitioner filed her petition and medical records on August 5, 2019. Pet., Pet'r's Exs. 1–2, ECF No. 1. She filed additional medical records and a statement of completion between December 3, 2019, and June 4, 2020. Pet'r's Ex. 3, ECF No. 10; Pet'r's Exs. 4–9, ECF No. 12; Pet'r's Exs. 10–11, ECF No. 18; ECF No. 19. Petitioner filed additional medical records on September 1, 2020. Pet'r's Exs. 12–13, ECF No. 24.

Respondent filed his Rule 4(c) report, opposing compensation, on October 5, 2020. Resp't's Rep. Specifically, Respondent argued that Petitioner's medical records reflected a reported onset date contradicting her petition, and that Petitioner's treating physicians had attributed her CIDP to an underlying malignancy, in addition to Petitioner failing to meet her burden under *Althen*. *Id.* at 14.

The presiding special master held a status conference on December 9, 2020, to discuss the onset issue raised in Respondent's Rule 4(c) report. *See* Min. Entry, docketed Dec. 9, 2020. She detailed the substantial contradictions between Petitioner's self-reported onset of symptoms and the apparent onset reflected in her medical records, as well as the potential for alternative causation from Petitioner's chronic lymphocytic leukemia ("CLL")[4]. ECF No. 26 at 2–3. Accordingly, the special master ordered Petitioner to file detailed affidavits and any other evidence supporting her onset claim within 90 days. *Id.* at 3.

On March 25, 2021, Petitioner filed affidavits from herself, friends, and coworkers in support of her claim. Pet'r's Exs. 14–17, ECF No. 29. Petitioner filed an expert report from Lawrence Steinman, M.D., his curriculum vitae ("CV"), and supporting medical literature on June 29, 2022. Pet'r's Exs. 18–37, ECF No. 39. Respondent filed an expert report from Brian Callaghan, M.D., his CV, and supporting medical literature on October 27, 2022. Resp't's Ex. A, Tabs 1–6, Resp't's Ex. B, ECF No. 41. Petitioner filed a responsive report from Dr. Steinman and additional medical literature on January 18, 2023. Pet'r's Exs. 38–41, ECF No. 43. Respondent filed a responsive report from Dr. Callaghan on March 6, 2023. Resp't's Ex. C, ECF No. 44.

At the request of the parties, a second status conference was scheduled for May 23, 2023. *See* Min. Entry, docketed May 23, 2023. The special master explained that "the record as currently filed provides no documentary support for the facts submitted by [Petitioner] and her witnesses" regarding onset. ECF No. 46 at 2. Accordingly, the special master instructed Petitioner to file "any supportive evidence of onset of the CIDP symptoms as attested to by [P]etitioner and her witnesses

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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.").

[4] CLL is "a common form [of leukemia] mainly seen in the elderly; symptoms include lymphadenopathy, fatigue, renal involvement, and pulmonary leukemic infiltrates. Circulating malignant cells are usually differentiated B lymphocytes; a minority of cases have mixed T and B lymphocytes or entirely T lymphocytes." *Chronic Lymphocytic Leukemia*, DORLAND'S.

as being in September of 2016" through October 2016, within 45 days. *Id.* at 2–3. On July 24, 2023, Petitioner filed three additional affidavits. Pet'r's Exs. 42–44, ECF No. 48. Petitioner also filed a status report indicating that two of her treating providers could not provide sworn affidavits voluntarily, and requested subpoenas be issued. ECF No. 49. The special master noted that onset remained an issue to be decided before entitlement could be considered, and directed the parties to file a joint status report regarding next steps. ECF No. 50.

On August 24, 2023, the parties filed a joint status report. ECF No. 51. In the status report, Petitioner argued that the opinions of her two treating physicians were necessary and would speak to the timing of her CIDP onset; Respondent argued that these treaters would not speak to onset, and would only be able to speak of her symptoms in the context of her CLL diagnosis. *Id.* Petitioner then filed an affidavit, an undated 'get well' card from a coworker, and a status report on August 28, 2023. Pet'r's Exs. 45–46, ECF No. 52; ECF No. 53. Petitioner's status report argued the greeting card contents supported an onset date of September 2016 and requested an "onset hearing" for December 2023, as well as "forensic analysis of this greeting card to determine the ink, paper and coffee stain age and authenticity." ECF No. 53.

During a status conference held on August 28, 2023, the special master "expressed concern with hiring an expert to confirm that the greeting card was not recently created, which would be of no assistance in supporting [P]etitioner's alleged onset of injury seven years ago." ECF No. 54 at 1. The special master scheduled an onset hearing for December 5, 2023, and ordered Petitioner to file motions for subpoenas for her treating physicians. *Id.* at 2.

Petitioner filed motions for subpoenas of her providers on September 26, 2023, which were both granted. *See* ECF Nos. 56–59. On November 3, 2023, Petitioner filed a letter from Francisco Hernandez-Ilizaliturri, M.D. Pet'r's Ex. 47, ECF No. 62. On November 13, 2023, the special master held another status conference and canceled the upcoming onset hearing due to the lack of cooperation from Petitioner's witnesses. Min. Entry, docketed Nov. 13, 2023; ECF No. 65. On December 22, 2023, Petitioner filed a status report indicating she would not be presenting any forensic evidence in support of her onset argument. ECF No. 66.

On January 16, 2024, Petitioner filed a motion for a ruling on the record. Pet'r's Mot., ECF No. 70. Respondent filed his response on May 2, 2024, and Petitioner filed her reply, as well as additional medical literature, on July 2, 2024. Resp't's Response, ECF No. 73; Pet'r's Reply, Pet'r's Exs. 49–53, ECF No. 75. This case was reassigned to my chambers on March 17, 2026. ECF No. 77.

This matter is now ripe for consideration.

II. Medical History

A. Pre-Vaccination Medical History

Petitioner's pre-vaccination medical history was significant for stage III CLL, Barrett's esophagus, lymphocytosis, right lower quadrant pain, night sweats, syncope, anemia from chemotherapy, sore bones, muscle aches, measle weakness, iron deficiency, intermittent fevers, vitamin B12 deficiency, GERD, rosacea, neuritis, tingling and painful hands and feet, radiculitis,

arthralgias, paresthesia, *H. Pylori* duodenitis, and hiatal hernia. Pet'r's Ex. 1 at 9, 10, 39, 43, 120–21, 124–26, 128, 132, 138, 239, 326; *see also* Pet'r's Ex. 2.

On July 28, 2016, Petitioner presented to Nurse Practitioner ("NP") Samantha Morreale for a follow-up visit for her CLL, which she had been diagnosed with in 2010. Pet'r's Ex. 1 at 100. A computed tomography ("CT") scan showed enlarged axillary lymph nodes and an enlarged spleen. *Id.* She presented with stage III palpable submandibular lymph nodes and "B" symptoms of weight loss, night sweats, and fever. *Id.* Petitioner had previously been on a course of Rituxan and Treanda, however, a negative reaction to Rituxan had this medication discontinued. *Id.* Petitioner reported right groin lymph node enlargement over the past two weeks, in addition to bilateral axillary aching, and expressed concern this was related to her CLL. *Id.* She had been experiencing fevers one to two times per month. *Id.* Petitioner also reported worsening fatigue and an elevated white blood cell ("WBC") count, according to her primary care provider ("PCP"). *Id.* On examination, NP Morreale reported positive findings for fever, fatigue, weakness, dyspnea on exertion, abdominal pain, and polyarthralgia. *Id.* at 101. She noted that Petitioner was in cytogenic remission following treatment and ordered blood work and a CT of the chest, stomach, pelvis, and neck. *Id.* at 103. Her CT scans revealed "numerous bilateral cervical and submandibular lymph nodes again seen and without any significant overall change from previous with stable splenomegaly." *Id.* at 113.

B. Vaccination and Post-Vaccination Medical History

Petitioner received the subject flu vaccine on August 22, 2016. Pet'r's Ex. 1 at 60. On September 15, 2016, Petitioner returned to NP Morreale to review her CT scan results and continued to complain of fatigue and bone soreness. *Id.* at 111. It was recommended that Petitioner undergo a bone marrow biopsy to screen for further developments of her CLL, which was scheduled for November. *Id.* at 114.

Petitioner completed her bone marrow biopsy on November 10, 2016. Pet'r's Ex. 1 at 105. She returned to NP Morreale on December 6, 2016, to discuss her results, and continued to report bone soreness and fatigue. *Id.* Her biopsy revealed involvement of CLL "with B lymphocytes accounting for 60-70% of marrow nucleated cells." *Id.* at 108. She received a favorable prognosis at stage II and was instructed to call back "if she has worsening 'B' symptoms." *Id.* at 108–09.

On February 18, 2017, Petitioner presented to her PCP, Ronald Clarke, D.O., with complaints of shortness of breath, leg numbness, gait disturbance, visual disturbances, and "trouble walking up stairs" for two months. Pet'r's Ex. 1 at 16. On examination Dr. Clarke noted a normal gait and normal neurologic features. *Id.* at 17. Dr. Clarke ordered bloodwork and mentioned the possibility of a neurology consult if bloodwork was negative. *Id.* His differential diagnosis was tachycardia versus "[o]ther idiopathic peripheral autonomic neuropathy." *Id.* Petitioner returned to Dr. Clarke on March 6, 2017, with further complaints of leg numbness and shortness of breath. *Id.* at 508. He diagnosed Petitioner with fatigue and folate deficiency anemia and referred her to a neurologist. *Id.* at 509.

Petitioner presented to neurologist Xiuli Li on March 29, 2017. Pet'r's Ex. 1 at 317. Petitioner reported that "she had a bone marrow test in November 2016 and ever since then she has had gradual weakness of the legs without pain." *Id.* Her weakness had been getting worse, and

Petitioner could no longer go up stairs well, had difficulty standing from a seated position, and shuffled her steps. *Id.* Her bloodwork was normal, and she reported no tingling sensation in any of her extremities and no weakness in her arms. *Id.* On examination Dr. Li noted decreased reflexes in her legs and knees and a normal gait with no difficulty standing from a seated position. *Id.* at 318. Dr. Li ordered an electromyogram ("EMG") of both legs to rule out myopathy and magnetic resonance imaging ("MRI") of the lumbar spine to rule out radiculopathy. *Id.* at 319. Petitioner's EMG was completed on April 11, 2017, and was consistent with Guillain-Barré Syndrome ("GBS")[5] and CIDP. Pet'r's Ex. 3 at 16. The neurologist who conducted the EMG, Dr. Bennett Myers, ordered Petitioner to start a four-day course of intravenous immunoglobulin ("IVIG"). *Id.*

On April 27, 2017, Petitioner returned to Dr. Li for a follow-up visit. Pet'r's Ex. 3 at 12. Petitioner reported feeling much better after receiving IVIG, though her strength was not back to baseline. *Id.* "On further questioning she said she had the weakness starting about November 2016 after she had a bone marrow draw for testing for the CLL." *Id.* Dr. Li's differential diagnosis was GBS versus CIDP and Petitioner was referred back to Dr. Meyers for further care. *Id.* at 14.

Petitioner presented to her PCP on May 18, 2017, for complaints of a possible urinary tract infection ("UTI"). Pet'r's Ex. 1 at 33. Dr. Clarke noted Petitioner's examination was normal and listed GBS in her history of present illness. *Id.* at 35.

Surveillance of Petitioner's CLL was conducted on May 26, 2017, and showed slightly increased WBC count with low-grade anemia. Pet'r's Ex. 1 at 147. Petitioner was reported to have "no concerning B symptoms . . . and ha[d] no obvious disease related symptoms." *Id.* Petitioner also reported that she had been diagnosed with GBS in April and that she had an upcoming appointment with neurology. *Id.* Petitioner's attending physician, Dr. Seema Bhat, also recommended "avoiding flu shots in the future if this is indeed [GBS]." *Id.* at 148.

Petitioner's neurology follow-up was conducted on May 31, 2017, by registered physician assistant ("RPA") Tanya Geist. Pet'r's Ex. 1 at 312. Petitioner's symptom onset was reported as "three months" from March 29, 2017. *Id.* Petitioner reported that she had fallen once since her last evaluation, that she was feeling depressed, and that she had developed low back pain and hand numbness. *Id.* She also reported starting physical therapy in April 2017, which provided no relief. *Id.* On examination, RPA Geist reported decreased strength and globally absent reflexes of the biceps, triceps, brachioradialis, patellar tendons, and Achilles tendons. *Id.* at 313. She also reported a slightly ataxic gait. *Id.* RPA Geist's impression removed GBS from Petitioner's differential diagnosis and listed CIDP, a history of CLL, and impaired functional mobility, with fall risk and a high risk for medication use. *Id.* at 314. RPA Geist noted that "CIDP can be associated with blood malignancies, though more commonly multiple myeloma[6] and paraproteinemias.[7] A

[5] GBS is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection." *Guillain-Barré Syndrome*, DORLAND'S.

[6] A myeloma is "a tumor composed of cells of the type normally found in the bone marrow." *Myeloma*, DORLAND'S.

[7] Paraproteinemia, or plasma cell dyscrasias, is "a diverse group of neoplastic disease involving proliferation of a single close of cells producing a serum M component . . . the cells usually have plasma cell morphology, but may have lymphocyte morphology or a combination of lymphocytic and plasma cellular." *Plasma Cell Dyscrasias*, DORLAND'S.

paraneoplastic CIDP related to her [CLL] is possible." *Id.* RPA Geist recommended Petitioner avoid chemotherapies with peripheral neuropathy side effects and directed her to start monthly IVIG. *Id.*

Petitioner was admitted to the hospital at Niagara Falls Memorial Medical Center on July 1, 2017, for a fainting spell. Pet'r's Ex. 2 at 180. Her history reported that she had recently been diagnosed with GBS, and she related her onset back to her bone marrow biopsy. *Id.* at 180–81. Impression notes stated "[s]yncope secondary to autonomic neuropathy due to [GBS]." *Id.* at 181. A head CT was unremarkable. *Id.* Petitioner was advised to monitor her blood pressure and exercise her calf muscles. *Id.*

On August 7, 2017, Petitioner returned to RPA Geist for a follow-up of her CIDP. Pet'r's Ex. 3 at 6. Her history noted that her CLL was not in remission but that she was also not undergoing treatment. *Id.* Her hand and leg weakness had gotten worse, but the tingling in her feet had improved. *Id.* She also reported a neurology consultation that was negative for seizures while she was hospitalized; however, RPA Geist noted these records were unavailable for her to review. *Id.* On examination, Petitioner continued to have absent reflexes and gait problems. *Id.* at 7. Due to the lack of improvement from subsequent IVIG infusions, RPA Geist canceled Petitioner's remaining treatments. *Id.* at 8. She also reiterated the possibility that Petitioner's IVIG was connected to her CLL and noted that her upcoming treatment regimen of Gazyza could also treat her CIDP. *Id.*

Petitioner presented to neurologist David Polston at the Cleveland Clinic for a second opinion on August 8, 2017. Pet'r's Ex. 10 at 1. She reported that she was "diagnosed with GBS in March 2017, then diagnosis changed to CIDP more recently." *Id.* She reported her symptoms had been worsening and that she walked "like a duck," and had to crawl up stairs. *Id.* at 2. Dr. Polston wrote that Petitioner was last well "in Fall 2016 (September/October) and was ambulating fine." *Id.* A "Time course of events" was provided in Dr. Polston's notes:

> Aug 2016: flu shot
> Sept/Oct: no gait symptoms, doing well
> Nov 2016: bone marrow test in left hip to monitor leukemia. . . . Started having tingling in hands and feet shortly after biopsy. Some difficulty with writing with hands
> Dec: walking fine
> Feb: started waddling, no weakness right away. Symptoms "snuck up" on her as she wasn't paying too much attention to her body
> March: went to see doctor [because] of gait concerns. Felt tired and weak
> April: EMG on 4/11/17, diagnosed with GBS. First course of gamma-guard 4/14-4/18 with some improved strength initially
> June: passed out, hospitalized. Legs felt weak, sat down, then passed out. Felt "dream-land." Niagara Falls Memorial. Observed overnight, imaged overnight, thought to be related to hypotension +/- dehydration. Brain imaging ok. Saw neurologist[.]

Id. In Dr. Polston's assessment, he listed February 2017 as the beginning of her gait abnormalities and noted her neurologic examination was significant for "positive areflexic patellar and ankle bilaterally, 4/5 proximal [bilateral upper and lower extremitity] weakness, positive Gower sign, and everted toes and right leaning on gait." *Id.* at 5. He characterized Petitioner's symptoms as more consistent with CIDP than GBS and noted the possibility that her CLL was contributing to her CIDP. *Id.* Dr. Polston acknowledged that Petitioner did not have a typical presentation for myasthenia gravis.[8] *Id.* Petitioner was also seen by neurologist Chen Yan, who opined that an underlying autoimmune or paraneoplastic disorder could be at play given her CLL. *Id.* at 6. He agreed with the decision to cancel Petitioner's IVIG treatments and review her EMG and imaging before proceeding with next steps. *Id.* He wrote Petitioner the following note: "Your CLL [] may make you more prone to autoimmune diseases such as CIDP. It may be possible that treating the CLL may also improve the CIDP. This possibility may be the source of disagreement among your doctors." *Id.* at 7.

On August 22, 2017, Petitioner returned to Dr. Bhat for follow-up surveillance of her CLL. Pet'r's Ex. 1 at 149. Petitioner reported that she had been diagnosed with GBS and that she was told her GBS was "likely from the flu shot she received in August or the bone marrow done in November." *Id.* Dr. Bhat started Petitioner on a course of Ibrutinib for her CLL and recommended she follow up in five weeks. *Id.* at 151.

Petitioner presented to neurologist Ajay Abad on September 8, 2017, for a new patient consultation. Pet'r's Ex. 1 at 153. She reported her diagnosis to be "an acute inflammatory demyelinating polyneuropathy ([GBS])," and that her symptoms began in late March or early April of 2017. *Id.* Petitioner now complained of persistent proximal weakness in her legs and difficulty climbing stairs or standing from a seated position. *Id.* Dr. Abad recommended Petitioner restart IVIG for 10 days to see how she responds and advised her to follow up in three weeks. *Id.* at 156. She returned on September 27, 2017, and reported an overall improvement in strength during the early parts of the day. *Id.* at 161. Dr. Abad recommended Petitioner follow up again in three weeks to reassess her treatment plan. *Id.* at 163. This follow-up occurred on October 18, 2017, where Petitioner continued to report improvement in her strength but continued to experience deficits in her fine motor skills. *Id.* at 170. Dr. Abad paused Petitioner's IVIG treatment pending further progression and recommended she continue physical therapy. *Id.* at 172.

On November 10, 2017, Petitioner returned to Dr. Bhat for a follow-up of her CLL. Pet'r's Ex. 1 at 174. She complained of bone pain and severe muscle cramping in both legs "every night for the past [three] weeks," as well as a rash on her face that had persisted for one week. *Id.* She also reported that her fatigue had worsened. *Id.* at 176. In Dr. Bhat's assessment of Petitioner's CIDP, which he listed as GBS in his chart, Dr. Bhat noted Petitioner had a follow-up appointment with Dr. Abad and that her CIDP "was felt related to vaccine received prior. She is therefore not a candidate for further flu vaccination or for shingles vaccinations." *Id.* at 178.

On December 5, 2017, Petitioner presented to the ED at Niagara Falls Memorial Medical Center with complaints of body-wide pain and fever. Pet'r's Ex. 1 at 570. A workup revealed "acute cystitis and with clinical symptoms of UTI." *Id.* Her past medical history section included

[8] Myasthenia gravis is "an autoimmune disease of neuromuscular function due to the presence of antibodies to acetylcholine receptors at the neuromuscular junction." *Myasthenia Gravis*, DORLAND'S.

a note regarding "[GBS two] years ago after receiving a flu shot." *Id.* A catheter was inserted to assist with urinary retention and Petitioner was discharged home on December 11, 2017. *Id.* at 572; Pet'r's Ex. 2 at 399. Petitioner returned to the ED on December 15, 2017, with complaints of leg weakness for the past four days. Pet'r's Ex. 1 at 694. Petitioner reported a prior history of GBS and her providers noted that she previously had electrolyte disturbances at her last visit. *Id.* at 696. Petitioner was transferred to Buffalo General Hospital ("BGH") that same day due to a lack of intensive care unit ("ICU") beds available. *Id.* at 698.

Upon her arrival to BGH, Petitioner reported that she left work early the day prior due to urinary incontinence, and that when she woke up the next morning "she was unable to ambulate [with] weakness and decreased sensation in her lower extremities." Pet'r's Ex. 6 at 57. Niagara Falls Memorial Medical Cener then diagnosed Petitioner with GBS given her history and transferred her to BGH due to their inability to administer IVIG or plasmapheresis. *Id.* Petitioner underwent a neurology consultation with neurologist Maria Zambrano on December 16, 2017, which noted that Petitioner "was diagnosed with GBS last year after she had progressive weakness in her lower extremities." *Id.* at 61. Petitioner's physical examination revealed "decreased sensation [in] a stocking distribution [and] distal weakness." *Id.* at 64. A lumbar puncture was performed, which revealed elevated CSF protein of 133. Dr. Zambrano also opined that Petitioner's "[p]attern of weakness [was] atypical for GBS as well as the presence of reflexes." *Id.* An MRI of Petitioner's spine revealed a potential lesion at T1, consistent with lymphoma. *Id.* at 57.

On December 19, 2017, oncologist Dzenita Manning consulted with Petitioner due to the lesion seen on her MRI. Pet'r's Ex. 6 at 57. On examination Dr. Manning observed weakness in Petitioner's arms, legs, and grip. *Id.* at 59. Dr. Manning opined that while her lesion may be related to her CLL, it did "not appear [to be] the cause of her weakness that brought her to the hospital." *Id.* Petitioner received five days of IVIG and was discharged to the inpatient rehabilitation unit on December 21, 2017. Pet'r's Ex. 1 at 556. Petitioner's rehabilitation specialist, Dr. Jill Schliefer-Schneggenburger, noted that Petitioner presented with impaired functional independence and weakness in all limbs resulting from GBS. *Id.* Petitioner was discharged from inpatient rehabilitation on January 5, 2018, at which point she could ambulate without assistance and climb stairs with a handrail. Pet'r's Ex. 7 at 173.

Petitioner returned to Dr. Abad for a follow-up on January 11, 2018. Pet'r's Ex. 1 at 181. She reported weakness, more present in her legs than arms, and she felt her arms were relatively strong. *Id.* at 182. Dr. Abad noted that he incorrectly listed Petitioner's diagnosis as GBS instead of CIDP and recommended Petitioner return to Dr. Meyers to investigate the possible relapse of her CIDP. *Id.* at 183–84.

Petitioner underwent additional EMG testing on January 17, 2018, which revealed "demyelinating, motor more than sensory peripheral polyneuropathy" that had progressed since her last EMG in April 2017. Pet'r's Ex. 3 at 5.

On January 24, 2018, Petitioner returned to RPA Geist for her CIDP with complaints of gradual weakness over the past week, particularly in her legs. Pet'r's Ex. 1 at 307. RPA Geist noted a "clinical suspicion of a paraneoplastic CIDP related to her [CLL]" and "clinical suspicion of

relapse of suspected CIDP in the context of infection/sepsis versus exposure to Ibrutinib/BTK enzyme inhibitors." *Id.* at 308. Petitioner's onset of symptoms was reported as November 2016. *Id.* RPA Geist also noted that an MRI of Petitioner's lumbar spine revealed "a possible infiltrative process throughout the vertebral column." *Id.*

The next day, January 25, 2018, Petitioner presented to hematologist/oncologist Francisco Hernandez-Ilizaliturri for follow-up of her CLL. Pet'r's Ex. 1 at 189. Petitioner reported that she began to experience difficulty walking up stairs following her November 2016 biopsy and that she was diagnosed with GBS in April 2017. *Id.* "She state[d] they told her the [GBS] is likely from the flu shot she received in August or the bone marrow done in November." *Id.* She also reported that she experienced a flare of her symptoms following her December 2017 hospitalization. *Id.* Petitioner had previously completed a CT scan from her skull to mid-thigh on January 19, 2018, which revealed "findings consistent with metabolically active lymphoma involving lymph node chains above and below the diaphragm." *Id.* at 194. Dr. Hernandez-Ilizaliturri noted that Petitioner's CLL had relapsed and advised a hold on her medication until she had fully recovered from her UTI. *Id.*

Petitioner presented to neurologist Gil Wolfe at the referral of her PCP on February 1, 2018. Pet'r's Ex. 13 at 5. Dr. Wolfe opined that Petitioner had "clear evidence on exam[ination] and on review of her [nerve conduction study ("NCS")] of an acquired demyelinating polyneuropathy, specifically CIDP. . . . The entity can be seen more commonly in the setting of chronic blood dyscrasias[9] as in her case." *Id.* at 7. Dr. Wolfe recommended Petitioner restart IVIG in accordance with literature he had reviewed, and for her to be placed on steroids if this failed. *Id.* at 8.

On February 21, 2018, it was noted that Petitioner had remained ambulatory following IVIG until two days ago when she had an acute onset of weakness in her proximal legs after a short bout of diarrhea. Pet'r's Ex. 1 at 201. The weakness in her legs intensified and she could not bear weight. *Id.* at 202. Her upper extremities were not affected. *Id.*

On February 26, 2018, Petitioner presented to the emergency room ("ER") with progressive worsening of strength in her lower extremities for the past two months. Pet'r's Ex. 1 at 322. She had improved and participated in the Turkey Trot in November 2017, but spiraled in December with urosepsis and increased weakness. *Id.* IVIG helped but she had a cough recently and now suffered from increased numbness and tingling in her extremities. *Id.* Her differential diagnosis was secondary infection versus CIDP. *Id.* at 324. Petitioner was admitted to the rehabilitation unit for two weeks with a plan to treat her infection first before starting steroids or plasmapheresis. *Id.* at 48, 324.

Petitioner returned for a medical rehabilitation consultation on March 8, 2018. Pet'r's Ex. 1 at 48. The attending physician noted that Petitioner was "a little wishy-washy in her description of her capabilities over the past couple months," describing feeling well and also feeling like she had "been [in] a decline." *Id.* The hospital's physical therapy department found Petitioner to require "moderate to maximum assistance for bed mobility and not transferring or ambulating at that time." *Id.* It was recommended Petitioner begin high dose steroids due to a lack of response

[9] Chronic blood dyscrasias is referring to Petitioner's CLL.

to IVIG. *Id.* at 49. Petitioner was transferred for short-term rehabilitation on April 7, 2018, where she remained until her discharge on April 27, 2018. Pet'r's Ex. 12 at 57, 78.

On May 23, 2018, Petitioner returned to Dr. Abad for further management of her CIDP. Pet'r's Ex. 1 at 209. Dr. Abad recorded Petitioner's symptom onset as "late March/early April 2017." *Id.* He detailed Petitioner's recent hospitalizations and recommended restarting Petitioner on IVIG after noticing a potential relapse of her symptoms. *Id.* at 211. Petitioner then followed up with Dr. Hernandez-Ilizaliturri for her CLL on June 8, 2018, which he reported was relapsing. *Id.* at 213. Dr. Hernandez-Ilizaliturri's summary noted, "she state[d] they told her the [GBS] is likely from the flu shot she received in August or the bone marrow done in November." *Id.* Dr. Abad reported Petitioner was responding well to IVIG therapy, and he planned to taper her off Prednisone next week. *Id.*

Petitioner presented for the beginning of physical therapy sessions on June 18, 2018, and reported her symptom onset as September 1, 2016. Pet'r's Ex. 1 at 331. She reported this is when she was diagnosed with GBS. *Id.* Her physical therapist noted decreased strength, endurance, and balance, with a plan to continue physical therapy for eight weeks. *Id.* at 332–33.

Petitioner presented to Dr. Hernandez-Ilizaliturri on December 17, 2018, at the Roswell Cancer Center for a follow-up. Pet'r's Ex. 5 at 13. Dr. Hernandez-Ilizaliturri included a full history in his record, which included a bone marrow biopsy in November of 2016 with Dr. Mohamed Ahmed, though Petitioner was unsure of the results. *Id.* at 14. Petitioner reported an overall improvement in her symptoms, though she had developed neck pain when swallowing. *Id.* at 15. Dr. Hernandez-Ilizaliturri noted Petitioner was handling her Ibrutinib well, though she was experiencing mild anemia. *Id.* at 20. He ordered a positron emission tomography ("PET") scan to evaluate for nodal response. *Id.* Dr. Hernandez-Ilizaliturri also noted that it was "[u]nclear if flu vaccine contributed [to Petitioner's CIDP, and] therefore[, Petitioner] cannot get flu vaccine." *Id.*

On January 16, 2019, Petitioner returned to Dr. Abad, and reported that she was receiving IVIG, taking steroids, and was feeling "ok." Pet'r's Ex. at 81–82. Petitioner felt her gait had regressed and she had been using an assistive device. *Id.* at 82. Given Petitioner's positive response to IVIG, Dr. Abad planned to increase her dose with a plan to decrease treatment frequency if she plateaued. *Id.* at 85–86. He scheduled a follow-up for her in three weeks. *Id.* at 86.

Petitioner presented for a follow-up appointment the same day with Dr. Hernandez-Ilizaliturri to evaluate her tolerance to Ibrutinib. Pet'r's Ex. 5 at 106. She reported balance issues when bending over and occasional difficulty swallowing. *Id.* at 108. Dr. Hernandez-Ilizaliturri noted that Petitioner's PET scan showed improvement and her WBC count improved, but she still had an iron deficiency. *Id.* at 112. He planned to continue Ibrutinib and for Petitioner to receive iron infusions. *Id.* A central venous line with a right chest port was inserted on January 18, 2018, for administration of medications and intravenous solutions. *Id.* at 131, 134.

On January 20, 2019, Petitioner was hospitalized at Niagara Falls Memorial Medical Center with complaints of a high fever and urinary incontinence. Pet'r's Ex. 2 at 915. In her history, she reported GBS "in 2015 and again in December 2017." *Id.* Her lab work revealed an elevated

WBC count, and Petitioner was admitted under the suspicion of an acute UTI and discharged on February 4, 2019. *Id.* at 916; Pet'r's Ex. 5 at 175.

Petitioner followed up with Dr. Abad on February 6, 2019, where she reported redness around her chest port before her hospital admission. Pet'r's Ex. 5 at 175. While in the hospital, she was started on antibiotics and IVIG, which were subsequently canceled after developing an acute kidney injury and pulmonary congestion. *Id.* She improved without the need for dialysis and now felt "generally weaker but [did] not appreciate a significant drop off in strength." *Id.* Dr. Abad noted Petitioner was "neurologically stable" and that she was scheduled to see Dr. Hernandez-Ilizaliturri the following week for a repeat of her labs. *Id.* at 181.

At a follow-up with Dr. Hernandez-Ilizaliturri on February 13, 2019, he noted that Petitioner's Ibrutinib was discontinued during her hospital admission and not resumed following her discharge. Pet'r's Ex. 5 at 221. He noted that Petitioner's labs had improved, and he planned to restart her Ibrutinib. *Id.* at 227. He also noted that following discussion with Dr. Abad, Petitioner would restart IVIG therapy. *Id.* Petitioner continued monthly follow-up examinations with Dr. Hernandez -Ilizaliturri on March 13, 2019, and April 18, 2019. *Id.* at 261, 297.

Petitioner was hospitalized in May of 2019, for hypotension and an allergic rash from her antibiotics. Pet'r's Ex. 5 at 1158. During a post-hospitalization follow-up on May 26, 2019, oncologist Michelle Patel canceled Petitioner's antibiotics. *Id.* at 1164.

Petitioner continued to receive IVIG in 2019 with marginal improvement followed by regressions. Pet'r's Ex. 1 at 231, 233, 240, 250, 260, 266. At a June 5, 2019 visit with Dr. Abad, Petitioner reported "aching, buming (sic), cramping, crushing, deep, nagging, numbness/tingling, radiating and tightening pain in the [h]ands[,] feet[, and] shoulder" that began six months ago. Pet'r's Ex 5 at 1218.

On July 19, 2019, Petitioner presented to Dr. Wolfe for another consultation for her CIDP. Pet'r's Ex. 13 at 9. She reported that "[i]n the late summer of 2016 she underwent vaccination and a few weeks later developed weakness and numbness which initially began in her legs and slowly progressed to involve her arms as well." *Id.* She stated she had minimal symptoms for the past month and that "it is the best she has felt in a while." *Id.* Dr. Wolfe summarized Petitioner's clinical course as "a roughly [three] year history of CIDP which has occurred in conjunction with a hematologic malignancy, not an uncommon occurrence." *Id.* at 11. He noted that he was reluctant to make any changes to Petitioner's treatment because she appeared to be doing well. *Id.* Dr. Wolfe observed only mild deficits on examination, and planned for Petitioner to return for a reevaluation in a few months. *Id.*

Dr. Wolfe conducted a telehealth visit on April 20, 2020. Pet'r's Ex. 13 at 13. Petitioner reported switching chemotherapies in January 2020, and stated that she was doing much better on the new treatment regimen. *Id.* She also continued to receive IVIG and had started rituximab. *Id.* Petitioner reported normal strength everywhere except her hip flexors and had mild balance issues and tremors. *Id.* Dr. Wolfe recommended increasing the interval of her IVIG dosages, and recommended Petitioner follow up in six months. *Id.* at 14.

No other relevant medical records were filed.

III. Affidavits and Letters

A. Petitioner's Affidavit

On March 25, 2021, Petitioner filed an affidavit. Pet'r's Ex. 14. Petitioner stated that "[o]n or about on September 4, 2016, while shopping for school supplies and some house hold goods . . . [she] experienced weakness in [her] thighs and legs and tingling in [her] feet when [she] bent down to retrieve some items." *Id.* at ¶ 2. She also reported that one of her coworkers, John Testa, noticed her symptoms and unsteadiness during the week of September 5, 2016, and "commented that [Petitioner] was walking like a duck." *Id.* at ¶ 3. She reported that she visited Dr. Ahmed on September 15, 2016, with "complaints of ten days of tingling and weakness in [her] legs along with leg pain." *Id.* at ¶ 4. She reported this was the reason for her bone marrow biopsy. *Id.* Petitioner also stated that at a Halloween party on October 31, 2016, her "legs were so weak that [she] could not raise [herself] from sitting on the floor," and that her friend Marc Mistretta had to help her stand. *Id.* at ¶ 5.

Petitioner reported the pain and tingling in her legs continued at her December 7, 2016 visit with Dr. Ahmed, and continued to worsen until her April 11, 2017 GBS diagnosis, that was later changed to CIDP. Pet'r's Ex. 14 at ¶¶ 7–8. As of February 22, 2021, Petitioner continued to receive treatment for her CLL and CIDP. *Id.* at ¶ 10.

B. Affidavit of William LaRue, Petitioner's Husband

On March 25, 2021, Petitioner filed an affidavit from her husband, William LaRue. Pet'r's Ex. 15. Mr. LaRue stated that Petitioner began to experience weakness in her legs and tingling in her feet on September 4, 2016, and that her symptoms persisted for the next few days. *Id.* at ¶ 2. "She started to walk funny within a week or so and her altered gait just worsened. We were worried that her leukemia was coming out of remission." *Id.* He stated Petitioner reported numbness, weakness, and tingling to her doctor on September 15, 2016. *Id.* at ¶ 3. Mr. LaRue also stated that Petitioner needed help standing after sitting on the floor at his son's Halloween party on October 31, 2016. *Id.* at ¶ 4.

C. First Affidavit of John Testa, Petitioner's Coworker

On March 25, 2021, Petitioner filed an affidavit from her coworker, John Testa. Pet'r's Ex. 16. He stated that he had been co-teaching courses with Petitioner for over 17 years, and "meet and interact daily during the school year in each of [their] respective classrooms and in the common connecting area." *Id.* at ¶ 1. He stated that he "specifically recall[ed] that during the week of September 5, 2016, while [he and Petitioner] were preparing [their] respective classrooms, . . . [he] noticed that [Petitioner] was unsteady when standing on a table setting up exhibits." *Id.* at ¶ 2. He also stated that she was "walking in a funny way that [they] described as walking like a duck." *Id.* Mr. Testa expressed concern that Petitioner's symptoms were related to her CLL coming out of remission and that Petitioner's symptoms continued from the first week of September 2016 onward. *Id.*

D. Affidavit of Marc Mistretta, Petitioner's Friend

On March 25, 2021, Petitioner filed an affidavit from her friend, Marc Mistretta. Pet'r's Ex. 16. Mr. Mistretta's affidavit detailed the events of the October 31, 2016 Halloween party, where he stated that he had to help Petitioner off the floor because her legs were too weak to stand. *Id.* at ¶ 1. He stated Petitioner had not been drinking and that she "did not have the strength to stand up unassisted." *Id.* at ¶ 2.

E. Second Affidavit of John Testa

On July 24, 2023, Petitioner filed a second affidavit from Mr. Testa. Pet'r's Ex. 42. Mr. Testa stated that he was submitting a second affidavit "with specific detail as [he] underst[ood] that [the special master] has indicated to [Petitioner's attorney] that [his] affidavit alone was not satisfactory proof of the timing of the start of [Petitioner's] symptoms." *Id.* at ¶ 1. He was "1000% sure that [Petitioner] was walking with difficulty and having balance difficulties and what seemed to be leg weakness in early September 2016 before the students arrived on September 7, 2016." *Id.* at ¶ 3. He stated Petitioner was in normal health and appearance during the 2015-16 school year, and that when he met up with Petitioner "in September 2016 [she] was physically a different person." *Id.* at ¶¶ 4–5. Mr. Testa stated that Petitioner was wobbly, unsteady, slow going, and needed help fulfilling her teaching duties. *Id.* at ¶ 5. "I know and I remember this without reservation because I was the one who had to help her do her job." *Id.* Mr. Testa stated that he had to carry Petitioner's workload starting in September 2016, and has continued to help Petitioner with her work duties. *Id.* at ¶ 7. Mr. Testa stated he shared this information with his partner and coworkers, specifically Patricia Bruning, as he was "worried about [their] student's and [his] department's integrity as well as [Petitioner's] health." *Id.* at ¶ 11. "Unfortunately, I do not have any emails or text messages to 'document' my recollection that I swear is '1000%' accurate." *Id.*

F. Affidavit of Patricia Bruning, Petitioner's Coworker

On July 24, 2023, Petitioner filed an affidavit from her coworker, Patricia Bruning. Pet'r's Ex. 43. Ms. Bruning stated her first personal observations of Petitioner's "problems with walking, balancing and climbing stairs" occurred in September 2016, and that these "statements are true and '1000 percent' accurate." *Id.* at ¶ 2. Ms. Bruning stated that Petitioner had no problems at the end of the prior school year, but that at the beginning of September 2016 Petitioner "was walking in an usual way and her feet seemed to be turned outwardly." *Id.* at ¶ 3. She also stated that Mr. Testa came to speak to her and said "'something was not right with [Petitioner].'" *Id.* She stated she was aware that Petitioner fell once at the beginning of the school year and that the faculty "were worried she was not going to be able to do her job," meaning Mr. Testa and other teachers covered for Petitioner starting in September 2016. *Id.* at ¶ 4. Ms. Bruning further stated that Petitioner's problems still persisted and she continues to cover for Petitioner at work. *Id.* at ¶¶ 5–7.

G. Affidavit of Dina Udell, Petitioner's Coworker

On July 24, 2023, Petitioner filed an affidavit from her coworker, Dina Udell. Pet'r's Ex. 44. Ms. Udell stated that "without question [Petitioner] was having [] problems involving weakness, walking and balance in September 2016. Unfortunately, [she] . . . cannot find any messages confirming [Petitioner's] difficulties at that time." *Id.* at ¶ 3. Ms. Udell stated that at a 'welcome back' meeting on September 1, 2016, Petitioner was "walking and holding onto the walls to support herself." *Id.* at ¶ 4. She stated she remembered this date because these meetings were annually held on September 1. *Id.* She remembered "telling [her] husband about [Petitioner] explaining to him that she looked to be sick at the meeting especially with the way she walked and seemed to have balance difficulties." *Id.* Ms. Udell also reported she found Petitioner on the floor of her classroom and needed assistance standing in the first week of school in September 2016. *Id.* at ¶ 5. She reported that teachers had to make accommodations for Petitioner starting in September 2016 and continuing int the next school year. *Id.*

H. Get Well Card and Third Affidavit of John Testa

On August 28, 2023, Petitioner filed an undated 'get well' card and a third affidavit from Mr. Testa. Pet'r's Exs. 45–46. The card contained the following handwritten message:

> Cands,
>
> Your (sic) working to (sic) hard. You need to slow down. I can do it for you. I am affraid (sic) your (sic) gonna fall, pass out, collapse, or something. Please don't take offense to this we just care an (sic) now your (sic) not doing good. You should take some time off – rest. I don't think you should be here. Its (sic) to (sic) hard for you. You almost feel (sic) a few times – you gotta lay back – let me help. I don't mind at all. You have worked your entire life – rest my friend.
>
> Sending you bright and sunny thoughts until you're feeling better! & Always
>
> Love,
>
> John & Trish

Pet'r's Ex. 45 at. In Mr. Testa's third affidavit he stated that he sent this card, along with a gift card, to Petitioner "in late September 2016 after [he] observed her new difficulties on September 1, 2016." Pet'r's Ex. 46 at ¶ 4. He was "1000% sure that [Petitioner] was walking with difficulty and having balance difficulties and what seemed to be leg weakness in early September 2016 before the students arrived on September 7, 2016. That change in her apparent health status prompted [him] to write the attached note in September 2016." *Id.* at ¶ 6.

I. Letter from Dr. Francisco Hernandez-Ilizaliturri, Petitioner's Oncologist

On November 3, 2023, Petitioner filed a letter dated September 13, 2021, from her treating oncologist, Dr. Hernandez-Ilizaliturri. Pet'r's Ex. 47. Dr. Hernandez-Ilizaliturri noted the purpose of the letter was because Petitioner was "seeking to excuse herself from receiving the COVID-19 vaccine." *Id.* The letter stated, "[t]he patient has [CLL] and [GBS] that was triggered by prior

vaccinations. Therefore, the COVID-19 vaccination is relatively contraindicated, especially because her neurological problems that resulted from the GBS." *Id.*

J. Affidavit of Dr. Mohamed Ahmed, Petitioner's Oncologist

On January 9, 2024, Petitioner filed an affidavit from her oncologist, Dr. Ahmed. Pet'r's Ex. 48. Dr. Ahmed stated that Petitioner "was seen at the Roswell Park Cancer Institute Niagara Falls satellite office on September 15, 2016, and December 6, 2016, and [he] reviewed her care." *Id.* at ¶ 1. Dr. Ahmed stated that on September 15, 2016, Petitioner "reported new symptoms including 'bone soreness' and lower extremity discomfort in addition to worsening fatigue." *Id.* at ¶ 2. He explained that these new symptoms led to the conduction of a bone marrow biopsy, after which it was noted in Petitioner's chart that "she is still fatigued and that her bones are sore" on December 6, 2016. *Id.* at ¶ 3–4. He noted that Petitioner's biopsy did not reveal aggressive CLL, and that Petitioner "was not exhibiting the 'B symptoms' which typically require treatment including fever, weight loss, and night sweats." *Id.* at ¶ 5. "Even though [Petitioner] complained of fatigue and bone pain, these symptoms may or may not have been associated with CLL." *Id.* at ¶ 6. Dr. Ahmed concluded by stating that he had "no independent recollection, however, [his] habit, standard practice, the review of the medical record[,] and recent conversation with [Petitioner] support the above. [Petitioner] had new symptoms in her lower extremities in September 2016 that may or may not have been associated with leukemia." *Id.* at ¶ 7.

IV. Experts

A. Expert Qualifications

1. Petitioner's Expert, Dr. Lawrence Steinman, M.D.

Dr. Steinman is a board-certified neurologist and currently serves as a Professor of Neurology at Stanford University. Pet'r's Ex. 18 at 1. He received his M.D. from Harvard University and completed his medical internship and residencies in pediatric and adult neurology at Stanford University Hospital. Pet'r's Ex. 19 at 1. Throughout his clinical career Dr. Steinman has "cared for hundreds of adults and children with various forms of inflammatory neuropathy," including CIDP. Pet'r's Ex. 18 at 1. Dr. Steinman has also published 12 articles in the field of molecular mimicry, in addition to numerous other publications. *Id.* He has also received several awards for his work in the field of neuro-immunology. *Id.* at 2–4.

2. Respondent's Expert, Dr. Brian Callaghan, M.D.

Dr. Callaghan is a board-certified neurologist and Associate Professor of Neurology at the University of Michigan, "and a neuromuscular specialist with a primary interest in patients with neuropathy such as [CIDP]." Resp't's Ex. A at 1. He received his M.D. from the University of Pennsylvania Medical Center, where he also completed his medical internship and neurology residency. Resp't's Ex. B at 1. He also completed fellowships in neuromuscular and healthcare research policy at the University of Michigan. *Id.* Dr. Callagan has "published more than 120 articles, with most focusing on neuropathy, including the appropriate diagnostic evaluation and

treatment thereof. Resp't's Ex. A at 1. He also stated he sees about "30 patients with CIDP each year." *Id.*

B. Expert Reports

1. Dr. Steinman's Initial Report

Dr. Steinman began his initial report with a recitation of Petitioner's medical history, citing to Petitioner's statements in her affidavit to establish an onset date of September 4, 2016, 12 days after vaccination. Pet'r's Ex. 18 at 5. His broader theory of causation relied on showing that "a component of the vaccine has extensive molecular mimicry with two proteins at the Node of Ranvier in both the central and peripheral nervous systems." *Id.* at 6. "Contactin-1 and contactin-2 are associated with central nervous system diseases like multiple sclerosis [("MS")] as well as inflammatory peripheral inflammatory neuropathies. *Id.* (citing Pet'r's Ex. 23;[10] Pet'r's Ex. 24;[11] Pet'r's Ex. 25).[12]

Dr. Steinman defined molecular mimicry as "an evolutionary adaption whereby viruses and bacteria attempt to fool the body into granting them free access. Such mimicry works by showing the immune system stretches of amino acids that look like self." Pet'r's Ex. 18 at 8 (citing Pet'r's Ex. 27).[13] He explained that even short stretches of amino acids could induce molecular mimicry, citing to a study which purported to show that paralysis was induced in mice after "exposing them to a short stretch of 10 amino acids, of which only five were actually identical to myelin basic protein." *Id.*[14] He also referenced a study which purported to show the inducement of experimental autoimmune encephalitis ("EAE") in rabbits after introducing a stretch of six identical amino acids. *Id.*[15]

Dr. Steinman relied on Fujinami et al.,[16] which stated that "[m]olecular mimicry . . . [is one of] three mechanisms that can initiate immunoreactivity leading to autoimmune disease." Pet'r's Ex. 18 at 9 (citing Pet'r's Ex. 28). The authors explained that molecular mimicry "can also take

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[10] Madhurima Chatterjee et al., *Contactin-1 and Contactin-2 in Cerebrospinal Fluid as Potential Biomarkers for Axonal Domain Dysfunction in Multiple Sclerosis*, 4 MULTIPLE SCLEROSIS J. EXPERIMENTAL, TRANSLATIONAL & CLINICAL 1 (2018).

[11] Lawrence Steinman, *The Gray Aspects of White Matter Disease in Multiple Sclerosis*, 106 PNAS 8083 (2009).

[12] Yumako Miura et al., *Contactin I IgG4 Associates to Chronic Inflammatory Demyelinating Polyneuropathy With Sensory Ataxia*, 138 BRAIN J. NEUROLOGY 1484 (2015).

[13] Lawrence Steinman, *Autoimmune Disease: Misguided Assaults on the Self Produce Multiple Sclerosis, Juvenile Diabetes, and Other Chronic Illnesses. Promising Therapies Are Emerging*, 269 SCI. AM. 106 (1993).

[14] Dr. Steinman did not provide this article as a reference in his report and it was not filed as an exhibit by Petitioner. Instead, Dr. Steinman references this study in an article he authored in 1993, which was filed as Petitioner's Exhibit 27, and he discusses the study in the context of his own reference in the article he authored.

[15] Dr. Steinman similarly did not provide a reference for this study apart from his own internal reference in a paper he authored in 1993.

[16] Robert S. Fujinami et al., *Molecular Mimicry, Bystander Activation, or Viral Persistence: Infections and Autoimmune Disease*, 19 CLINICAL MICROBIOLOGY REVS. 80 (2006).

place at the level of the T-cell," and pointed to examples of hepatitis B virus polymerase reacting in this way with myelin basic protein in rabbits, inducing EAE, T-cell reactivity, and the development of antibodies against myelin basic protein. Pet'r's Ex. 28 at 2. The authors explained that "cross-reactive immune responses between viruses and host are relatively common; but, in order for autoimmune disease to occur, we predict that the cross-reaction takes place between the virus and host at a 'disease related epitope." *Id.* If this does not occur, an autoimmune reaction may arise but without a disease process. *Id.* The authors also noted that "[i]n most if not all the models where molecular mimicry has been used to induce an autoimmune disease, an adjuvant such as [complete Freund's adjuvant] or an actual infection is required." *Id.* Thus, "in addition to having a cross-reacting disease, inducing epitope-sufficient activation of [antigen-presenting cells] is required." *Id.*

Dr. Steinman also cited to publications of his own work to show that molecular mimicry could occur with five out of 12 identical, but non-consecutive, amino acids in a chain. Pet'r's Ex. 18 at 10 (citing Pet'r's Ex. 29;[17] Pet'r's Ex. 30;[18] Pet'r's Ex. 31).[19] He explained that studies he conducted showing this mechanism between the Epstein-Barr Virus and MS were supportive of the theory of molecular mimicry generally, but also that it could occur with five non-consecutive identical amino acids in a peptide chain of 12. *Id.* at 13 (citing Pet'r's Ex. 32;[20] Pet'r's Ex. 33;[21] Pet'r's Ex. 34).[22]

Turning to the case of Petitioner, Dr. Steinman stated that because he could not test Petitioner specifically for the presence of mimics, he would use "*in silico* computer searches on platforms like BLAST and the Influenza Research Database." Pet'r's Ex. 18 at 16. In order to show the presence of potential molecular mimics to contactin-1 and contactin-2 in the contents of Petitioner's flu vaccine, Dr. Steinman relied on the FDA lot released for the 2016-2017 flu season. *Id.* at 7 (citing Pet'r's Ex. 26).[23] The lot release indicated that all trivalent and quadrivalent flu vaccines contained a strain of the A/California/7/2009 (H1N1)-like virus, which Dr. Steinman input into his BLAST search against the contactin-1 protein. *Id.* at 16; Pet'r's Ex. 26 at 1. His search revealed a 12-length sequence with six identical matches and a nine-length sequence with five identical matches. Pet'r's Ex. 18 at 18. He next conducted the same BLAST search for contactin-2, which found "numerous examples of homologies with sequences of [five] or more identities in runs of 12 amino acids when looking at contactin-1 and contactin-2 and the H1N1 component of Petitioner's vaccine." *Id.* at 22. "These molecular mimics fulfill the requirements

[17] Anand M. Gautam et al., *A Polyalanine Peptide With Only Five Native Myelin Basic Protein Residues Induces Autoimmune Encephalomyelitis*, 176 J. EXPERIMENTAL MED. 605 (1992).
[18] Anand M. Gautam et al., *Minimum Structural Requirement for Peptide Presentation by Major Histocompatibility Complex Class II Molecules: Implications in Induction of Autoimmunity*, 91 PNAS 767 (1994).
[19] Anand M. Gautam et al., *A Viral Peptide with Limited Homology to a Self Peptide Can Induce Clinical Signs of Experimental Autoimmune Encephalomyelitis*, 161 J. IMMUNOLOGY 60 (1998).
[20] Tobias V. Lanz et al., *Clonally Expanded B Cells in Multiple Sclerosis Bind EBV EBNA1 and GlialCAM*, 603 NATURE 321 (2022).
[21] William H. Robinson & Lawrence Steinman, *Epstein-Barr Virus and Multiple Sclerosis*, 375 SCIENCE 264 (2022).
[22] Kjetil Bjornevik et al., *Longitudinal Analysis Reveals High Prevalence of Epstein-Barr Virus Associated With Multiple Sclerosis*, 375 SCIENCE 296 (2022).
[23] FOOD & DRUG ADMIN., INFLUENZA VIRUS VACCINE FOR THE 2016-2017 SEASON (2018).

noted [above], where we showed that such degrees of homology were sufficient to trigger neuroinflammation." *Id.*

Dr. Steinman next proposed a "third gate" for establishing molecular mimicry in addition to his prior explanations, by "probing the Government funded Immune Epitope Database [("IEDB")] to see whether other investigators have studied these regions." Pet'r's Ex. 18 at 22. He stated the KVDDGFLDIWT peptide chain contained in contactin-2 contained "[five] identical amino acids within a stretch of 11 consecutive amino acids" had been "studied repeatedly" and that investigators "reported positive immune assays for the longer epitope in the IEDB." *Id.* at 23. Dr. Steinman also argued that BLAST revealed a strong similarity between contactin-1 and contactin-2, and that both had "very strong homology" with GlialCAM, which "is expressed in myelin and thus the molecular mimicry between contactin-1 and . . . contactin-2 and the H1N1 component of Petitioner's vaccine may explain the neuroinflammation seen in MS and in other neuroinflammatory conditions of the central and peripheral nervous systems." *Id.* at 26. "When considering that the adaptive immune system recognizes 'chunks of proteins', called epitopes of approximately [six to]20 amino acids, these relationships show that contactin-2 and GlialCAM are exceptionally close relatives." *Id.* at 29.

Dr. Steinman then addressed Petitioner's diagnosis of CIDP, which he stated was "closely related to [GBS] and it is considered the chronic counterpart of that acute disease." Pet'r's Ex. 18 at 30 (citing Pet'r's Ex. 36).[24] Regarding the timing of Petitioner's symptoms, Dr. Steinman stated Petitioner's onset began on September 4, 2016, per her affidavits, and that this was "consistent with what is known from classic studies on inflammatory neuropathy after [flu] vaccine." *Id.* (citing Pet'r's Ex. 36). Dr. Steinman acknowledged the "various dates concerning the onset of symptoms that are recorded by various practitioners documented in the record," but opined that "by a preponderance of the evidence as found in the affidavits, medical record, [and] the natural history of the disease that Petitioner's symptoms of CIDP began within 12-14 days of Petitioner's vaccine injection on August 22, 2016." *Id.* at 31.

Turning to potential alternative causes of Petitioner's CIDP, Dr. Steinman noted that Petitioner suffered from CLL, and that Dr. Wolfe opined "that checkpoint inhibitor for her CLL may have contributed to a worsening of her CIDP." Pet'r's Ex. 18 at 31. However, while Dr. Steinman noted the presence of literature supporting this, "she was not on a checkpoint inhibitor at the time of her [flu] immunization in 2016." *Id.* "Preexisting medical conditions including [CLL,] its treatment and diagnostic testing, have no causation or triggering of Petitioner's CIDP." *Id.* at 32.

2. Dr. Callaghan's Initial Report

Dr. Callaghan agreed with Petitioner's diagnosis of CIDP, but disagreed that a link between the flu vaccine and the development of CIDP existed. Resp't's Ex. A at 6. He took issue with Dr. Steinman's comparison of CIDP to GBS, explaining that "CIDP is not just a chronic form of GBS; therefore, the evidence supporting a link between [flu] vaccine and GBS is not relevant to CIDP."

[24] 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).

Id. at 8. Nonetheless, Dr. Callaghan critiqued the use of case reports as only suggesting "a proximate temporal relationship" between the flu vaccine and CIDP, and cited to Doneddu et al.,[25] which found that only 1.5% of CIDP patients had been vaccinated in the six weeks before onset. *Id.* at 7 (citing Resp't's Ex. A, Tab 1). The authors thus concluded that "antecedent events are unlikely to play a role in the risk of CIDP," and Dr. Callaghan argued "the epidemiological evidence does not support an association" between flu vaccination and CIDP. *Id.*

Dr. Callaghan next focused on the onset of Petitioner's symptoms, noting that her medical records largely indicated a self-reported onset date of November 2016 and included instances of Petitioner explicitly reporting no symptoms in September and October of 2016. Resp't's Ex. A at 6. He stated that although Dr. Steinman relied on Petitioner's affidavits to determine onset, "this is not borne out in the medical record and is even inconsistent with [P]etitioner's statements to various treating providers." *Id.* at 7. "Notably, none of the medical records Dr. Steinman references in his section on timing support his opinion that the [P]etitioner's symptoms began on [September 4, 2016]." *Id.* Dr. Callaghan also acknowledged that while CIDP was not associated with the flu vaccine, GBS was, and typically involved an onset of six weeks following vaccination. *Id.* However, "more than 11 weeks after vaccination is too much time for the development of an autoimmune neuropathy after vaccination." *Id.*

Turning to Petitioner's CLL, Dr. Callaghan disagreed with Dr. Steinman that CLL did not cause Petitioner's CIDP. Resp't's Ex. A at 7. "A systemic review of the literature found frequent cases of CIDP with many types of malignances, and leukemias/lymphomas were the most common, including CLL." *Id.* (citing Resp't's Ex. A, Tab 3).[26] He also noted that several of Petitioner's treating physicians opined that her CIDP was linked to her CLL, as well as Petitioner's B symptoms around the time of her CIDP onset. *Id.*

Dr. Callaghan argued that no evidence had been presented involving molecular mimicry in the development of CIDP following flu vaccination, and that no evidence existed of an alternative mechanism by which CIDP was caused by flu vaccination. Resp't's Ex. A at 8. He did not dispute the findings of the studies proposed by Dr. Steinman that referenced molecular mimicry as a causative mechanism, but noted that "none of these articles pertain to the [flu] vaccine or to the develop[ment] of CIDP." *Id.* Dr. Callaghan instead provided the following four criteria which he stated were required to establish molecular mimicry:

(1) similarity between a host epitope and an epitope of a microorganism or environmental agent
(2) detection of antibodies or T-cells that cross-react with both epitopes in patients with the disease
(3) epidemiological link between exposure to the environmental agent or microbe and development of the disease

[25] P. E. Doneddu et al., *Risk Factors for Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP): Antecedent Events, Lifestyle and Dietary Habits. Data from the Italian CIDP Database*, 0 EUR. J. NEUROLOGY 1 (2019).

[26] Yusuf A. Rajabally et al., *Chronic Inflammatory Demyelinating Polyneuropathy and Malignancy: A Systematic Review*, 57 MUSCLE NERVE 875 (2018).

(4) reproducibility of autoimmunity in an animal model following sensitization with the appropriate epitopes either following infection with the microbe or exposure to the environmental agent

Id. (citing Resp't's Ex. A, Tab 6).[27] "[N]one of these criteria are fulfilled for [flu] vaccination and CIDP." *Id.* Dr. Callaghan noted the homology Dr. Steinman identified for contactin-1 and contactin-2, but argued that "the degree of homology described has not been demonstrated to lead to antibodies produced against both epitopes as described in criteria [two]." *Id.* Dr. Callaghan also questioned the relevance of discussing MS, GlialCAM, and the Epstein-Barr virus, as "CIDP is a disease of the peripheral nervous system whereas [MS] is a very different disease of the central nervous system." *Id.*

3. Dr. Steinman's Supplemental Report

In his supplemental report, Dr. Steinman took issue with the Rajabally et al. study, noting that in their efforts to show an association between CIDP and CLL, the authors "did not search for 'seasonal [flu] vaccination,' and thus did not "elevate malignancy as a more important cause of CIDP, than vaccination, because vaccination was never part of the 'search criteria,'" and these patients likely received the flu vaccine. Pet'r's Ex. 38 at 2 (citing Resp't's Ex. A, Tab 3). Dr. Steinman also responded to Dr. Callaghan's critique of his molecular mimicry theory, arguing that he "fail[ed] to mention that the section on the importance of homologies including [five] identities out of 12 . . . is relevant to the theory." *Id.* According to Dr. Steinman, the articles which highlight the importance of a five-match homology "were recognized as 'runners up' for Breakthrough of the Year for 2022 by Science Magazine" behind the James Webb Telescope. *Id.* (citing Pet'r's Ex. 40).[28] "Though the research had nothing to do with [flu] vaccine or CIDP, it showed that [five] of 12 identical amino acids could identify a very remarkable 'molecular mimic,'" which Dr. Steinman opined to be GlialCAM and contactin-1 and contactin-2. *Id.*

Dr. Steinman next argued that the evidentiary standard articulated by Dr. Callaghan is higher than what is appropriate for the Program, stating that the four criteria referenced by Dr. Callaghan are "unattainable in cases before the [Program]." Pet'r's Ex. 38 at 3. Nonetheless, Dr. Steinman argued that he had satisfied criterion one, that criterion two was impossible to obtain, that criterion three was not required in the Program, and that criterion four would require an animal model, which is "an unrealistic goal for an expert to have to fulfill in this [P]rogram." *Id.* Dr. Steinman noted his disagreement with Dr. Callaghan's identified onset date and repeated his assertion of September 4, 2016. Pet'r's Ex. 38 at 3.

4. Dr. Callaghan's Supplemental Report

Dr. Callaghan began his supplemental report by claiming that Dr. Steinman's theory refuting a link between CIDP and CLL "does not make sense." Resp't's Ex. C at 1. "One, [flu] vaccinations are not a known cause of CIDP. Two, none of the articles reviewed by Rajabally et al. [] mention vaccines, which one would expect, since the authors of these articles would likely

[27] Lisa K. Peterson & Robert S. Fujinami, *Molecular Mimicry*, *in* AUTOANTIBODIES (2007).
[28] Elizabeth Pennis et al., *Runners-Up*, 378 SCIENCE 1162 (2022).

note other potential antecedent events within a physiologic time period of CIDP." *Id.* He then contrasted Rajabally et al. to the reviews provided by Dr. Steinman for vaccine causation. *Id.* Rajabally et al. was a "systemic review of the literature, which generated numerous case reports," and that "in contrast to [flu] vaccines, which are quite common, hematologic malignancies are quite rare. A co-occurrence of two rare entities would not be expected to be commonly reported," while a common intervention such as flu vaccination would expect to be reported with higher frequency. *Id.* And "[t]hree, the scientific community agrees that hematologic malignancies can cause CIDP," demonstrated by both lymphoma and neoplasms being associated with the development of CIDP. *Id.* (citing Resp't's Ex. A, Tab 4;[29] Resp't's Ex. A, Tab 5).[30] Dr. Callaghan asserted that "no such consensus exists pertaining to a causal association between vaccination and CIDP." *Id.*

Dr. Callaghan next disputed Dr. Steinman's comparison of contactin and GlialCAM, noting that it was "unclear" why a closely related epitope would be sufficient to explain molecular mimicry between contactin and the flu vaccine. Resp't's Ex. C at 2. Dr. Callaghan also disputed that it was impossible to satisfy the four criteria he laid out for the establishment of molecular mimicry, arguing that the relationship between *C. jejuni* and the development of GBS satisfied these criteria, and thus "the real issue in this case is current lack of evidence." *Id.* He also challenged Dr. Steinman's argument that GBS and CIDP are related, as "[t]he statement by NINDS is geared towards providing a simple explanation to the general public and not necessarily an explanation made to the standards of the medical/scientific community." *Id.* He explained that while both were "acquired demyelinating neuropathies," they differed in terms of presentation, natural history, treatment responsiveness, antibody differences, and associations with environmental triggers. *Id.* (citing Resp't's Ex. A, Tab 5).

V. Applicable Legal Standards

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as modified by 42 C.F.R. § 100.3; or (2) that the petitioner suffered an "off-Table injury," one not listed on the Table, as a result of her receiving a covered vaccine. *See* § 11(c)(1)(C); *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, 1319–20 (Fed. Cir. 2006). In this case, CIDP is not a Table injury associated with the flu vaccine, and thus Petitioner must prove by preponderant evidence that her injury was caused-in-fact by a Table vaccine.

A. 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*

[29] Hubertus Koller et al., *Chronic Inflammatory Demyelinating Polyneuropathy*, 352 N. ENG. J. MED. 1343 (2005).

[30] Jean-Michel Vallat et al., *Chronic Inflammatory Demyelinating Polyradiculoneuropathy: Diagnostic and Therapeutic Challenges for a Treatable Condition*, 9 LANCET NEUROLOGY 402 (2010).

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). Contemporaneous medical records, "in general, warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *but see Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejection the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 538 (2001) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance").

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting *Murphy v. Sec'y of the Dep't of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991)). Ultimately, a determination regarding a witness' credibility is needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009). However, despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. *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.").

B. Causation-In-Fact

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. § 300aa-13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999).

In the seminal case of *Althen v. Sec'y of Health & Hum. Servs.*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(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." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *Id.* "[C]lose calls regarding causation are resolved in favor of injured claimants." *Id.* at 1280. Further, evidence used to satisfy one prong of the test may overlap to satisfy another prong. *Capizzano*, 440 F.3d at 1326.

Under the first prong of *Althen*, 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. den'd*, 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). Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. *Id.* at 548–49 (explaining that such a theory need only be "legally probably, not medically or scientifically certain."); *see also Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *Veryzer v. Sec'y of Health & Hum. Servs.*, 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"), *aff'd* 475 F. App'x 765 (Fed. Cir. 2012).

Petitioners are 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. However, 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). Indeed, the Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon*, 941 F.3d at 1360 (citing *Moberly*, 592 F.3d at 1322; *LaLonde*, 746 F.3d at 1339). 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. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. *See Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision oftentimes is based on the credibility of the experts and the relative persuasiveness of their competing theories"); *Perriera v. Sec'y of Health & Hum. Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing *Fehrs v. United States*, 620 F.2d 255 (Ct. Cl. 1980))). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) requires that courts determine the reliability of an expert opinion before it may be considered as evidence.

"In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establish a standard of evidentiary reliability." *Daubert*, 509 U.S. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support

the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. 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." *Synder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 7664475, at *24 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (stating that the Vaccine Act "require[s] a chain of reliable propositions supporting [a] petitioner's theory").

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*, 400 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. *Id.* at 1325–26.

Under the second prong of *Althen*, 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. Proof of a logical sequence of cause and effect is required, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). 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). 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). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibily raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen* 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). 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*, 993 F.2d at 1528. However, there is no "presumption that medical records are accurate and complete as to all of the patient's physical conditions." *Kirby*, 997 F.3d at 1383 (finding that a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition). 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.*

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to finger causation-in-fact." *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 time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under *Althen* prong one). *Id.*; *Koehn v. Sec'y of Health & Hum. Servs.*, 773 F.3d 1239, 1243 (Fed. Cir. 2014); *Shapiro*, 101 Fed. CL. At 542; *see Pafford*, 451, F.3d at 1358.

Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. *See, e.g., Veryzer*, 100 Fed. CL. At 356. (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury"). The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of health & Hum. Servs.*, 98 Fed. Cl. 719, 726 (2011). A petitioner who demonstrates by a preponderance of the evidence that she suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen*, 35 F.3d at 547. In such a case, the government must not merely prove the existence of an alternative cause, but that such an alternative actually caused the injury. *Kundsen*, 35 F.3d at 549. Consequently, when and if the petitioner establishes a prima facie case, the burden the shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *See de Bazan*, 539 F.3d at 1354; *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). 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 v. Sec'y of Health & Hum. Servs., 601 F.3d 1349 (Fed. Cir. 2010) (stating that an idiopathic diagnosis cannot be a "factor unrelated," as it is idiopathic).

VI. Analysis

A. Symptom Onset and Temporal Relationship to Vaccination (*Althen* Prong Three)

Although a traditional analysis of the *Althen* prongs begins with *Althen* prong one, the dispositive issues in this case relate to the onset of Petitioner's symptoms. Because this issue is inherently tied to a discussion of the second and third prongs of *Althen*, I find it reasonable to begin the analysis with a discussion of *Althen* prong three.

The parties agree that Petitioner suffered from CIDP, but they dispute whether her symptoms likely began in early September 2016, approximately three to four weeks after vaccination, or November 2016, approximately 11 weeks after vaccination. Petitioner first began to complain of fatigue and aching in July 2016, which progressed to reports of bone soreness in September 2016. *See* Pet'r's Ex. 1 at 100, 111. This progression ultimately led to her November 2016 bone marrow biopsy over concerns of a CLL relapse. However, it was not until Petitioner's February 18, 2017 visit with Dr. Clarke that she reported leg numbness, gait disturbances, and difficulty walking up stairs for two months, which ultimately led to her CIDP diagnosis. *Id.* at 16. Petitioner contends that her report of "bone soreness" in September 2016 was the onset of her CIDP symptoms, and submitted the affidavits of her husband, friends, and coworkers to support this claim. Respondent instead contends that the medical record reflects an onset of November 2016, following Petitioner's bone marrow biopsy, which Petitioner consistently reported to her treating physicians throughout the management of her CIDP.

A thorough review of the case record reveals Petitioner has not provided preponderant evidence that her CIDP symptoms began in September 2016. Petitioner primarily relies on her report of bone soreness in 2016, as well as the filed affidavits, to support her claim of September 2016 onset. The affidavits paint a compelling picture of disability, inability to walk, balance issues, and falling with the need for her coworkers and friends' help between the start of school on September 1, 2016, and when she stopped working in the winter of 2017. However, despite the descriptions of what appeared to be a debilitating, physical disability, there were no reports to any physician, nor were there any observations by any medical professional of this condition until her presentation on February 18, 2017. In fact, Petitioner's only complaints prior to February 2017 were fatigue, bone soreness, fever, night sweats, and weight loss. Despite her witnesses' best efforts, contemporaneous medical records are more likely to contain an accurate chronology and timing than statements from individuals recalling events witnessed seven years prior. *See Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later."); *see also Curacas*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that [] testimony in conflict with contemporaneous documentary evidence deserves little weight.").

Throughout her course of treatment, Petitioner's treating physicians also consistently linked her CIDP to her CLL, even in the few instances where she reported a potential association

with her flu vaccine. *See* Pet'r's Ex. 3 at 8 (RPA Geist noting that "CIDP related to her [CLL] is possible" on August 7, 2017) ; Pet'r's Ex. 10 at 5 (Dr. Polston noting that Petitioner's CIDP was "in setting of known hematologic malignancy (CLL)" on August 8, 2017); Pet'r's Ex. 1 at 307 (Dr. Clarke noting Petitioner's CIDP was in the setting of her ongoing CLL on January 24, 2018); Pet'r's Ex. 13 at 11 (Dr. Wolfe noting that Petitioner has "a roughly [three] year history of CIDP which has occurred in conjunction with a hematologic malignancy, not an uncommon occurrence," on July 19, 2019).

Further, Petitioner's fatigue and aching existed prior to her vaccination, as she complained of these symptoms at a July 28, 2016 appointment with NP Morreale during a follow-up for her CLL. Pet'r's Ex. 1 at 100 (complaining of "bilateral axillary aching" and "worsening fatigue"). It was the continuation of these symptoms into September that caused concern for a relapse of her CLL and her subsequent bone marrow biopsy. *See Id.* at 111. Though Dr. Ahmed's affidavit indicates that these were "new symptoms" for Petitioner in September 2016, his own admitted lack of recollection and the specific notation of these symptoms in Petitioner's July 2016 visit makes this affidavit unpersuasive. *See* Pet'r's Ex. 48.

Despite Petitioner's assertions in her affidavit of several new and significant symptoms, she did not present with any complaints to any doctor in September of 2016, even after an alleged fall and the need for assistance from her coworkers. She reported continued fatigue and sore bones at a December 6, 2016 visit, and refused treatment for her stage II CLL and symptoms of fever, night sweats, and weight loss. Pet'r's Ex. 1 at 1. There are no records again until February 13, 2017, when she reported to her PCP that she had been experiencing numbness of her legs, abnormal gait, and difficulty walking up stairs for two months. *Id.* at 16. She later presented to Dr. Li, a neurologist, and reported her symptoms as beginning in November 2016 following her bone marrow biopsy. *Id.* at 317. Petitioner would continue to report her symptom onset as November 2016 or later through May 2018. *See* Pet'r's Ex. 3 at 12 (reporting November 2016 onset on April 27, 2017); *see also* Pet'r's Ex. 1 at 312 (reporting November 2016 onset on May 31, 2017); Pet'r's Ex. 2 at 180 (reporting November 2016 onset on July 1, 2017); Pet'r's Ex. 10 at 1 (reporting November 2016 onset on August 8, 2017); Pet'r's Ex. 1 at 149 (reporting she had been told her GBS was "likely from the flu shot she received in August or the bone marrow done in November" on August 22, 2017); Pet'r's Ex. 1 at 153 (reporting late March or early April 2017 onset on September 8, 2017); Pet'r's Ex. 1 at 189 (reporting November 2016 onset on January 25, 2018); Pet'r's Ex. 1 at 209 (reporting late March or early April onset on May 23, 2018). It was not until a June 18, 2018 physical therapy visit that Petitioner reported the onset of her symptoms and GBS diagnosis both occurred in September 2016. Pet'r's Ex. 1 at 331. Her provided medical history became less consistent following this appointment, and during a January 20, 2019 hospitalization, Petitioner reported GBS "in 2015 and again in December 2017." Pet'r's Ex. 2 at 915. On July 19, 2019, Petitioner again reported to Dr. Wolfe that her symptoms began in "the late summer of 2016" following her flu vaccination Pet'r's Ex. 13 at 9.

Given Petitioner's history of cancer, it seems unlikely that she would not have reported new symptoms immediately to her treating physicians in September 2016, particularly since she had reported lymph node swelling, fatigue, hip pain, and other symptoms earlier that summer in July. She also consistently reported a two-month history of CIDP symptoms in February 2017 and a three-month history of symptoms in March 2017. This timeline with a November 2016 onset

remained for over a year of medical treatment for her CIDP, before she began reporting an onset date of early September 2016 in June 2018. Based on all of these accounts, her onset of symptoms appeared between 11 and 16 weeks after vaccination. Further, Petitioner's expert, Dr. Steinman, provides little analysis as to why he believes Petitioner's onset of symptoms occurred in September 2016. Though Dr. Steinman places heavy reliance on Petitioner's affidavits, he does not explain why she would have consistently reported an onset of November 2016 to her providers, if in fact her symptoms did start in September 2016.

After consideration of all the relevant evidence, I find Petitioner's arguments in support of her timeline unpersuasive. There is not preponderant evidence that Petitioner's symptoms began on September 1, 2016. Rather, the record reflects preponderant evidence that Petitioner's symptoms began sometime in the period following her November 2016 bone marrow biopsy, or 11 to 16 weeks after her flu vaccination.

Dr. Steinman characterized Petitioner's onset as temporally appropriate, based on a purported date of September 4, 2016, and he opined that this period of "12–14 days" following flu vaccination was consistent with Schonberger et al. However, Schonberger et al. does not discuss CIDP—rather, it discusses GBS following flu vaccination. Dr. Steinman argued that the similarities between GBS and CIDP afford the use of the former as a proxy for the latter. Putting aside this issue, Petitioner's November 2016 onset falls outside of what is accepted by the authors in Schonberger et al. The authors noted the period for "increased risk [for the development of GBS] was concentrated primarily with the [five]-week period after vaccination, although it lasted for approximately [nine] or 10 weeks." Pet'r's Ex. 36 at 1. Giving Petitioner the most favorable timeline, from her August 22, 2016 vaccination to her November 10, 2016 bone marrow biopsy, would amount to 11 weeks and four days after vaccination, falling well outside of the Schonberger et al. timeframe. Given that during Petitioner's initial presentations, she reported an onset of December 2016, reliance on the statements made closest in time to the events described would remove Petitioner even further from the risk period identified by the authors. Dr. Steinman made no comment regarding whether a November 2016 onset would be appropriate to support a temporal relationship between the flu vaccine and Petitioner's CIDP, and he provided no literature to support such a claim. Accordingly, I find there is not preponderant evidence of a proximate temporal relationship between Petitioner's vaccination and her injury, and thus Petitioner has failed to satisfy the third *Althen* prong.

B. But-for Causation (*Althen* Prong Two)

Under *Althen* prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Capizzano*, 440 F.3d at 1324 (quoting *Althen*, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm.'" *Pafford*, 451 F.3d at 1356 (internal citations omitted).

Here, Petitioner has failed to provide preponderant evidence of a logical sequence of cause and effect that shows her flu vaccine caused her CIDP. First, Dr. Callaghan noted and the medical record established that Petitioner suffered from CLL, a form of neoplastic leukemia that can be associated with the development of CIDP. Petitioner's treating physicians highly suspected this to be the case, as evidenced by frequent notations throughout Petitioner's medical history discussing the association of her CIDP with her ongoing CLL. These notations came at varying points in time throughout Petitioner's disease progression and by multiple doctors, including oncologists and neurologists who examined Petitioner. *See* Pet'r's Ex. 3 at 8 (discussing the relationship of CIDP to blood malignancies); Pet'r's Ex. 10 at 5 (noting Petitioner's CIDP was "in setting of known hematologic malignancy (CLL), concern for possible paraneoplastic process"); Pet'r's Ex. 1 at 307 (noting a "clinical suspicion of a paraneoplastic CIDP related to her [CLL]"); Pet'r's Ex. 13 at 11 (noting "a roughly [three] year history of CIDP which has occurred in conjunction with a hematologic malignancy, not an uncommon occurrence"). Petitioner's treating physicians also did not consider her flu vaccine to be related to the development of her CIDP, even when Petitioner provided a history of vaccination prior to the onset of her symptoms. *See* Pet'r's Ex. 13 at 9–11 (Petitioner reporting onset of CIDP symptoms "a few weeks" after receiving her flu vaccine to Dr. Wolfe, and Dr. Wolfe opining Petitioner's CIDP to be associated with her CLL).

Further, to the extent Petitioner's treating physicians considered a possible association between her flu vaccine and her symptoms, this was often in a setting where Petitioner self-reported a diagnosis of GBS in her history and then offered the flu vaccine as an explanation. *See* Pet'r's Ex. 1 at 178 (Petitioner self-reporting a diagnosis of GBS associated with the flu vaccine and her doctors holding subsequent vaccinations); *see also* Pet'r's Ex. 1 at 189 (Petitioner reporting that she had been diagnosed with GBS and stated it was associated with her August 2016 flu vaccine); Pet'r's Ex. 1 at 148 (Petitioner's doctors recommending avoiding future flu shots "if this is indeed [GBS]"); Pet'r's Ex. 1 at 151 (Petitioner reporting that she had GBS and that she had been told it was from her flu vaccine). However, despite Petitioner noting several times in her medical history that she had been told her GBS may have been caused by her flu vaccine, no record filed supports this assertion. Notably, Petitioner continued to tell her doctors that she suffered from GBS, and not CIDP, through 2018, long after her providers changed her diagnosis to CIDP. It is for these reasons that I find the filed 2021 letter from Dr. Hernandez-Ilizaliturri to be unpersuasive; it was Petitioner who reported to him that she had been diagnosed with GBS caused by the flu vaccine, which then led him to write his letter in support of contraindicating the COVID-19 vaccine. *See* Pet'r's Ex. 47. Notably, once Petitioner's chart was updated to reflect a diagnosis of CIDP, her providers stopped considering the flu vaccination etiology, and instead collectively opined that her CIDP was associated with her ongoing CLL. *See* Pet'r's Ex. 10 at 5 (Dr. Polston changing Petitioner's diagnosis from GBS to CIDP on August 8, 2017, and opining it was associated with her ongoing CLL).

Dr. Steinman argued that Petitioner's CIDP was not related to her CLL; however, his argument is flawed and unpersuasive. First, Dr. Steinman misconstrued Dr. Wolfe's note regarding a potential checkpoint inhibitor as being the sole causative factor for a CLL patient developing CIDP, which is not the case. In two separate notes at two separate presentations, Dr. Wolfe connected Petitioner's CIDP to her CLL independent of the presence of a checkpoint inhibitor, noting that CIDP "can be seen more commonly in the setting of chronic blood dyscrasias as in her case." Pet'r's Ex. 13 at 7. Though Dr. Wolfe did question whether a checkpoint inhibitor could

have worsened her symptoms, he in no way identified it as the sole reason for the development of her CIDP; rather, Dr. Wolfe connected CIDP as being a known complication of blood disorders such as CLL. Second, Dr. Steinman's critique of Rajabally et al. is less persuasive than Dr. Callaghan's refutation of his argument. Dr. Steinman is correct to note that Rajabally et al. did not discuss whether vaccines could have caused CIDP in the patients in this study, but whether the flu vaccine could have caused the condition in all of these patients is pure speculation, as is the assumption that most of the patients in the study received the flu vaccination. Notably, Rajabally et al. supports the assertion that CIDP can be a complication with or without checkpoint inhibitors, as they specifically excluded results from the study suspected to be associated with checkpoint inhibitor treatment to test the association of CIDP to underlying hematologic malignancies. *See* Resp't's Ex. A, Tab 3 at 3. Similarly, I find it persuasive that the authors did not feel the need to exclude patients who had received the flu vaccine from their study in the same way they excluded those who received checkpoint inhibitor treatment. This reflects a lack of concern that such a variable could significantly alter the data in the same way when analyzing a potential causal connection.

Accordingly, I find there is not preponderant evidence to show a logical sequence of cause and effect that the flu vaccine caused Petitioner's CIDP, and thus Petitioner has failed to satisfy the second *Althen* prong.

C. Causation Theory (*Althen* Prong One)

Dr. Steinman devotes significant attention in his expert reports attempting to explain the causal connection between CIDP and the flu vaccine via the theory of molecular mimicry. However, the factual questions raised by Petitioner's own medical history represent more significant (and, in fact, dispositive) issues. Prior decisions have diverged on whether GBS and CIDP are "related peripheral neuropathies that have a number of overlapping symptoms and share a common pathogenesis" despite being distinct conditions. *See Strong v. Sec'y of Health & Hum. Servs.*, No. 15-1108V, 2018 WL 1125666, at *19 (Fed. Cl. Spec. Mstr. Jan. 12, 2018) (distinguishing CIDP and GBS as separate conditions with "a common pathogenesis"); *but see Lucero v. Sec'y of Health & Hum. Servs*, No, 2026 WL 776495, at * 15 (Fed. Cl. Spec. Mstr. Feb. 20, 2026) (declining to characterize CIDP as "the chronic form" of GBS). Often, identical allegations are litigated using different experts, with similar (but not the same) theories, and different literature to fit the case's distinct facts. Given those nuances, it is not possible to extend a blanket holding on causation with respect to any particular vaccine-injury claim. It is also not necessary to make that determination in this case, because Petitioner's claim cannot overcome the lack of evidence necessary for *Althen* prongs two and three. Dr. Steinman's theory, as articulated, is inapplicable to Petitioner's presentation; therefore, for her purposes, it is irrelevant.

VII. Conclusion

After a careful review of the record, Petitioner has failed to provide preponderant evidence that her August 22, 2016 flu vaccine caused her 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). [31]

IT IS SO ORDERED.

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

[31] 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.