# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 22-01V**

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| CHRISTOPER BOST, | * | Chief Special Master Corcoran |
| Petitioner, | * | Filed: March 18, 2026 |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

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

*Dima Atiya*, U.S. Department of Justice, Washington, DC, for Respondent.

## RULING ON ENTITLEMENT[1]

On January 4, 2022, Christopher Bost filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§ 300aa-10 et seq. ("Vaccine Act" or "Vaccine Program").[2] Petitioner alleges that as a result of receiving a seasonal influenza ("flu") vaccine on September 18, 2020, he developed Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). *See* Petition at 1.

The matter was deemed appropriately resolved via ruling on the record, and both sides have completed briefing of their positions. *See* Petitioner's Motion, dated April 21, 2025 (ECF No. 42) ("Br."); Respondent's Opposition, dated June 23, 2025 (ECF No. 43) ("Opp."); Petitioner's Reply, dated July 21, 2025 (ECF No. 44) ("Reply"). Now the matter is ripe for resolution. For the reasons set forth in more detail below, I hereby find that the Petitioner has preponderantly established that

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

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

the flu vaccine likely did cause his CIDP, and I therefore grant entitlement.

## I. Petitioner's Medical History

*Vaccination and Initial Symptoms*

Petitioner was 57 years old at the time he received the flu vaccine on September 18, 2020. Ex. 1 at 4. He then reported a one-month history of left heel and toe pain/numbness. *Id*. at 5, 7. There is no other record evidence of any initial, if limited, adverse vaccine reaction (such as malaise or situs pain), at this time. However, Petitioner maintains in a witness statement that approximately one week later (September 26, 2020), his legs felt tired, and that he began to experience new toe numbness in his left foot. Ex. 2 at 2.

Approximately a month after vaccination (October 20, 2020), Mr. Bost saw Certified Registered Nurse Practitioner ("CRNP") Jessica Heffelfinger at St. Luke's Health Center, and reported weakening of both legs over the previous four weeks. Ex. 6 at 93. He specifically noted that he had initially experienced numbness in his toes (reported on the day of vaccination, as noted above) which had progressed, and he was now finding it difficult to climb hills or steps. *Id*. On examination, Petitioner exhibited abnormal coordination and gait, with difficulty lifting his legs. Ex. 6 at 93–94. CRNP Heffelfinger recommended an MRI of his spine and a blood test for Lyme disease, and although the antibody panel was negative, the MRI showed a discrete hypodense foci at L5, which was concerning for a neoplastic process and foraminal narrowing at L5-S1. Ex. 3 at 51; Ex. 6 at 85, 92.

Twenty days later, Petitioner went to neurosurgeon Evan S. Marlin, M.D., on November 10, 2020, and reported gait and balance issues related to the weakness in his legs and the numbness in his feet. Ex. 4 at 5. He now specifically stated that he had noticed weakness and numbness in his feet on September 26, 2020 (six days post-vaccination). *Id*. Exam revealed decreased deep tendon reflexes in Petitioner's knees and ankles, and a diminished sense of vibration in his left lower leg. Id. at 6. Dr. Marlin referred Petitioner to neurology. *Id.* On November 18, 2020, Mr. Bost underwent a CT of the abdomen and pelvis. Ex. 6 at 56. Its findings included "[c]ircumscribed 1.1 cm lesion . . . in the left kidney with borderline Hounsfield density and equivocal enhancement," gallstones, and a non-obstructing right renal calculus. *Id*. at 57.

On November 30, 2020—now more than two months post-vaccination—Petitioner had a follow-up visit with CRNP Heffelfinger for treatment of bilateral leg weakness and numbness. Ex. 6 at 47–48. An electromyogram ("EMG"), MRI of the thoracic spine and brain, and laboratory testing was ordered, and Petitioner was referred to neurology. *Id*. at 47. The MRI (performed on December 9, 2020) revealed an abnormality consistent with gait and leg weakness, but no

intracranial pathology. Ex. 3 at 7, 11, 17. It was interpreted as showing a mild thoracic degenerative spondylosis with no significant canal stenosis and no abnormal cord signal. *Id*. at 8.

Thus, by the end of 2020 (more than three months post-vaccination), Petitioner had yet to be diagnosed with CIDP, or any demyelinating polyneuropathy for that matter—although he clearly was experiencing a number of neurologic symptoms in this post-vaccination timeframe, with no etiology yet proposed for them.

*Treatment in 2021 and CIDP Diagnosis*

On January 18, 2021, Mr. Bost had a follow-up visit with CRNP Heffelfinger, and he now reported numbness in his fingertips and along his feet bilaterally. Ex. 6 at 4–5. He underwent an EMG a few days later, and its results were deemed abnormal, showing evidence of mixed motor and sensory neuropathy with acute and chronic axonal changes. Ex. 9 at 20.

On January 25, 2021, Petitioner saw neurologist Aaron C. Lasker, M.D., who was informed of Petitioner's history of ascending bilateral lower extremity weakness and numbness. Ex. 9 at 15 *Id*. On examination, Mr. Bost was unable to stand up from a chair unassisted, and ambulated with a walker. *Id*. at 16. Dr. Lasker also observed Petitioner's weakness in the lower extremities, and inability to move his feet, plus the presence of decreased knee reflexes, absent ankle reflexes, and decreased sensation in the legs. *Id*. at 16–17. Based on the results of this examination, the EMG study, and the MRI results, Dr. Lasker diagnosed Petitioner with CIDP and referred him to the hospital for admission. *Id.* at 15.

Petitioner was subsequently admitted to St. Luke's Hospital in Bethlehem, PA from January 26 – February 12, 2021. Ex. 10 at 123, 2345. On initial examination, he displayed pedal paresthesia, required a walker or cane to ambulate, had reduced strength in his arms and lower legs, and had absent strength and deep tendon reflexes in his ankles and toes, plus evidence of elevated protein in cerebrospinal fluid testing. *Id*. at 2344–45. Neurologist Shilpa R. Pradhan, D.O., analyzed Petitioner's EMG and nerve conduction studies ("NCS") of his arms and legs and found the findings to be "abnormal," showing "evidence of subacute demyelination polyneuropathy with conduction block, prolongation of distal latencies and temporal dispersion," all of which were considered to be consistent with CIDP. *Id.* at 2364. Dr. Pradhan and another St. Luke's neurologist also concurred that Petitioner's lumbar spine MRI showed an "enhancement of the nerve roots of the cauda equina consistent with an inflammatory process such as CIDP." *Id*. at 159.

While hospitalized, Petitioner received a five-day course of intravenous immune globulin ("IVIG") which ended on February 1, 2021. Ex. 10 at 2150. Petitioner had thereafter been scheduled to be discharged on February 4th, but at that time he displayed "increased numbness in

[his] bilateral hands as well as clumsiness in [his] right hand which was new," and instead was held over as an in-patient in order to receive a five-day course of plasmapheresis treatments. *Id*. These treatments resulted in some improvement, but failed to resolve petitioner's leg weakness. *Id*. Petitioner was ultimately discharged to inpatient rehabilitation on February 12, 2021, and he remained there until March 16, 2021. Ex. 10 at 123, 135. He thereafter participated in outpatient physical therapy ("PT") and occupational therapy ("OT") through July 6, 2021. Ex. 7 at 20, 77.

Petitioner subsequently saw Dr. Pradhan on four separate occasions between mid-March and early November 2021. Ex. 8 at 1–17. At the March 2021 visit, Petitioner exhibited an inability to stand or walk, but could transfer independently, and was experiencing stocking-glove pattern numbness. *Id*. at 4. He was prescribed oral prednisone and IVIG every three weeks, and it was recommended he continue PT and OT as an outpatient. *Id*. at 1–2.

By June, Petitioner was displaying improvement in his proximal muscles in his legs, and could now stand for short periods, although he was also experiencing hand weakness. Ex. 8 at 6. Petitioner could now stand for short periods of time. *Id*. In reaction (and since Petitioner did not seem to be experiencing any side effects from the IVIG treatments), Dr. Pradhan increased his IVIG dose. *Id*. The same combination of some improvement coupled with lingering weakness sequelae was observed in September 2021 and into November. *Id*. at 11; Ex. 10 at 13. Additional treatments with other medications were discussed (and the surgical implantation of a pain medication access device occurred in November). Ex. 10 at 32.

In September 2021, Petitioner also sought medical care for decreased vision in his left eye. Ex. 17 at 45. Although the vision issues were attributed to bilateral cataracts and papilledema, and MRI of the brain and optical orbit was scheduled for October. *Id*. at 49–50. The MRIs yielded normal results, and it was specifically noted that they showed "no CNS [central nervous system] inflammation." *Id*. at 43.

Records for subsequent treatment Petitioner received have been filed, but they do not aid in resolution of causation, or shed light on the parties' disputes, and are therefore not summarized or discussed herein.

## II. Experts

### A. *Petitioner's Experts*

1. Dr. Joseph Jeret – Dr. Jeret, a neurologist, prepared two reports on Petitioner's behalf. Report, dated Jan. 3, 2024, filed as Ex. 19 (ECF No. 23-1) ("First Jeret Rep."); Report, dated Aug. 15, 2024, filed as Ex. 147 (ECF No. 31-1) ("Second Jeret Rep.").

Dr. Jeret received his undergraduate degree from SUNY Brooklyn College, New York in 1984, and his medical degree from SUNY Health Science Center at Brooklyn in 1988. Curriculum Vitae, filed as Ex. 20 (ECF No. 23-2) ("Jeret CV") at 1. Thereafter, he completed a one-year general internal medicine preliminary year at Maimonides Medical Center, followed by a three-year residency in Neurology and a one-year fellowship in Clinical Neurophysiology at SUNY Downstate. *Id.* He is board certified in Neurology by the American Board of Psychiatry and Neurology and is currently employed by Optum Health Care as an active neurologist and is on staff at two community hospitals—Mount Sinai South Nassau Hospital and Mercy Medical Center. *Id.*; Jeret Rep. at 1. Dr. Jeret has published numerous articles in areas related to neurology, reflecting his broad general practice. *Id.* at 2–7; Jeret Rep. at 2.

*First Report*

Dr. Jeret's initial report included a review of Petitioner's medical history. First Jeret Rep. at 5–14. Based upon Petitioner's clinical symptoms, course, and EMG/NCS testing, Dr. Jeret concluded that Petitioner likely had CIDP. *Id.* at 14, 16. Dr. Jeret defined CIDP as falling within the context of other, related peripheral neuropathies, like GBS. *Id.* at 3–4. He deemed CIDP the "chronic counterpart" to GBS, highlighting the fact that both are immune-mediated, driven in part by damaging inflammation, involve demyelination (damage to a nerve's myelin sheath), and impact more than one nerve (hence "polyneuropathy"). *Id.*

The diagnostic criteria for CIDP, Dr. Jeret maintained, has been heavily debated for years. First Jeret Rep. at 4. The diagnostic criteria used by Dr. Jeret comes from the European Federation of Neurological Societies/Peripheral Nerve Society ("EFNS/PNS"), which requires:

1. Clinical: CIDP should be considered in any patient with a progressive polyradiculoneuropathy that progresses over more than 2 months.
2. Electrodiagnostic: at least one of the following:
    i. Distal motor latency prolonged > 50% from ULN in 2 nerves
    ii. Motor NCV reduced > 30% below LLN in 2 nerves
    iii. F-wave prolonged > 30% ULN in 2 nerves (> 50% if motor amplitude reduced <80% below LLN)
    iv. Absent F-waves in 2 nerves (with other criteria)
    v. Partial motor conduction block in 1-2 nerves (with other criteria)
    vi. Abnormal temporal dispersion in 2 nerves
    vii. Increased motor action potential duration

Joint Task Force of the EFNS and the PNS, *EFNS/PNS Guideline on Management of Chronic Inflammatory Demyelinating Polyradiculoneuropathy: Report of a Joint Task Force of the EFNS and PNS,* 12 J. Periph Nerv. Systm. 1–9 (2010), filed as Ex. 31 (ECF No. 23-13) ("EFNS/PNS

Guideline"). Based on Petitioner's medical history, Petitioner had satisfied these elements and was correctly diagnosed with CIDP, Dr. Jeret opined. First Jeret Rep. at 14.

Vaccines generally, Dr. Jeret maintained, are associated with CIDP. First Jeret Rep. at 4; K. Gorson & A. Ropper, *Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP): A Review of Clinical Symptoms and Treatment Approaches in Clinical Practice*, 4 J. Clin Neuromusc. Dis. 174, 177 (2003), filed as Ex. 29 (ECF No. 23-11) ("Gorson & Ropper"); P. McCombe et al., *Chronic inflammatory demyelinating polyradiculoneuropathy: A clinical and electrophysiological study of 92 cases*, 110 Brain 1617–30, (1987), filed as Ex. 34 (ECF No. 23-16) ("McCombe"). And Dr. Jeret deemed molecular mimicry (an autoimmune mechanism in which foreign antigens with similarity to a self-structure/tissue result in the production of antibodies against the antigen that mistakenly then attack self) an "immune error" that could trigger demyelinating neuropathies like GBS or CIDP. First Jeret Rep. at 15–16. The flu vaccine in particular could cause CIDP. *Id.* at 16. One study in particular found that 11% of CIDP patients had prior vaccinations, including the flu vaccine. *Id.* ((citing K. Kuitwaard et al., *Recurrences, Vaccination, and Long-Term Symptoms in GBS and CIDP,* 14 J. Periph. Nerv. Sys. 310, (2009), filed as Ex. 86 (ECF No. 25-11) ("Kuitwaard")).

Dr. Jeret also opined that Petitioner's CIDP did not begin before his flu vaccine. First Jeret Rep. at 14. Based on Petitioner's medical records, any pre-vaccination toe numbness was likely an outlier. *Id.* Multiple providers who reviewed Petitioner's history also did not believe this was not the beginning of Petitioner's CIDP symptoms. *Id.* Further evidence of pre-vaccination toe numbness being unrelated to Petitioner's CIDP was evident from the treater who administered the flu vaccine (since it was likely vaccination would not have been recommended otherwise). *Id.*

*Second Report*

Dr. Jeret used his second report to respond to Dr. Hawse's and Dr. Bromberg's reports and the criticisms of his arguments. Second Jeret Rep. at 1. Dr. Jeret asserted that Dr. Hawse had failed to appreciate how the flu vaccine-GBS association could be applied to CIDP as well. *Id.* The Vaccine Table finds such a relationship between the flu vaccine and GBS, which is sufficient of causation in and of itself for a Table claim. *Id.* Therefore, Dr. Hawse improperly minimized the epidemiologic evidence that the flu vaccine is causally associated with GBS, and how it can be used to show a causal relationship between the flu vaccine and CIDP. *Id.* Dr. Jeret also criticized Dr. Hawse's argument that the flu vaccine cannot both reduce the risk of GBS and also cause it. *Id*. at 1–2. While vaccines do prevent disease, they can also cause injury in rare cases (as evidenced by the petitioners who bring claims before the Program). *Id.*

Dr. Jeret agreed with Dr. Bromberg's opinion that the Petitioner did not suffer from GBS, and that some of Petitioner's symptoms can be seen with CIDP. Second Jeret Rep. at 2. This

included the fact that elevated CSF protein is not by itself diagnostic of CIDP; that papilledema is not a diagnostic clue; and that enlarged lumbosacral nerve roots, while associated with CIDP, are not definitive for diagnosis. *Id.* However, where the two disagreed was on the propriety of the CIDP diagnosis. Dr. Bromberg did not believe Petitioner's EMG/NCV results reflected CIDP. *Id.* Dr. Bromberg went so far as to claim that Petitioner's EMG results did not satisfy the EFNS/PNS diagnostic criteria—which contradicted his previous statements—and that Petitioner's exam was performed incorrectly by his treating providers. *Id.* Dr. Jeret pointed out Dr. Bromberg's contradiction, and Dr. Bromberg's concession that he has no evidence that the EMG test was improperly performed. *Id.*

Dr. Jeret otherwise defended his CIDP diagnosis. Not only did Petitioner's medical records satisfy the EFNS/PNS criteria, but multiple treating providers had diagnosed Petitioner with CIDP. Second Jeret Rep. at 3. Further, while Dr. Bromberg believed that these treating providers were mistaken in their diagnosis, Dr. Jeret held that their medical opinion should not be dismissed simply because formal research criteria were not fully met. *Id.* Dr. Jeret cited a 2023 study showing that 73.2% of CIDP patients do not satisfy the newest EFNS/PNS criteria, thereby underscoring the clinical legitimacy of Mr. Bost's diagnosis. *Id.* (citing K. Gable, *Chronic Immune-Mediated Demyelinating Neuropathies*, 29 Continuum 1357–77, (2023), filed as Ex. 149 (ECF No. 39-1) ("Gable")).

2. Dr. Noga Or-Geva – Dr. Or-Geva is a neuroimmunology research scientist who prepared two written reports on behalf of Petitioner advocating that the flu vaccine could cause a peripheral neuropathy like CIDP. Report, dated Jan. 3, 2024, filed as Ex. 21 (ECF No. 24-1) ("First Or-Geva Rep."); Report, dated Aug. 15, 2024, filed as Ex. 148 (ECF No. 31-2) ("Second Or-Geva Rep.").

Dr. Or-Geva received her bachelor's degree from Tel Aviv University, and her master's degree and Ph.D. in Immunology and Regenerative Medicine at the Weizmann Institute of Science. Curriculum Vitae, filed as Ex. 22 (ECF No. 24-2) at 1. She is currently a research scientist in Neuroimmunology and Transplantation Medicine at Stanford University, where she conducts research on post-infectious neuroimmune and psychiatric disease aimed at the discovery of novel mechanisms and the identification of biomarkers to improve patient treatment. *Id.* She has also published numerous articles in areas related to neuroimmunology. *Id.* at 2–3.

*First Report*

Dr. Or-Geva concluded that the Petitioner's CIDP developed in large part by the flu vaccine. *See* First Or-Geva Rep. at 38. Her first report centered around her review of the case and laying out her causal theory. She began by including a summary of Petitioner's medical history, an overview of autoimmune disease processes, and how vaccines might arguably relate to them (through the

functioning of the immune system). *See generally id.* While Dr. Or-Geva's credentials and expertise do not extend to diagnosing neurologic conditions, she accepted the CIDP diagnosis.

CIDP, Dr. Or-Geva contended, is known as an acquired autoimmune condition affecting the peripheral nervous system in approximately up to eight out of 100,000 individuals. First Or-Geva Rep. at 22 (citing H. Koller et al., *Chronic Inflammatory Demyelinating Polyneuropathy*, 352 N Engl J Med 1343 (2005), filed as Ex. 83 (ECF No. 25-8); J. Vallat et al., *Chronic inflammatory demyelinating polyradiculoneuropathy: diagnostic and therapeutic challenges for a treatable condition*, 9 Lancet Neurol. 402, (2010), filed as Ex. 132 (ECF No. 26-22) ("Vallat")). Its exact cause remains unidentified, but studies suggest that both cell-mediated and antibody-mediated immune responses are likely contributors. *Id.* (citing Y. Rajabally et al., *Antecedent Infections and Vaccinations in Chronic Inflammatory Demyelinating Polyneuropathy: A European Collaborative Study,* 64 Muscle & Nerve 657–61, (2021), filed as Ex. 116 (ECF No. 26-6)). Unlike GBS, where many cases are preceded by infections, only a small fraction of CIDP cases follow an infectious or post-vaccination event. *Id.* at 13–16.

The pathogenesis of CIDP involves multiple steps that could be implicated by or involve an immune response. T-helper cells (T cells that assist B cells in the production of antibodies) have been found to be elevated in CIDP, while T-regulatory cells have generally been recorded in lower numbers in CIDP patients. First Or-Geva Rep. at 10, 14 (citing L. Chi et al., *Impairment of Circulating CD4+ CD25+ Regulatory T Cells in Patients with Chronic Inflammatory Demyelinating Polyradiculoneuropathy*, 13 J. Peripheral Nervous System 54–63, (2008), filed as Ex. 54 (ECF No. 24-12) ("Chi")). This combination would reflect a skewing towards an inflammatory autoimmune chronic response. *Id.* at 14. Dr. Or-Geva opined that flu vaccines are known to provoke a comparable immune response—giving weight to the probability that the flu vaccine can cause CIDP. *Id.* at 25–26.

In addition, Petitioner had displayed indicators of immune dysregulation, including elevated cerebrospinal fluid protein, heightened inflammatory markers in the blood, and increased autoantibodies. First Or-Geva Rep. at 23, 35–36. Dr. Or-Geva opined that this immune dysregulation, in the absence of alternative triggers, pointed to an unresolved vaccine-induced autoimmune response—likely instigated by molecular mimicry between vaccine components and self structures. *Id.* at 35–36.

To support her opinion, Dr. Or-Geva conducted a homology analysis between the components of the 2020–21 Flublok Quadrivalent influenza vaccine and human neural proteins associated with CIDP. First Or-Geva Rep. at 30. Studies have shown that 50% amino acid similarity between host and vaccine proteins is sufficient to instigate an immune response. *Id.* at 10 (citing R. Root-Bernstein, *Rethinking Molecular Mimicry in Rheumatic Heart Disease and Autoimmune Myocarditis: Laminin, Collagen IV, CAR, and B1AR as Initial targets of Disease,* 2 Frontiers in

Pediatrics 1–17, (Aug. 2014), filed as Ex. 118 (ECF No. 26-9) ("Root-Bernstein")). Dr. Or-Geva conducted a BLAST[3] search between the Flublok vaccine and human proteins looking for results that had greater than fifty percent homology in a ten amino acid chain. *Id.* at 31. The results of Dr. Or-Geva's BLAST analysis between the Flublok vaccine and human neural proteins found that vaccine hemagglutinin proteins shared both sequence and structural similarity with human neural proteins such as Contactin-1, Contactin-2, Neurofascin, and Myelin associated glycoprotein. *Id*. at 31–33. From these results, Dr. Or-Geva reasoned that the similarities between the vaccine and these proteins provided a pathway for molecular mimicry to occur. *Id.* at 33.

Dr. Or-Geva's conclusions were, she contended, mirrored in reliable scientific literature. First Or-Geva Rep. at 36. Epidemiological data reveals that a small percentage of individuals experience CIDP-like symptoms after receiving a flu vaccine. *Id.* Also, animal models (specifically, Experimental Allergic Neuritis ("EAN") and Spontaneous Autoimmune Peripheral Polyneuropathy ("SAPP")), have been instrumental in helping medical science understand CIDP, by providing further information about the condition's likely pathologic features. *Id.* (citing K. Hagen & S. Ousman, *The Immune Response and Aging in Chronic Inflammatory Demyelinating Polyradiculoneuropathy*, 18 J. Neuroinflammation 1, 12 (2018), filed as Ex. 75 (ECF No. 24-33)). CIDP is likely a multifactorial autoimmune disease that involves innate immunity, T-cell responses, and autoantibody attacks, and not solely mediated by autoantibodies (as once previously thought). *Id*. Dr. Or-Geva acknowledged that the Flublok vaccine has not undergone direct testing in CIDP animal models, but held that the parallels with GBS research and Petitioner's presentation support biologic possibility. *Id.*

Dr. Or-Geva also discussed some post-vaccination studies purportedly establishing a connection between vaccination and the triggering of CIDP. First Or-Geva Rep. at 19. These studies show that although CIDP is less frequently associated with preceding infections and/or vaccines than GBS, it still can be seen to follow infection in a meaningful percentage of post-vaccination instances. *Id.* (discussing P. Doneddu et al., *Atypical CIDP: diagnostic criteria, progression and treatment response. Data from the Italian CIDP Database*, 90 J. Neurol. Neurosurg. Psychiatry 125–32, (2019), filed as Ex. 29 (ECF No. 23-9) ("Doneddu") ((finding that an antecedent event, such as vaccination, occurred within one to forty-two days before CIDP onset in 1.5% of the studied cohort)).

Dr. Or-Geva ended her first report maintaining Petitioner's CIDP onset likely began eight days post-vaccination, consistent with an accelerated onset often seen in patients with acute-onset

[3] According to its own website, the "Basic Local Alignment Search Tool" (BLAST) "finds regions of local similarity between sequences. The program compares nucleotide or protein sequences to sequence databases and calculates the statistical significance of matches. BLAST can be used to infer functional and evolutionary relationships between sequences as well as help identify members of gene families." *See* https://blast.ncbi.nlm.nih.gov/Blast.cgi (last visited Mar. 17, 2026). It is common in the Program for immunology experts to utilize BLAST searches when arguing about whether a vaccine's protein components mimic self-structures.

CIDP. First Or-Geva Rep. at 37–38. Roughly 16% of CIDP patients experience symptoms onset within eight weeks of a suspected trigger, with a more rapid onset in some instances (even if CIDP usually begins in a more insidious manner, and over time). *Id.* This kind of onset is consistent with the recognized general risk timeframe for many autoimmune injuries. *See id.* (citing *Adverse Effects of Vaccines: Evidence and Causality* (K. Stratton et al., eds., 2012), filed as Ex. 44 (ECF No. 23-24) (the "2012 IOM Report") (reporting a heightened risk of autoimmune reactions within the first six weeks after vaccination)).

*Second Report*

Dr. Or-Geva's authored a second report affirming her causation theory and responding to criticisms of Dr. Hawse. *See generally* Second Or-Geva Rep. The main criticism she had to overcome was Dr. Hawse's contention that there was insufficient evidence to support the causal theory.

Dr. Hawse claimed that Dr. Or-Geva provided no evidence to suggest that the flu vaccine induces bystander activation (a secondary and more non-specific immune cross-reactive response occurring in the wake of a primary response), but she provided scientific articles that, she contended, demonstrated the flu vaccine led to the expansion of both specific and nonspecific B cells that support the presence of vaccine-induced bystander effects. Second Or-Geva Rep. at 3 (discussing F. Horns et al., *Memory B Cell Activation, Broad Anti-influenza Antibodies, and Bystander Activation Revealed by Single-Cell Transcriptomics,* 30 Cell Reps. 905–13, (2020), filed as Ex. 159 (ECF No. 39-11)). In addition, Dr. Or-Geva conceded Dr. Hawse's argument that there was no evidence linking T cell cross-reactivity to post-flu vaccination CIDP, but held that this did not invalidate the causal hypothesis. *Id.* at 5. It is true that cross-reactivity is a common feature of T cells that does not regularly lead to autoimmune disease. *Id.* But such an activation *could* lead to an autoimmune response mediated by molecular mimicry or bystander activation, as seen in molecular mimicry's role in GBS. *Id.*

Dr. Or-Geva also defended her use of articles not directly relevant to both the flu vaccine and CIDP. The lack of direct evidence of a causal link between the flu vaccine and CIDP does not speak against the existence of the potential link. Rather, Dr. Or-Geva maintained, seeing case report or passive surveillance evidence that vaccines trigger autoimmune diseases "underscore[s] the potential for similar immunological mechanisms to occur with the flu vaccination." Second Or-Geva Rep. at 6. Dr. Or-Geva also used articles that discussed the flu vaccine and GBS and applied their logic to the flu vaccine and CIDP because the two are related neuropathies that share many of the same characteristics. *Id.* at 7–8. In addition, Dr. Or-Geva offered case reports and studies that discussed known infectious causes of GBS, COVID-19, or multiple sclerosis. *Id.* at 6–8. Dr. Or-Geva acknowledged that she was not suggesting that CIDP is associated with these, but that such evidence helped exemplify that similar immunological mechanisms shown in various

vaccines could also apply to the flu vaccine. *See id.* at 8, 10. And Dr. Or-Geva's intent with using articles that discussed other causes of CIDP (like melanoma-associated CIDP) was to illustrate that molecular mimicry can come from different sources, like tumors or vaccines. *Id.*

In addition, Dr. Or-Geva addressed challenges to her use of sequence and structural alignment tools to identify homology between the components of the flu vaccine and human proteins. Second Or-Geva Rep. at 4–5, 12–13. She maintained that a sequence of five out of ten peptides in an amino acid chain was sufficient to prove homology based on foundational studies. *Id.* at 4 (citing Root-Bernstein). Sequence structure alignment tools, like BLAST searches and 3-D models, are widely recognized and commonly used tools to perform sequence alignments. To show this, Dr. Or-Geva provided numerous articles supporting their use to identify potential molecular mimics. *Id.* at 12–13 (citing, *e.g.,* Root-Bernstein).

Dr. Or-Geva also corrected Dr. Hawse's assessment of some of her arguments. For instance, Dr. Hawse had asserted that Dr. Or-Geva's argument that the flu vaccine both reduces instances of GBS by preventing the flu, but also contribute to autoimmune reactions and the development of CIDP, is counter intuitive. Second Or-Geva Rep. at 1–2. In fact, both were possible. Dr. Hawse also opined that an increase in T regulatory cells seen after influenza vaccination would likely bulwark an immunity response. *Id*. In reaction, Dr. Or-Geva noted that Dr. Hawse's arguments did not account for the functional competence of regulatory T cells. *Id.* Even with a greater amount of T regulatory cells after vaccination, if those cells were functionally impaired, then they could fail to stop an autoimmune disease like CIDP. *Id.*

B. *Respondent's Witnesses*

1. Dr. Mark Bromberg – Dr. Bromberg, a neurologist, prepared two written reports on behalf of Respondent. Report, dated Apr. 18, 2024, filed as Ex. C (ECF No. 28-20) ("First Bromberg Rep."); Report, dated Oct. 28, 2024, filed as Ex. F (ECF No. 34-2) ("Second Bromberg Rep.").

Dr. Bromberg received his Ph.D. in Neurophysiology from the University of Vermont in 1973 and subsequently undertook a National Institute of Health Postdoctoral Fellowship at the University of Washington's Department of Physiology and Biophysics where he researched the peripheral nervous system. Curriculum Vitae, dated Apr. 18, 2024, filed as Ex. D (ECF No. 28-28) ("Bromberg CV") at 1. Afterwards, he pursued and obtained his M.D. from the University of Michigan, where he stayed to complete his residency in their Department of Neurology. *Id.* Dr. Bromberg has a lifelong certification in neurology from the American Board of Psychiatry and Neurology. First Bromberg Rep. at 1. Currently, Dr. Bromberg is an academic neurologist teaching at the University of Utah's Department of Neurology. where he performs clinical research focusing on neuromuscular disorders. Bromberg CV at 1; First Bromberg Rep. at 1. Dr. Bromberg's

research has led him to author over one hundred scientific articles, book and journal chapters, and reviews relating to neurology. *See* Bromberg CV at 19–43.

*First Report*

Relying on his understanding of CIDP and neuropathies, Dr. Bromberg contended that the CIDP diagnosis was not consistent with Petitioner's medical record or treatment course. First Bromberg Rep. at 9. He began with a full overview of Petitioner's medical history. *Id.* at 2–8. Dr. Bromberg noted, for example, that Petitioner was complaining about toe numbness before receiving the vaccine. *Id.* at 9. This toe numbness progressed into bilateral leg weakness. *Id.* Dr. Bromberg claimed that numbness preceding weakness is consistent with the course of peripheral neuropathies. *Id.* Therefore, Petitioner's symptoms likely began before vaccination. *Id.*

Dr. Bromberg then argued that Petitioner's underlying nerve pathology did not fit with CIDP. First Bromberg Rep. at 9. Dr. Bromberg provided his own description of CIDP based on the 2010 EFNS/PNS diagnostic criteria. *Id.* (citing EFNS/PNS Guideline). Based on these criteria, Dr. Bromberg opined that Petitioner did not meet the requirements for CIDP. *Id.* The Petitioner's medical records did not exhibit signs of absent tendon reflexes, his neuropathy only affected his distal arm nerves late into its progression, and his overall progression had extended longer than eight weeks. *Id.* at 9–10.

Looking at electrodiagnostic criteria of Petitioner's nerves, Dr. Bromberg conceded that Petitioner's electrodiagnostic test results did satisfy EFNS/PNS criteria, but just barely. First Bromberg Rep. at 10–12. Petitioner's motor nerve conduction study fulfilled the EFN/PNS criteria with a more than 30% reduction of proximal relative to the distal negative peak CMAP amplitude for the right and left median and the right ulnar motor nerves. *Id.* at 10–11. However, Dr. Bromberg noted inconsistencies in Petitioner's nerve conduction study results that would make a CIDP diagnosis improbable. *Id.* at 11. For example, Petitioner showed "uniform slowing," which is not internally consistent for CIDP. *Id.* Similarly, Dr. Bromberg expressed concern that Petitioner's nerve conduction studies were not properly conducted as there were only eight shocks to elicit F-waves instead of the customary ten to twenty. *Id.*

Dr. Bromberg also expressed doubts about Petitioner's CIDP diagnosis due to Petitioner's inadequate response to IVIG treatment. First Bromberg Rep. at 12. Dr. Bromberg maintained that CIDP is expected to respond to treatments such as IVIG, prednisone, and plasmapheresis. *Id.* However, the Petitioner did not respond to treatment for extended periods of time. *Id.* Therefore, Dr. Bromberg opined that Petitioner did not have an immune-mediated or immune-treatment responsive neuropathy—which would exclude a diagnosis of CIDP. *Id.* Because Petitioner did not fulfill the EFNS/PNS diagnostic criteria for CIDP, Dr. Bromberg held that differential diagnoses must be considered. *Id.* at 13–15.

Dr. Bromberg questioned as well Dr. Jeret's failure to comment on Petitioner's lack of distal and proximal weakness and the preservation of Petitioner's reflexes, plus some inconsistencies with Petitioner's electrodiagnostic criteria, and Petitioner's lack of treatment response. First Bromberg Rep. at 16–17. These omissions undermined Dr. Jeret's diagnosis, in Dr. Bromberg's opinion. *See id.*

*Second Report*

Dr. Bromberg's supplemental report reiterated his observations and beliefs about Petitioner's diagnosis. Second Bromberg Rep. at 1. CIDP, he noted, is an immune-mediated neuropathy the diagnosis of which relies on testing, clinical presentation, and response to treatment to diagnose. *Id.* The Petitioner's clinical presentation and medical records, however, were inconsistent with that diagnosis. *Id.* While Dr. Jeret noted that not all CIDP patients satisfy the EFN/PNS diagnostic criteria, Dr. Bromberg maintained that the clinical, electrodiagnostic features, and response to treatment for a chronic immune-mediated neuropathy were not met in this case. *Id.* For example, Petitioner did not exhibit a progression of weakness; did not lose his reflexes, contradictory to what Dr. Jeret claimed; and did not experience a clear response to treatment for immune-mediated neuropathies. *Id.* Rather, Dr. Bromberg held that Petitioner's injury progression had features of an axonal neuropathy, and other diagnoses beyond CIDP should be evaluated. *Id.*

2. Dr. William Hawse – An academic immunologist, Dr. Hawes offered two written expert reports on Respondent's behalf. Report, dated Apr. 18, 2024, filed as Ex. A (ECF No. 28-1) ("First Hawes Rep."); Report, dated Oct. 28, 2024, filed as Ex. E (ECF No. 34-1) ("Second Hawes Rep.").

Dr. Hawse is an Assistant Professor in the Department of Immunology at the University of Pittsburgh School of Medicine. *See* Curriculum Vitae, dated Apr. 18, 2024, filed as Ex. B (ECF No. 28-19) ("Hawse CV") at 1. He earned his Ph.D. in Biophysical Chemistry at Johns Hopkins and currently runs a laboratory studying CD4+ T-cell generation and immune tolerance to inform therapeutic strategies for autoimmune diseases. *Id.*; First Hawse Rep. at 1. Dr. Hawse has published multiple peer-reviewed articles on the subject. Hawse CV at 2–5. He is not, however, a medical doctor or experimental clinician, and thus does not offer commentary on diagnosis. *See* First Hawse Rep. at 2.

*First Report*

Dr. Hawse's first expert report focused on analyzing and responding to Dr. Or-Geva's immunological theory. The main thrust of Dr. Hawse's criticisms regarded his belief that there

was a general lack of direct evidence linking vaccine-induced immune changes to CIDP's pathogenesis. *See generally* First Hawse Rep. While Dr. Or-Geva's theory invoked several immune-mediated mechanisms for autoimmune diseases—epitope spreading, bystander activation, and molecular mimicry—there was a lack of reliable evidence that the flu vaccine can cause CIDP, with evidence suggesting the opposite. *Id.* at 4. Scientific studies, for example, do not observe significant bystander activation as occurring in individuals who have received a flu vaccine. *Id.* (citing F. Wimmers et al., *The Single-Cell Epigenomic and Transcriptional Landscape of Immunity to Influenza Vaccination*, 184 Cell 3915–35, (Jul. 22, 2021), filed as Ex. A Tab 9 (ECF No. 28-10); K. Murali-Krishna et al., *Counting Antigen-Specific CD8 T cells: A Reevaluation of Bystander Activation During Viral Infection*, 8 Immunity 177–87, (Feb 1998), filed as Ex. A Tab 3 (ECF No. 28-4); S. Ehl et al., *Bystander Activation of Cytotoxic T cells: Studies on the Mechanism and Evaluation of In Vivo Significance in a Transgenic Mouse Model*, 185 J. Exp. Med. 1241–51 (Apr. 7, 1997), filed as Ex. A Tab 4 (ECF No. 28-5)). In addition, the studies provided did not support a direct causal link between the flu vaccine and CIDP. *Id.* at 13 (discussing Vallat at 402 ("[h]owever, by contrast with GBS, a single triggering antigen has not yet been found, except in rare cases of CIDP associated with melanoma, in which tumor cells share carbohydrate epitopes with Schwann cells")).

Dr. Hawse also noted a contradiction in the logic behind Dr. Or-Geva's T cell theory. First Hawse Rep. at 3. Dr. Or-Geva had maintained that flu vaccines reduce the instances of GBS by preventing influenza—but at the same time are thought to contribute to autoimmune reactions capable of causing CIDP. *Id.* This occurs, in Dr. Or-Geva's opinion, due to a vaccine-instigated reduction in the number of T regulatory cells. *Id.* However, Dr. Hawse cited studies showing that T regulatory cells *increase* after vaccination. *Id.* (citing S. Wang et al., *The Regulatory T cells in Anti-Influenza Antibody Response Post Influenza Vaccination*, 8 Hum. Vaccine Immunotherapy 1243–49, (Sep. 2012), filed as Ex. A Tab 1 (ECF No. 28-2) ("Wang") (finding T regulatory cells increased significantly in patients after receiving the flu vaccine)). The increase in T regulatory numbers post-vaccination, as reported by Wang, would suggest increased protection from the influenza vaccination against CIDP, not the contrary. *See id.*

Dr. Or-Geva's reliance on articles that discuss different vaccines and injuries was also unpersuasive, Dr. Hawse contended. Multiple pieces of literature offered by Dr. Or-Geva involved molecular mimicry in the development of GBS after a *C. Jejuni* infection, or in the context of diseases like multiple sclerosis. First Hawse Rep. at 6 (citing First Or-Geva Rep. at 11). These articles have no bearing on CIDP's association with the flu vaccine. *Id.* at 6–7. Also, while CIDP has been characterized as the chronic form of GBS, the two demyelinating conditions have distinct pathologies, and the studies on GBS cannot be extrapolated to CIDP. *Id.* GBS has actually been recorded to follow infections in higher numbers than CIDP. *Id.* at 12 (discussing Doneddu, which suggests that antecedent events including infection or vaccination are unlikely to be causal for CIDP); B. Kieseier et al., *Immune-Mediated Neuropathies*, 4 Nature Revs. Disease Primers 31,

(2018), filed as Ex. 81 (ECF No. 25-6) (finding no pathogens associated with CIDP that have been verified)). In addition, there is strong epidemiologic data that the flu vaccine is not even properly associated with GBS. *Id.* at 7 (citing R. Baxter et al., *Lack of association of Guillain-Barre syndrome with vaccinations*, 57 Clin. Infect. Dis. 197–204, (Jul. 2013), filed as Ex. A Tab 8 (ECF No. 28-9) (finding no association between vaccination and development of GBS).

Dr. Hawse also took issue with Dr. Or-Geva's homology approach, which involved only matching common peptide chains by 50%. First Hawse Rep. at 5, 19. But a sequence of 5 out of 10 peptides in an amino acid chain is not sufficient to prove homology, as one different peptide can have significant and unpredictable immunological outcomes. *Id.* (citing L. Nicholson et al., *An Altered Peptide Ligand Mediates Immune Deviation and Prevents Autoimmune encephalomyelitis*, 3 Immunity 397–405, (Oct. 1995), filed as Ex. A Tab 6 (ECF No. 28-7)). Dr. Or-Geva held that current research indicates that limited similarities between foreign agents and host components are sufficient for an autoimmune cross-reaction, but Dr. Hawse maintained there was insufficient evidence supporting that conclusion. *Id.* at 6 (citing D. Mason, *A Very High Level of Cross Reactivity is an Essential Feature of the T-Cell Receptor*, 19 Immunol. Today 395–404, (Sep. 1998), filed as Ex. A Tab 7 (ECF No. 28-8)). If, Dr. Hawse opined, Dr. Or-Geva's contentions were true, then the estimated prevalence of CIDP would increase significantly. *Id.*

Dr. Hawse raised additional problems with reliance on molecular mimicry to explain an autoimmune cross reaction. He noted, for example, that shape homology between two proteins is not sufficient alone to predict if an antibody will cross react between two proteins. First Hawse Rep. at 20. Further, there was no evidence offered in this case that any of the proposed epitopes can elicit an autoreactive immune response, nor are there any animal models that demonstrate that these epitopes can cause CIDP. *Id.* at 19 (citing First Or-Geva Rep. at 51–58). Conducting his own review, Dr. Hawse was unable to identify a structural homologue between molecular mimic sequences between hemagglutinin and Contactin-1 (a putative self-protein involved in the pathogenesis of CIDP). *Id.* at 21–24.

*Second Report*

Dr. Hawse used his supplemental expert report responding to Dr. Jeret's criticisms of the argument that studies of other diseases and vaccines had limited application to the specific context of this case. Second Hawes Rep. at 1–2. Dr. Hawse retorted that CIDP has fundamental differences from GBS, as well as other neuropathic and/or demyelinating conditions. *Id.* at 2. Dr. Hawse reiterated that there is no peer-reviewed epidemiological evidence that supports a causal relationship between the flu vaccine and GBS anyway. *Id.* Without Drs. Jeret and Or-Geva providing new evidence relevant to how the influenza vaccination could cause CIDP, Dr. Hawse maintained, his conclusion that the flu vaccination more likely than not did not generate an autoreactive response to injure Petitioner was likely accurate.

## III. Procedural History

This matter was initiated in January 2022. After Respondent filed his Rule 4(c) Report a year later opposing entitlement, the parties began the process of obtaining expert opinions in support of their respective positions, with the final such report filed in August 2024. The parties briefed the claim on the record in 2025, and the matter is now ripe for resolution.

## IV. Parties' Arguments

***Petitioner***

Petitioner contends that he suffered CIDP caused by his receipt of a flu vaccine on September 18, 2020. Br. at 2. In his brief, Petitioner address his diagnosis plus all three prongs of the test for causation set by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

First, Petitioner asserts that his medical records, clinical presentation, diagnostic testing, treatment response, and expert opinions confirm that he suffers from CIDP. Br. at 56–61. He maintains that his pre-diagnosis evaluations and response to treatment support his diagnosis. Those records establish that he was experiencing hallmark symptoms of CIDP, which include fatigue, peripheral numbness, and lower extremity weakness. Br. at 56–57. While his symptoms started as numbness in the foot, they gradually progressed into fatigue, bilateral extremity weakness, unsteady gait that worsened until reaching a nadir in January of 2021. *Id.* As Dr. Jereth opined, Petitioner's nadir occurring months after symptom onset was indicative of a slower onset neuropathy like CIDP. *Id.* at 58. Diagnostic and EMG testing also revealed findings supportive of the diagnosis. *Id.* at 57. And his symptoms persisted despite repeated IVIG treatments—all indicative of CIDP. *Id*. at 57–58

Thus, Petitioner maintains he can satisfy the EFNS/PNS diagnostic criteria for CIDP (something even Respondent's expert grudgingly conceded). Br. at 59–60. At most, Dr. Bromberg raised concerns that Petitioner's inconsistent response to IVIG therapy and preserved reflexes undermined the diagnosis. *Id*. at 60. But Dr. Bromberg admitted that a lack of therapeutic response did not exclude CIDP either. *Id.* Also, Petitioner's record revealed declining and absent reflexes. *Id.* at 61 (citing Ex. 4 at 5–7; Ex. 10 at 2124, 2344–55). And literature offered in the case, like Gable, demonstrated that more than 70% of confirmed CIDP patients fail to meet the totality of revised EFNS/PNS diagnostic criteria. *Id.* at 60.

Second, Petitioner reviews each *Althen* prong, contending they were all satisfied. He began with the first, "can cause" prong. Br. at 85–86. In many prior decisions, other special masters have

found that the flu vaccine can cause CIDP (even if barely in some instances). *Id.* at 84–85 (*citing Davis v. Sec'y of Health & Hum. Servs.*, No. 14-978V, 2022 WL 1654743, at *55 (Fed. Cl. Spec. Mstr. Apr. 27, 2022) (granting entitlement where Petitioner claimed the flu vaccine caused his CIDP); *Nieves v. Sec'y Health & Hum. Servs*., No. 18-1602V, 2023 WL 3580148, at *46 (Fed. Cl. Spec. Mstr. May 22, 2023) (finding the evidence weighed presented a close call, thus compelling the special master to find Petitioner had preponderantly showed the flu vaccine can cause CIDP, but finding against entitlement as Petitioner did not satisfy *Althen* prong two and three), *mot. for review den'd*, 167 Fed. Cl. 422 (2023)).

Petitioner also notes that he offered reliable evidence associating CIDP with vaccination. Br. at 86. Examples of GBS following vaccination have been well-documented through the mechanism of molecular mimicry, and this theory can be extrapolated to other similar neuropathies. *Id.* (*citing* J. Brostoff et al., *Post-Influenza Vaccine Chronic Inflammatory Demyelinating Polyneuropathy*, 37 Age and Ageing 229–30, (2008), filed as Ex. 24 (ECF No. 23-6); 2012 IOM Report). And CIDP has been shown to develop after other vaccines like smallpox, polio, flu, and tetanus vaccinations. *Id.* (citing Kuitwaard at 313–14; McCombe at 1617; Gorson & Ropper at 176).

Petitioner's causation theory relies on molecular mimicry—where the flu vaccine is positive to trigger an inflammatory response due to cross-reaction between antibodies generated to components of the flu vaccine and human proteins that the vaccine components mimic. Br. at 88. Shortly after vaccination, innate immune cells (like macrophages and dendritic cells) detect viral proteins and release cytokines to alert the immune system. *Id.* Within the next few days, the immune system produces antibodies to defend against future flu exposure. *Id.* Next, the process of molecular mimicry takes place, where the immune system produces antibodies that mistake host proteins for vaccine components based on similar makeup resulting in a cross-reactive attack. *Id.* at 90. Thereafter, a number of secondary, aberrant immune reactions (like bystander activation of nonspecific immune cells) can contribute to the damaging autoimmune process. *Id.* at 91–93 (citing Chi at 60–61).

Dr. Or-Geva's reports, Petitioner maintained, establish that molecular mimicry is well-supported in scientific literature, and that short peptide matches between vaccine components and host proteins are sufficient for the cross-reaction due to mimicry to occur. Br. at 90 (citing Root-Bernstein). And, Dr. Or-Geva's BLAST results established the existence of amino acid chains in the Flublok vaccine that share over 50% homology in human host proteins. *Id.* at 90–91. Such homology would be sufficient for an autoimmune process leading to CIDP to occur. *Id.* at 94–96. Dr. Or-Geva further emphasized the individuals who experience this adverse reaction might also be predisposed to underlying sensitivities influenced by genetic and environmental factors. *Id.*

Next, Petitioner argues that he has preponderantly showed that the flu vaccine at issue

likely did cause his injury. The relevant inquiry on whether a vaccine *did* cause injury, Petitioner maintained, is based upon record evidence of a clinical course consistent with the mechanism and time frame within which the injury *can* occur following vaccination. Br. at 99 (citing *Introini v. Sec'y of Health & Hum. Servs.,* No. 20-176V, 2022 WL 16915818 (Fed. Cl. Spec. Mstr. Oct. 19, 2022)). Petitioner's proposed medical theory is consistent with the development of autoimmune disorders, he argues, based on his experts, medical records, and current scientific understanding of autoimmune disorders. Relevant medical records show that Petitioner started experiencing symptoms eight days after vaccination that progressed into numbness in his toes and calves alongside progressive weakness—symptoms indicative of an autoimmune response by day sixteen *Id.* at 101–03. His condition continued to worsen over the subsequent months following an ascending pattern consistent with immune-mediated neuropathies. *Id.* During this time, Petitioner's physicians ruled out differential diagnoses of infection, malignancy, or metabolic disorders—leaving a diagnosis of CIDP. *Id.* at 103.

Finally, Petitioner contends that he has preponderantly shown that the timing of his onset was medically appropriate, measured from the time of his vaccination. *See* Br. at 103–11. The record establishes that Petitioner's onset occurred eight days after vaccination. *See id.* at 104. While there is evidence of pre-vaccination toe numbness, Petitioner argues that this symptom (and the heel pain, fatigue, and skin tags he also complained of at his September 18, 2020, visit) were minor, localized, non-specific, and isolated from a neurologic dysfunction. *Id.* at 105 (citing Ex. 1 at 5, 8, 10). Petitioner's first symptoms of true neurologic dysfunction appeared September 26, 2020, when he experienced fatigue in his legs and a new numbness in the toes of his left foot that progressed into fatigue and new numbness in his toes, and bilateral leg weakness. *Id.* Petitioner thereafter continued to relay to his medical providers that his neurologic symptoms began after a walk on September 26, 2020, and both Drs. Or-Geva and Jeret concur that this was the most likely onset date based on Petitioner's medical history. *Id.* at 107–08.

Petitioner acknowledges that autoimmune diseases involve a complex interplay between the innate and adaptive immune system that takes time to develop. Br. at. 107. And, while an eight-day onset is generally considered short for immune-mediated injuries, Petitioner's experts confirmed it could be medically appropriate. *Id.* at 107–11. Dr. Or-Geva noted that 16% of patients with CIDP develop symptoms within eight weeks if they are experiencing a form of acute CIDP. *Id.* at 107–08 (citing First Or-Geva Rep. at 37). The timeframe at issue in this matter was consistent with that longer period. *See id.* at 107–11.

Petitioner also filed a reply, which largely reiterated these prior points.

***Respondent***

Respondent disputes both the Petitioner's alleged CIDP diagnosis and his success in

satisfying his burden under *Althen*. Opp. at 1–2.

Establishing a claimant's injury can be a prerequisite to analyzing causation-in-fact. *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010). Here, Respondent deems the CIDP diagnosis to lack preponderant support based on Dr. Bromberg's findings. Opp. at 9, 15. Dr. Bromberg stressed that fulfillment of diagnostic criteria for CIDP is set forth by the EFNS/PNS, as CIDP is commonly misdiagnosed. *Id.* And those criteria are not met. *Id.* at 15–16. For example, one diagnostic requirement is "absent reflexes or reduced reflexes in all limbs." *Id.* at 15 (citing First Bromberg Rep. at 9). But Petitioner maintained his arm and knee reflexes. *Id.* (citing First Bromberg Rep. at 9).

Petitioner's neurologic and limb muscle evaluation results were also inconsistent with CIDP. Opp. at 16–17. Petitioner's motor nerve EMG results returned findings that only marginally met the EFNS/PNS criteria, and were missing some features that would be normal to observe in CIDP patients. *Id.* at 16 (citing First Bromberg Rep. at 10–11). Petitioner's sensory nerve test results, while consistent for CIDP, returned abnormalities present in large fiber neuropathies generally and are not specific to CIDP. *Id.* at 17 (citing First Bromberg Rep. at 12). Petitioner's reaction to treatment was also inconsistent with CIDP. Opp. at 17. As Dr. Bromberg noted in his report, patients with CIDP usually respond positively to either IVIG, prednisone, and/or plasmapheresis treatment. *Id.* (citing First Bromberg Rep. at 12). But Petitioner did not respond to any of these treatments over an extended period of time. *Id.* Lack of positive response indicates to Dr. Bromberg and Respondent that the Petitioner did not likely have an immune-mediated or immune-treatment responsive neuropathy. *Id.*

Respondent next attacked Petitioner's causation-in-fact claim, arguing that Petitioner has failed to submit preponderant evidence that would satisfy the *Althen* prong requirements. First, he contended that Petitioner has not set forth a reliable medical theory establishing causation between the flu vaccine and CIDP. Opp. at 18. There is no reliable, scientific evidence demonstrating that the influenza vaccine, or any of its components, can cause CIDP via molecular mimicry. *Id.* at 19. Dr. Jeret simply relies on the mere mention of molecular mimicry to support his theory. *Id.* And the studies he cites either do not relate to both the flu vaccine and CIDP, or do not conclude that there is a causal link between the two. *Id.* at 19–20. For example, McCombe retroactively looked at CIDP patients and the six-weeks preceding their neuropathy onset. Of the patients reviewed, only four patients received a preceding smallpox, tetanus, or polio vaccine before developing CIDP. *See generally* McCombe. Gorson & Ropper did not conclude there is any causal connection between vaccination and CIDP. Gorson & Ropper at 176. The authors of Kuitwaard evaluated post-vaccine symptoms in patients who were diagnosed with GBS or CIDP before revieing the subject vaccines, which does not speak to vaccine causation. Kuitwaard at 310. And Petitioner's experts conceded there is a lack of epidemiologic proof of causation between vaccines and CIDP, likely driven by the disorder's rarity. Opp. at 19 (citing Br. at 86).

In addition, Respondent noted that Dr. Or-Geva simply relies on the mere mention of some other possible mechanisms, like epitope spreading and bystander activation, to support a causation theory driven by one of those mechanisms, but without additional evidence tying the mechanism to the specific injury and/or vaccine at issue. Opp. at 20. And the evidence she provided relating to molecular mimicry itself was flawed. As Dr. Hawse noted, Dr. Or-Geva's theory regarding immune regulatory cells and the initiation of the adaptive immune response is counterintuitive, as the influenza vaccination has been seen to increase the number of T-reg cells, which would protect against autoimmune reactions. *Id.* at 21 (discussing First Hawse Rep. at 3; Wang at 1243). Dr. Or-Geva's reliance on demonstrations of sequential homology is also misplaced, since a partial amino acid chain match "is unreliable to invoke homology," given the impact of just one non-homologous amino acid in a sequence. *Id.* at 21–22. And studies cited by Dr. Or-Geva either do not relate to both the flu vaccine and CIDP, or discuss antecedent events—like infection—and CIDP not found in the present case. *See id.* at 24 (discussing Vallat at 402 (finding that antibody triggering antigens have only been found in rare cases of CIDP associated with melanoma)).

Respondent further argued that Petitioner has failed to establish that the flu vaccine likely "did cause" his injury, or that there was a medically appropriate timeframe between onset and vaccination. Opp. at 25–27. As Dr. Hawse explained, there was no reliable molecular mimic between the flu vaccine and a human protein, and there is no reliable evidence that any proposed mimics between the two can cause CIDP. *Id.* at 26 (citing First Hawse Rep. at 25). In addition, while Petitioners claims his symptoms started eight days after vaccination, the record shows that he was complaining of toe and heel numbness on the day of vaccination. *Id.* (citing Ex. 1 at 4). This not only serves to undermine Petitioner's argument that the vaccine "did cause" his injury, but also the argument that there is a medically appropriate timeframe between Petitioner's vaccine and his injury. *See id.* at 26, 28

## V. Applicable Law

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

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d

1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[4] There is no Table claim for CIDP caused by the flu vaccine.

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

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

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

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or even a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed.Cir.2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not

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

empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs*, 121 Fed. Cl. 230, 245 (2015), *vacated and remanded*, 844 F.3d 1363 (Fed. Cir. 2017).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Cerrone v. Sec'y of Health & Hum. Servs.*, 146 F.4th 1113, 1121 (Fed. Cir. 2025) (the argument that *Althen* prong one requires only a showing of plausibility "understates the burden [a petitioner] bears under the first factor in the *Althen* formulation"); *Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment,

test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

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

B. *Legal Standards Governing Factual Determinations*

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

is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

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

*Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

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

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

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

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health &*

*Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See*, *e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

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

D. *Consideration of Medical Literature*

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

## ANALYSIS

### I. Overview of CIDP and its Treatment in Prior Program Cases

CIDP is an immune-mediated demyelinating neuropathy that affects both large and small fiber peripheral nerves, resulting in symptoms of numbness, tingling, weakness, imbalance, loss of coordination and pain. *See* Gorson & Roper 174–75. CIDP shares some characteristics of GBS—but it is *not* simply a chronic form of GBS, for there are key differences in clinical presentation that distinguish the two, and they cannot be assumed to have the same pathogenic mechanisms either. In particular, CIDP progresses over a longer period of time than GBS, which features acute weakness within one to two weeks after onset. *See* Vallat at 404. In addition, little is known about CIDP's most likely causes, triggers, or pathogenesis, in comparison to GBS (where a variety of specific infectious triggers have been identified, as well as the situs of cross-reactive autoimmune attack). *Id.* at 402–03. Thus, although many Program decisions *seem to have assumed* that what is known about GBS applies fully to CIDP given their similarities, this is not a well-founded assumption.

Prior decisions have associated different vaccines with CIDP (more often than not the flu vaccine), and petitioners have settled many such cases on favorable terms.[5] *See Jastisan v. Sec'y of Health & Hum. Servs.*, No. 13-937V, 2016 WL 4761950 (Fed. Cl. Spec. Mstr. Aug. 10, 2016). I have myself acknowledged these outcomes in my own prior decisions, and the fact that such determinations should be given *some* consideration as persuasive guidance. *See, e.g., Mason v. Sec'y of Health & Hum. Servs.,* No. 17-1383V, 2022 WL 600415, at *21 (Fed. Cl. Spec. Mstr. Feb. 4, 2022); *Houston v. Sec'y of Health & Hum. Servs.*, No. 18-420V, 2021 WL 4259012, at *16 (Fed. Cl. Aug. 19, 2021); *Strong v. Sec'y of Health & Hum. Servs.*, No. 15-1108V, 2018 WL 1125666 (Fed. Cl. Spec. Mstr. Jan. 12, 2018).

I have thus been able to find that when the *flu vaccine* is at issue—as here—the reasoning applicable to the flu vaccine-GBS association (which is far better substantiated than any other covered vaccine) can be extended to CIDP, even though CIDP is not simply "chronic GBS." *See Nieves*, 2023 WL 3580148, at *45; *Mason,* 2022 WL 600415, at *27; *Strong*, 2018 WL 1125666, at *19. I have been far less willing to engage in this kind of reasoning where other vaccines are

[5] Of course, prior decisions from different cases do not control the outcome herein (and this goes double for cases that are settled, and hence resolved without a reasoned determination). *Boatmon*, 941 F.3d at 1358–59; *Hanlon*, 40 Fed. Cl. at 630. But special masters are empowered to draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs*., 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim") (emphasis added). They would therefore be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

involved[6]—but the Program's interest in consistent outcomes (coupled with the treatment of the flu vaccine as associated not just with GBS, but other acute CNS demyelinating diseases like optic neuritis and transverse myelitis) had encouraged me to reach this conclusion—even though there are good, scientifically-reliable reasons to question this association. While my prior decisions do not mandate the outcome herein, they provide helpful guidance.

## II. Petitioner Likely Experienced CIDP

A special master's function is not to diagnose vaccine-related injuries, but to determine whether it has been shown "based on the record evidence as a whole and the totality of the case . . . " that a given diagnosis possesses preponderant evidentiary support (the same standard applicable to any element of a claimant's *Althen* burden of proof). *Andreu*, 569 F.3d at 1382 (quoting *Knudsen*, 35 F.3d at 549). In many cases. determination of whether an alleged injury has been preponderantly established bears on a case's resolution. *Broekelschen*, 618 F.3d at 1349.

Here, and despite reasoned objections by Respondent's neurologic expert Dr. Bromberg, the medical record preponderates in favor of the CIDP diagnosis. As literature filed in this case establishes, there exist accepted and medically-reliable criteria for diagnosing this disorder. *See* EFNS/PNS Guideline. Dr. Jeret persuasively referenced numerous aspects of the medical record that supported Petitioner's CIDP diagnosis. Petitioner's clinical progression took between three to four months to reach its nadir, which is inconsistent with the typically rapid progression of GBS—and thus the first requirement of the EFNS/PNS CIDP diagnostic criterion was met. The second was also met, as Petitioner's test results showed prolonged distal motor latency by over 50%, slowed nerve conduction velocity by more than 30%, and abnormal temporal dispersion in two nerves. Ex. 5 at 16. In addition, Petitioner's treaters accepted the CIDP diagnosis, even when Petitioner's condition did not improve during IVIG treatments (and in any event, the record is more inconclusive as to the effects of IVIG treatment overall than in establishing its failure).

Dr. Bromberg raised fair points undermining a CIDP diagnosis, like Petitioner's preserved reflexes. However, Dr. Bromberg *did* concede that Petitioner's test results fell within the EFNS/PNS diagnostic guidelines, and there are more factors favoring the diagnosis in this case than suggesting its error. Petitioner has offered enough evidence for me to deem it more likely than not that he did experience CIDP.

[6] I have repeatedly found that CIDP has not been preponderantly shown to be caused by *other* vaccines, like Tdap—and in so doing, have rejected attempts to apply in blanket fashion evidence specific to the flu vaccine-GBS context. *See generally DeVaughn v. Sec'y of Health & Hum. Servs.*, No. 22-832V, 2025 WL 758128, at *18–21 (Fed. Cl. Spec. Mstr. Feb. 10, 2025) (Td vaccine not shown to likely cause CIDP); *Howard v. Sec'y of Health & Hum. Servs*., No. 16-1592V, 2022 WL 4869354, at *23 (Fed. Cl. Spec. Mstr. Aug. 31, 2022) ("for purposes of Program determinations, it is improper to think of GBS and CIDP as 'two sides of the same coin,' despite their overlap…Petitioners cannot just 'borrow' what is known about GBS and vaccination generally as a template for proving causation in the context of a CIDP injury"), *mot. for review den'd,* 2023 WL 4117370, (Fed. Cl. May 18, 2023), *aff'd,* 2024 WL 2873301 (Fed. Cir. June 7, 2024).

## III. Petitioner's CIDP Did Not Likely Predate Vaccination

Respondent also contends that Petitioner's CIDP likely predated vaccination, based upon evidence of his complaints of toe numbness the very day he received the flu vaccine at issue. Opp. at 15. It is of course the case that (except in the context of claims that a vaccine significantly aggravated a preexisting illness) vaccine causation cannot be shown for a condition or injury that began *before* vaccination. *Shalala v. Whitecotton*, 514 U.S. 268, 274, 115 S. Ct. 1477, 1480, 131 L. Ed. 2d 374 (1995) (quoting § 11(c)(1)(C)(i)). Thus, this matter presents the fact question of whether Petitioner's neurologic injury already existed on the day he was vaccinated.

In the Vaccine Program, onset of an alleged vaccine injury is marked by the "first symptom or manifestation of onset." *See* Section 16(a)(2). As the Federal Circuit stated in *Markovich v. Sec'y of Health & Hum. Servs*., 477 F.3d 1353, 1357 (Fed. Cir. 2007), there is a difference between a "symptom" and "manifestation of onset"—but because of the Act's use of the disjunctive "or," either can constitute the start of a disease process (even though a symptom could be nonspecific, or hard to link to what was later viewed as a full disease). *Markovich*, 477 F.3d at 1357–59. By contrast, the date of diagnosis (which may in turn result from the accumulation of clinical and testing evidence over time) does *not* mark onset. *Carson v. Sec'y of Health & Hum. Servs*., 727 F.3d 1365, 1369 (Fed. Cir. 2013). Onset may therefore have occurred even before the ill individual understands a presenting symptom to be concerning. *See Markovich*, 477 F.3d at 1357 ("[a] symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury") (emphasis added).

Here, Petitioner unquestionably reported heel and toe pain/numbness for a month prior to the date he was vaccinated—and this report was made *the day of vaccination*. Ex. 1 at 5. But the record otherwise supports onset beginning after vaccination—something Petitioner consistently reported in his subsequent medical encounters. Ex. 4 at 5; Ex. 5 at 16; Ex. 6 at 93–94. Moreover, the complaints Petitioner made at the time of vaccination had a non-specific character to them. And Petitioner was not experiencing generalized neurological issues, such as dizziness, weakness, headaches, or paresthesia at the same time that would corroborate a pre-existing neuropathy. *See* Ex. 1 at 8. Such symptoms are in fact more suggestive of the start of CIDP. *See* Gorson & Ropper at 175. In addition, Petitioner maintains he experienced *new* toe numbness and leg fatigue on September 26, 2020—several days post-vaccination. Ex. 2 at 2. Petitioner maintained that it was within weeks of this new symptom that he started to decline and experienced additional numbness, bilateral leg weakness, and increasing fatigue, ultimately prompting medical attention. *Id.*

I conclude from all of the above that it is more likely Petitioner's CIDP actually began in the post-vaccination timeframe (although this still leaves the question whether onset began in a medically-acceptable timeframe).

## III. Petitioner Has Carried His *Althen* Burden of Proof

A. *Prong Three*

A temporal association alone between a vaccination and subsequent disease "does not suffice to show a causal link" between the two. *Grant*, 956 F.2d at 1148. Rather, the third *Althen* prong requires petitioners to establish a "*proximate* temporal relationship." *Althen*, 418 F.3d at 1281 (emphasis added). To do so, the claimant must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan*, 539 F.3d at 1352. The explanation for what is a "medically acceptable timeframe" must align with the theory of how the relevant vaccine can cause an injury. *Id*.

In this case, the majority of Petitioner's treating providers, including neurologists, neurosurgeons, and physiatrists, placed his neurological symptoms as beginning within one to two weeks after vaccination—not before. *See* Ex. 10 at 136–148, 322, 522, 2124. Notably, Petitioner's neurologist noted that his symptoms (bilateral leg weakness) began after his vaccination. Ex. 5 at 11. Also, Petitioner's neurosurgeon documented the symptom onset date as September 26, 2020, which matches representations contained in Petitioner's affidavit. *See* Ex. 4 at 5; Exhibit 2 at 2. Petitioner's expert has provided evidence that an eight-day onset is medically appropriate. Dr. Or-Geva in particular referenced the 2012 IOM Report, which underscores that an autoimmune process can begin as late as six weeks after the trigger. *See* First Or-Geva Rep. at 37 (citing 2012 IOM Report).

There is prior vaccine caselaw supporting the medical acceptability of such onsets for vaccine-induced CIDP. *See, e.g.*, *Kelley v. Sec'y of Health & Hum. Servs*., 68 Fed. Cl. 84, 102 (Fed. Cl. 2005) (CIDP onset approximately two weeks after vaccination); *Daily v. Sec'y of Health & Hum. Servs.,* No. 07-173V, 2011 WL 2174535 (Fed. Cl. Spec. Mstr. May 11, 2011) (finding that onset of CIDP within a few weeks of vaccination was a medically acceptable timeframe). I similarly have noted this kind of timeframe to be reasonable (albeit in cases involving different vaccines—and where prong one was not met). *Houston,* 2021 WL 4259012, at *20 (onset within one to three weeks) I have only rejected vaccine-CIDP timeframes that were substantially longer. *See, e.g.*, *Patel v. Sec'y of Health & Hum. Servs*., No. 16-848V, 2020 WL 2954950, at *18–21 (Fed. Cl. Spec. Mstr. May 1, 2020) (seven months for vaccine-caused CIDP too long); *Strong*, 2018 WL 1125666, at *21 (Four months between flu vaccine and onset of CIDP was too long). Thus, the third *Althen* prong has been satisfied.

B. *Prong One*

Petitioner's *Althen* prong one theory, and the evidence offered in its support, is not particularly robust. For starters, the theory frequently relies on the flu vaccine-GBS association, and evidence supporting it—even though CIDP is not only distinguishable but far more lightly studied. Some literature specific to CIDP was offered in this case, but hardly in bulk quantity—and the lack of availability of such proof does not excuse a claimant from meeting his preponderant burden.

Another more prominent weakness is Petitioner's reliance on molecular mimicry to "save the day" in establishing a causation theory—a practice I have criticized in numerous prior decisions. *See, e.g., McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) ("[b]ut merely chanting the magic words 'molecular mimicry' in a Vaccine Act case does not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or vaccine in question") (emphasis in original), *mot. for review denied*, 76 Fed. Cl. 452 (2007). It is simply *unlikely*, from a general standpoint (meaning not substantiated by studies or other secondary proof), that any given covered vaccine can cause any given autoimmune disease by cross-reactivity due to experimentally-demonstrated homology between some vaccine components and some putative antigenic self-target. And the lazy invocation of molecular mimicry in every case involving an autoimmune injury gains less and less persuasive thrust as time wears on.

At the same time, however, and as noted above, I have generally followed prior Program case law and decisions finding that for purposes of the *flu vaccine*, it is reasonable to some degree to accept the conclusions from prior decisions that the science applicable to the flu vaccine-GBS association bears on CIDP as well. My embrace of that logic (which I have not extended to other kinds of demyelinating neuropathies—or other vaccines)[7] helps ensure a degree of Program consistency in how it treats comparable claims that are often litigated in these matters. I thus similarly find in this case that overall prong one causation is met, despite my reasoned sense that the theory may be a bit threadbare.[8]

I note, however, that a stronger showing by Respondent in a future case *could* raise grounds for re-evaluation of the assumed flu vaccine-CIDP association. In this case, much of Dr. Hawse's argument amounts to either a denial that Petitioner can support his theory with epidemiologic

[7] Thus, special masters have very explicitly not found this kind of "cookie cutter" application of molecular mimicry theory, based on what is known about the flu vaccine and GBS, should be applied to multiple sclerosis, even though it too is a neuroinflammatory polyneuropathy with some features of demyelination. *Townsend v. Sec'y of Health & Hum. Servs*., 170 Fed. Cl. Spec. Mstr. 130, 143–44 (2024), *aff'd*, No. 2024-1740, 2026 WL 570042 (Fed. Cir. Mar. 2, 2026).

[8] While special masters deciding cases 15 to 20 years ago may have deemed the mechanistic capabilities of molecular mimicry to spark an autoimmune disease to be limitless, the "march of science" has not corroborated that view.

evidence (something no claimants are ever required to do), or that aspects of Petitioner's theory lack enough reliable support. More direct evidence relating to CIDP would breathe new life into such arguments, and might occasion reconsideration of the wisdom of my going along with prior Program assumptions that the flu vaccine likely can cause CIDP. But *in this case,* the tenor and nature of Respondent's arguments, while logical and reasonable, do not tip the scales away from Petitioner.

C. *Prong Two*

There is no strong evidence in favor or against a finding that the vaccine "did cause" Petitioner's CIDP, but the record on this question *slightly* preponderates in favor of Petitioner.

A threshold question presented by the "did cause" analysis is whether Petitioner's neurologic symptoms began before or after his vaccine. Both parties have addressed the fact that the Petitioner did complain of toe and heel numbness the day of his vaccination, and assert different onset dates depending on their views as to the significance of this evidence. However, as explained above, multiple treating providers considered this an outlier since Petitioner was not experiencing any other neurological symptoms at the time. *See* Ex. 1 at 8; *see also* Ex. 10 at 136–148, 322, 522, 2124. Also, Petitioner's post-vaccination foot pain continued to worsen over the course of months and develop into more serious neurologic symptoms. While the first report of toe numbness it is suspicious, the record evidence more likely that not weighs in favor of a post-vaccination onset (consistent with the discussion above).

Another challenge to finding in favor of Petitioner on this prong is the short timeframe between vaccination and Petitioner's onset. Petitioner's onset likely occurred within eight days of vaccination—a fairly swift period for the adaptive response to vaccination to begin, and then *subsequently* to result in clinical neurologic symptoms. CIDP onset would more commonly begin at least a few weeks after vaccination (perhaps consistent with its indolent/insidious course). *See, e.g.*, *Kelley*, 68 Fed. Cl. at 102 (CIDP onset approximately two weeks after vaccination); *Daily,* 2011 WL 2174535 (finding that onset of CIDP within a few weeks of vaccination was a medically acceptable timeframe). However, Petitioner's experts were able to provide reliable evidence that, while rare, patients with an acutely-presenting form of CIDP may actually see a faster post-trigger onset. *See* 2012 IOM Report. And this case does not involve the kind of lengthy timeframe I have deemed facially unreasonable. *Patel*, 2020 WL 2954950 at *18–21; *Strong*, 2018 WL 1125666, at *21. All things being equal, an onset closer in time to vaccination has more heft to it than one that occurs long after—and thus I cannot in this case highlight a long quiescent period as suggesting no vaccine reaction was likely.

Other record evidence is inconclusive as to whether the flu vaccine was the likely cause of Petitioner's injury. Treater support for a vaccine association in this case is largely lacking, or was

deemed a question they could not answer pro or con. *See, e.g.,* Ex. 174 at 71, 77. Petitioner's treating providers did continue to mention that he had *received* a vaccine one to two weeks before his symptom onset, but no treating provider opined his CIDP was likely attributable to the flu vaccine.

Overall, however, Respondent's challenges to Petitioner satisfying this prong are not illuminating or all that persuasive. Respondent mainly relies on onset beginning before vaccination—a finding I do not reach. While the evidence in this case of a "logical sequence of cause and effect" is not all that compelling, I can conclude based on this record that it slightly preponderates in Petitioner's favor.

## CONCLUSION

Petitioner has prevailed in establishing entitlement to a damages award. An order establishing the parties' initial obligations with respect to determining damages will follow.

**IT IS SO ORDERED**.

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