# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 23-1056V**

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| EMILY MENDEZ, | * | Chief Special Master Corcoran |
| Petitioner, | * | Filed: June 25, 2026 |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

*Leigh A. Finfer*, Muller Brazil, Dresher, PA, for Petitioner.

*Alyssa M. Petroff*, U.S. Department of Justice, Washington, DC, Respondent.

## ENTITLEMENT DECISION[1]

On July 11, 2023, Emily Mendez filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program).[2] Petitioner alleges that she suffered Guillain-Barré syndrome ("GBS") as a result of receiving a tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine on January 6, 2022. Petition, dated July 11, 2023 (ECF No. 1) at 1.

I determined that this matter could be fairly resolved via ruling on the record, and both sides have filed briefs in support of their positions. *See* Petitioner's Brief, dated Sep. 12, 2025 (ECF No. 26) ("Br."); Respondent's Opposition, dated Nov. 12, 2025 (ECF No. 27) ("Opp."). The matter is now ripe for resolution. For the reasons set forth in more detail below, I hereby deny

[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 Decision will be available to the public in its present form. *Id.*

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

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entitlement. Petitioner has not preponderantly established that the Tdap vaccine can cause GBS, or likely did so to her.

## I. Factual Background

Petitioner was 25 years old (and 36 weeks pregnant as well) when she received the Tdap vaccine at issue on January 6, 2022. Ex. 2 at 83, 84. There is no record evidence of any immediate vaccination reaction, or reports of the kind of malaise-like reactions common with recently-vaccinated individuals.

Almost three weeks later, on January 25, 2022, Ms. Mendez went to the Obstetric Emergency Department reporting difficulty swallowing when eating and drinking, leg numbness, facial numbness, and tingling all over her body over the prior four days. Ex. 3 at 2135. On exam, she displayed equal bilateral hand strength. *Id*. At first, Petitioner was evaluated for a stroke and preeclampsia, but later diagnosed with antepartum hypertension and facial asymmetry (although the differential also included complicated migraine, facial neuralgia, hypertension, Bell's Palsy, and allergies, among other things). *Id*. at 2132–33, 2135, 2064–65.

Ms. Mendez was subsequently admitted to the hospital, remaining an in-patient overnight (through January 26th). Ex. 3 at 1105–06, 2025. Neurologist Christopher Jimenez, M.D., diagnosed her with Bell's palsy,[3] and recommended she begin a course of prednisone[4] 40 mg a day and valacyclovir[5] 500mg twice daily for the next seven days. *Id*. at 2136–37.

Slightly more than a week later, Ms. Mendez was again admitted to the hospital on February 3, 2022, for delivery of her child via cesarean-section ("C-section"). Ex. 3 at 1103–05. She remained hospitalized until February 11, 2022. *Id*. at 1041. Her C-section was complicated by preeclampsia, plus neurological symptoms that petitioner's doctors believed to be Bell's Palsy. *Id*. at 1103. While admitted, petitioner had another encounter with Dr. Jimenez. She informed him that two days before hospitalization (February 1, 2022), she had developed lower extremity weakness, and that her facial symptoms had not improved since her first hospital discharge in

[3] Bell palsy is defined as the "unilateral facial paralysis of sudden onset, due to lesion of the facial nerve and resulting in characteristic distortion of the face." *Bell palsy,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=95779&searchterm=Bell%20palsy (last visited May 28, 2026).

[4] Prednisone is "a synthetic glucocorticoid derived from cortisone, administered orally as an anti-inflammatory and immunosuppressant in a wide variety of disorders." *Prednisone,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=40742&searchterm=prednisone (last visited June 22, 2026).

[5] Valacyclovir is a drug "used as an antiviral agent in the treatment of genital herpes and herpes zoster in immunocompetent adults." *Valacyclovir,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=52462 (last visited June 22, 2026).

January. *Id*. at 1199. She was now unable to elevate her legs, though her upper extremities remained stable. *Id.* at 1104. Dr. Jimenez diagnosed Petitioner with GBS. *Id*.

During the February hospitalization, Petitioner's symptoms progressed to her upper extremities and worsened in her lower extremities, such that by February 7, 2022, she could no longer ambulate. Ex. 3 at 1199. A lumbar puncture performed during this time revealed elevated protein levels, white blood cell count levels, and red blood cell levels in her cerebral spinal fluid ("CSF"). *Id.* at 162.

By February 10, 2022, Ms. Mendez's condition showed improvement after treatment with IVIG as well as physical and occupation therapy. Ex. 3 at 1191–92. She was discharged February 11, 2022, with a diagnosis of GBS. *Id*. at 1041. At discharge, Petitioner could speak but not smile, and her upper extremity weakness had resolved; her lower extremity weakness had improved, though she could not elevate her legs. *Id.* Discharge records noted her prior receipt of the Tdap vaccine. *Id.*

Following discharge, Petitioner began outpatient physical therapy, and she continued to follow up with Dr. Jimenez over the following year. Ex. 4 at 8–35. By January 25, 2023, she could stand without assistance and her facial movements had improved, though she required assistance to walk. *Id.* at 35. However, on May 9, 2023, when petitioner presented to the hospital for a second C-section, she reported she had recently been unable to walk on her own due to bilateral lower extremity paralysis. Ex. 3 at 131. No other records for treatment subsequent to this date bear on the claim's resolution.

## II. Expert Reports

### A. Petitioner's Experts

1. *Dr. Joseph Jeret* – Dr. Jeret prepared two written reports for Petitioner. Report, dated September 17, 2024, filed as Ex. 6 (ECF No. 20-2) ("First Jeret Rep."); Report, dated February 18, 2025, filed as Ex. 34 (ECF No. 22-2) ("Second Jeret Rep.").

Dr. Jeret is a neurologist working in the Department of Neurology at Optum Health Care in New York. First Jeret Rep. at 1. He received his medical degree with a Distinction in Research from SUNY Health Science Center at Brooklyn, where he also completed his residency in Neurology. Curriculum Vitae, dated October 18, 2024, filed as Ex. 33 (ECF No. 20-29) at 1. Dr. Jeret is board certified by the American Board of Psychiatry and Neurology and is a fellow for the American Academy of Neurology, the American Stroke Association, and the American Heart Association. *Id.* at 1. Along with seeing patients, Dr. Jeret has published extensively in the field of neurology in a significant number of peer-reviewed articles. *Id.* at 2–7.

*First Report*

Dr. Jeret's initial report included an introduction to diseases of the peripheral nervous system and a summary of Petitioner's relevant medical facts. First Jeret Rep. at 2, 3, 4–6. Dr. Jeret opined that Petitioner satisfied the diagnostic criteria for GBS. *Id.* at 7 (citing P. Donofrio, *Guillain-Barre Syndrome*, 23 Continuum 1295, 1297 tbl. 4-1 (2017), filed as Ex. 10 (ECF No. 20-6) ("Donofrio"); A. Habib, *Guillain-Barre Syndrome*, 29 Continuum 1327, 1331–32 (2023), filed as Ex. 13 (ECF No. 20-9) ("Habib")). She had exhibited progressive weakness in the arms and legs, plus areflexia. *Id.* (citing Ex. 3 at 1176). This diagnosis was made without Petitioner having received an EMG,[6] but Dr. Jeret deemed that unnecessary, since GBS could be diagnosed based on the kinds of clinical symptoms Petitioner had demonstrated. *Id.* (citing Donofrio at 1297 tbl. 4-1; Habib at 1331–32).

Dr. Jeret next opined that Petitioner's injury was likely caused by the Tdap vaccine she had received in January 2022. First Jeret Rep. at 7. Instances of the Tdap vaccine leading to the development of GBS are well documented. *Id.* In support, Dr. Jeret noted the existence of government-issued warnings associating GBS with the Tdap vaccine, as well as medical literature connecting tetanus toxoid-containing vaccines and GBS. *Id.* at 7–9.

Dr. Jeret also offered a number of case reports in which persons receiving a tetanus toxoid-containing vaccine went on to develop GBS. *See, e.g.,* H. Ammar, *Guillain-Barre Syndrome After Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine: A Case Report*, 5 J. Med. Case Rep. 502, 502–04 (2011), filed as Ex. 7 (ECF No. 20-3) ("Ammar"); R. Bakshi & M. Graves, *Guillain-Barre Syndrome After Combined Tetanus-Diphtheria Toxoid Vaccination*, 147 J. Neurol. Sci. 201, 201-02 (1997), filed as Ex. 8 (ECF No. 20-4) ("Bakshi & Graves"); M. Pan et al., *Guillain Barre Syndrome After Combined Diphtheria, Tetanus, and Acellular Pertussis (DTap) Vaccine: A Rare Pediatric Case Report and Review of Literature*, 19 Hum. Vaccine Immunotherap. 1 (2023), filed as Ex. 20 (ECF No. 20-16) ("Pan"); T. Myers et al., *Adverse Events Following Quadrivalent Meningococcal Diphtheria Toxoid Conjugate Vaccine (Menactra) Reported to the Vaccine Adverse Event Reporting System (VAERS), 2005-2016*, 38 Vaccine 6291, 6291–98 (2020), filed as Ex. 18 (ECF No. 20-14); J. Pollard & G. Selby, *Relapsing Neuropathy due to Tetanus Toxoid. Report of a Case.*, 37 J. Neurol. Sci. 113, 113–25 (1978), filed as Ex. 21 (ECF No. 20-17) ("Pollard & Selby").

Dr. Jeret next assessed the likelihood of the GBS being a result of Petitioner's pregnancy, but favored vaccination as causal. First Jeret Rep. at 10. Statistically, he maintained, there were

[6] EMG studies assess the extracellular activity of muscles at rest when introduced to electric shocks. *Electromyography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited June 17, 2026).

more reports of GBS being associated with vaccination than pregnancy. *Id.* at 9. In addition, Dr. Jeret posited the question of whether the right facial palsy Ms. Mendez experienced was secondary to preeclampsia versus GBS, but ultimately recognized it was impossible to reach a definite answer. *Id.* at 9. While the Bell's palsy could be a result of the former based on its presentation in association with elevated blood pressure, it also could have been a component of the later-diagnosed GBS. *Id.*

Regardless, the onset timeframe for Petitioner's facial palsy was still consistent with probable Tdap vaccine-caused GBS. First Jeret Rep. at 10; *see* A. Habib & W. Waheed, *Guillain-Barre Syndrome,* 29 Continuum 1327, 1330 (Oct. 2023), filed as Ex. 13 (ECF No. 20-9) (noting how the progression of different subtypes of GBS range from less than four weeks to over eight weeks long); J. Collet et al., *Monitoring Signals for Vaccine Safety: The Assessment of Individual Adverse Event Reports by an Expert Advisory Committee*, 78 Bull. World Health Org. 178, 181 tbl.2 (2000), filed as Ex. 9 (ECF No. 20-5) ("Collet") (listing WHO causality assessment criteria and noting that clinical events with a reasonable time relationship to vaccine administration that is unlikely to be attributed to concurrent disease or other drugs or chemicals is probable for vaccine causation). And Dr. Jeret more generally concluded that this onset occurred in a medically-acceptable timeframe, measured from the date of vaccination. First Jeret Rep. at 7. In so maintaining, he noted that Respondent had incorrectly listed the vaccination date at January 5, 2022, when it was actually administered a day later. *Id.* (referencing Ex. 1 at 1). This meant the time between vaccination and onset was 19 days—consistent with the understanding that GBS (due to receipt of the influenza ("flu") vaccine) is understood to develop within 3–42 days. *Id.*

In addition, Dr. Jeret noted that his opinion was supported by Petitioner's treating providers. At Petitioner's February 7, 2022 physical, for example, although treaters "did not directly implicate the Tdap vaccine in the development of [Petitioner's] GBS," the possibility was "certainly implied." First Jeret Rep. at 4 (citing Ex. 3 at 1103).

*Second Report*

Dr. Jeret's supplemental report solely reacted to the report issued by one of Respondent's experts, Dr. Vinay Chaudhry. Dr. Jeret now maintained that Petitioner's facial palsy was most likely associated with her GBS rather than her pregnancy. Second Jeret Rep. at 2. Dr. Chaudhry, in Dr. Jeret's estimation, was too focused on tests not performed, or diagnoses not considered, for Petitioner (such as myelitis, B12 deficiency, or MOGAD[7]). *Id.* at 3. Instead, Dr. Jeret argued they

[7] "Myelin oligodendrocyte glycoprotein (MOG)-associated disease (MOGAD) is a rare, antibody-mediated inflammatory demyelinating disorder of the central nervous system (CNS) with various phenotypes starting from optic neuritis, via [TM] to acute demyelinating encephalomyelitis (ADEM) and cortical encephalitis." Wojciech Ambrosius et al., *Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease: Current Insights into the Disease Pathophysiology, Diagnosis and Management*, 22 Int'l J. Molecular Scis. 100 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7795410/ (last visited June 23, 2026).

must make do with the tests and evaluations actually administered to the patient, and those pointed to a diagnosis of GBS. *Id.* at 2. Dr. Jeret also drew on language from the Vaccine Injury Table for the GBS diagnosis, noting that notwithstanding shortcomings in the testing performed, there was not an "identified," more likely alternative diagnosis. *Id.* at 3 (discussing 42 CFR § 100.3 (c)(15)(ii)).

Dr. Jeret next evaluated the theory posited by Dr. Chaudhry that either reactivated herpes simplex or zoster infections had resulted in post-infectious GBS. Second Jeret Rep. at 3. This theory, according to Dr. Jeret, lacked substantiation in the medical record or literature. *Id.* at 4. Dr. Jeret also criticized Dr. Chaudhry's lack of extrapolation from reports based on other vaccines, and his continued citations to governmental analyses of GBS as a potential adverse effect of the Tdap vaccine. *Id.*; *Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality* (K. Stratton, et al., eds., 2012), filed as Ex. C-18 (ECF No. 21-44) ("2012 IOM Rep.")). Dr. Jeret directed attention to the 2012 IOM Report's statement that the "evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-tetanus toxoid, or acellular pertussis-containing vaccines and GBS," thus allowing for a potential association. *Id.* (quoting 2012 IOM Report at 481).

2. *Dr. Michael Blaiss* - Dr. Blaiss prepared two written reports for Petitioner. Report, dated February 26, 2025, filed as Ex. 35 (ECF No. 22-3) ("First Blaiss Rep."); Report, dated June 26, 2025, filed as Ex. 63 (ECF No. 24-2) ("Second Blaiss Rep.").

Dr. Blaiss is a practicing allergist/immunologist at Good Samaritan Health Center of Gwinnett in Norcross, Georgia. Curriculum Vitae, filed Mar. 6, 2026 (ECF No. 22-2) at 1. He also serves as a Clinical Professor of Pediatrics at the Medical College of Georgia at Augusta University. *Id*. Dr. Blaiss received his medical degree from the University of Tennessee, Center for Health Sciences before completing his residency at the University of Tennessee/LeBonheur Children's Medical Center. *Id.* at 1–2. He is board certified by the American Board of Pediatrics and the American Board of Allergy & Immunology. *Id.* at 3. In addition to seeing patients, Dr. Blaiss has published more than 200 scientific peer-reviewed articles and has served as a member on multiple editorial boards for medical journals. *Id.* at 24–37; First Blaiss Rep. at 2.

*First Report*

Dr. Blaiss's initial report aimed to offer a biologically plausible link between Petitioner's GBS and the Tdap vaccine she received. First Blaiss Rep. at 6. Dr. Blaiss began by first recognizing that a significant proportion of GBS cases are preceded by infections, with one specific kind of wild bacterial infection (*Campylobacter jejuni*) being strongly linked to the onset of GBS through

the mechanism of molecular mimicry. *Id.* at 6–7 (citing S. Sam et al., *A review on Guillain-Barre Syndrome and its Association with Covid 19*, 11 J. Drug Deliv. & Therapeutics 188, 188–93 (2021), filed as Ex. 56 (ECF No. 22-24); R. Louwen et al., *A Novel Link Between Campylobacter Jejuni Bacteriophage Defence, Virulence and Guillain-Barré Syndrome*, 32 Europ. J. Clin. Microbiol. Infect. Dis. 207, 207–26 (2012), filed as Ex. 49 (ECF No. 22-17); J. Goodfellow & H. Willison, *Guillain-Barré Syndrome: A Century of Progress*, 12 Nat. Rev. Neurol. 723, 723–31 (2016), filed as Ex. 43 (ECF No. 22-11) ("Goodfellow & Willison")).

Additionally, Dr. Blaiss cited (like Dr. Jeret) case report evidence demonstrating the occurrence of GBS following vaccinations, with causation speculated to be related to the immune response provoked by a vaccine. *Id*. at 7 (citing Pan; M. Ullah, A. Qaseem, & A. Amray, *Post Vaccination Guillain Barre Syndrome: A Case Report*, 10 Cureus 1, 1–3 (2018), filed as Ex. 59 (ECF No. 22-27) ("Ullah") (case report describing the development of GBS in a 15 year-old girl 24 days after receiving a neural tissue sheep brain anti-rabies vaccine); P. Cohen, *Combined Reduced-Antigen Content Tetanus, Diphtheria, and Acellular Pertussis (tdap) Vaccine-Related Erythema Nodosum: Case Report and Review of Vaccine-Associated Erythema Nodosum*, 3 Dermat. and Ther. 191, 191–97 (2013), filed as Ex. 40 (ECF No. 22-8) ("Cohen"); J. Dhadwad et al., *Guillain-Barré Syndrome Triggered by Tetanus Vaccination During Pregnancy: A Rare Case Report*, J. of Clin. Diag. Rsch. 1 (2025), filed as Ex. 41 (ECF No. 22-9) ("Dhadwad")). Dr. Blaiss opined that such individual case reports can contribute to a broader understanding of adverse events even if they constitute weak evidence of causation otherwise. *Id*. at 8.

In Petitioner's case, Dr. Blaiss argued, several factors suggested that her GBS was likely caused by the Tdap vaccine she had received. Blaiss First Rep. at 8. These include a lack of alternative explanations and the literal temporal association. *Id*. at 8–9. These factors, along with the case reports of instances where such a vaccine was associated with GBS, were sufficient to prove more likely than not that the Tdap vaccine was the cause of Petitioner's GBS. *Id.* at 9.

Dr. Blaiss disagreed with the argument that larger studies do not show a connection between GBS and the Tdap vaccine. First Blaiss Rep. at 9. One such study (referenced by Dr. Lindsay Whitton, Respondent's immunology expert) does not in fact indicate that tetanus toxoid-containing vaccines do *not* cause GBS. *Id.* (citing J. Tuttle et al., *The Risk of Guillain-Barre Syndrome After Tetanus-Toxoid-Containing Vaccines in Adults and Children in the United States*, 87 Am. J. Pub. Health 2045, 2045–48 (1997), filed as Ex. 58 (ECF No. 22-26) ("Tuttle")). Instead, it merely concluded that the risk was insufficiently high enough to be considered a threat to public safety. *Id.* Dr. Blaiss raised similar concerns with other studies cited by Respondent. *See, e.g.*, J. Nordin et al., *Tdap and GBS Letter*, 29 Vaccine 1 (2011), filed as Ex. 52 (ECF No. 22-20) ("Nordin"); W. Yih et al., *An Assessment of the Safety of Adolescent and Adult Tetanus-Diphtheria-Acellular Pertussis (Tdap) Vaccine, Using Active Surveillance for Adverse Events in*

*the Vaccine Safety Datalink*, 27 Vaccine 4257, 4257–62 (2014), filed as Ex. 61 (ECF No. 22-29) ("Yih").

As a possible mechanism for how GBS would occur due to receipt of the Tdap vaccine, Dr. Blaiss invoked the theory of molecular mimicry. First Blaiss Rep. at 10. The pathophysiology of GBS involves an "aberrant immune response that targets the peripheral nervous system." *Id*. This immune-mediated attack can lead to demyelination and axonal damage, resulting in GBS. *Id.* (citing Ullah). *Campylobacter jejuni* is the most frequently identified infectious agent associated with GBS, and it is understood to have the capacity to trigger an "immune response that cross-reacts with gangliosides." *Id.* (citing N. Shahrizaila & N. Yuki, *Guillain-Barré Syndrome Animal Model: The First Proof of Molecular Mimicry in Human Autoimmune Disorder*, Biomed. Rsch. Int'l. (2010), filed as Ex. 57 (ECF No. 22-25) ("Shahrizalia & Yuki")). This phenomenon takes place when the immune system mistakenly targets self-antigens because of structural or sequential similarities with microbial components. *Id.* (citing Shahrizalia & Yuki at 2–3; M. Koga, *Experimental Approach in Research of Guillain-Barré Syndrome: A Range of Pathogenesis Mediated by Molecular Mimicry*, 9 Clin. Exp. Neuroimmunol. 93, 93–100 (2018), filed as Ex. 46 (ECF No. 22-14)).

Dr. Blaiss also referenced an article which he contended established the potentiality of molecular mimicry as a mechanistic explanation for how tetanus toxoid-containing vaccines like Tdap could result in the autoimmune attack characteristic of GBS. First Blaiss Rep. at 10 (citing A. Inic-Kanada et al., *Murine Monoclonal Antibody 26 Raised Against Tetanus Toxoid Cross-Reacts with b2-Glycoprotein I: Its Characteristics and Role in Molecular Mimicry*, 61 Am. J. Reprod. Immunol. 39, 39–51 (2009), filed as Ex. 44 (ECF No. 22-12) ("Inic-Kanada")). Inic-Kanada's authors had noted that a "murine monoclonal antibody raised against tetanus toxoid cross-reacts with β2-glycoprotein I (β2-GPI)," which arguably suggests, Dr. Blaise maintained, a pathway for autoimmune reactions following vaccination. *Id.* (citing Inic-Kanada at 41). This is because the anti-β2-GPI antibody itself can interact with certain gangliosides, which could lead to the formation of immune complexes that further activate the complement system and promote inflammatory responses in the peripheral nervous system. *Id.* (citing Goodfellow & Willison).

The presence of anti-β2-GPI antibodies in some patients with GBS is further evidence that these antibodies may contribute to the pathogenesis of GBS by enhancing the immune-mediated attack on peripheral nerves. First Blaiss Rep. at 11–12 (citing G. Nakos et al., *Anti-phospholipid Antibodies in Serum from Patients with Guillain-Barré Syndrome*, 31 Intensive Care Med. 1401, 1401–08 (2005), filed as Ex. 51 (ECF No. 22-19) ("Nakos")). Additionally, Dr. Blaiss opined, the interaction between β2-GPI and various vaccinations may contribute to the development of GBS through "mechanisms such as the activation of Toll-like receptors (TLRs) and subsequent inflammatory pathways." *Id*. at 11; A. Capozzi et al., *Tissue Factor Over-Expression in Platelets of Patients with Anti-Phospholipid Syndrome: Induction Role of Anti-B2-gpi Antibodies*, 196 Clin.

Exp. Immun. 59, 59–66 (2019), filed as Ex. 39 (ECF No. 22-7); A. Islam et al., *Antiphospholipid Antibodies in Epilepsy: A Systematic Review and Meta-Analysis*, 17 Autoimmun. Rev. 755, 755–67 (2018), filed as Ex. 45 (ECF No. 16) ("Islam").

*Second Report*

Dr. Blaiss maintained in his second report that there was no sign or symptom of an infection, such as herpesvirus, that would be a credible alternative explanation as a cause of Petitioner's GBS. Second Blaiss Rep. at 2. There was no documented rash connected with Petitioner's facial weakness, no mention in the treating physician's notes of herpesvirus as a cause of the Bell's palsy, and no diagnostic testing results would confirm such an infection (with no such tests having been performed). *Id.* (citing Chaudhry Rep. at 8; Ex. 3 at 2136–37). Additionally, the valacyclovir prescribed to Petitioner, Dr. Blaiss opined, was likely given as a precaution, and thus was not evidence of the fact that Petitioner had been suspected by treaters to be suffering from a herpesvirus infection. *Id.*

Dr. Blaiss next responded to criticism of his use of case reports. Second Blaiss Rep. at 2. According to Dr. Blaiss, case reports "play a critical and complementary role" in identifying vaccine-related injuries. *Id.* at 3. Case reports have historically been used to flag potential safety concerns in vaccines, indicating they have a more foundational role in pharmacovigilance than simply being anecdotes. *Id.* Additionally, Dr. Blaiss defended his statement that rare adverse events can be vaccine-related, particularly when there is a strong temporal association. *Id.* The lack of mechanistic detail or explanation should not prevent reasonable inferences when timing and medical judgment align. *Id.* at 4.

Dr. Blaiss also expanded on his discussion of molecular mimicry as a possible pathogenic mechanism. Second Blaiss Rep. at 5. Inic-Kanada, he maintained, was an animal study designed to demonstrate that antibodies to β2-GPI could be generated after exposure to tetanus toxoid. *Id.* at 6 (citing Inic-Kanada at 41). These antibodies, although not definitively linked to GBS, have been observed in the context of comparable neurological demyelinating conditions. *Id.* (citing M. Renaud et al., *Isolated Anti-β2-Glycoprotein I Antibodies In Neurology: A Frontier Syndrome Between Multiple Sclerosis and Antiphospholipid Syndrome?*, 21 Eur. J. Neurol. 901, 901–06 (2014), filed as Ex. 68 (ECF No. 24-7)). Thus, it was reasonable to extrapolate from this that the same antibodies could drive a peripheral neuropathy like GBS.

Dr. Blaiss admitted that anti-ganglioside antibodies (which are known to arise through molecular mimicry) are the understood immunological driver of GBS. Second Blaiss Rep. at 6. But the experimental model in a different study (albeit 30 years old) demonstrated the potential for tetanus toxoid to trigger the generation of these anti-ganglioside antibodies. *Id.* (citing M. Alfonso & J. Zeuthen, *Generation of Human Monoclonal Antibodies Against Ganglioside*

*Antigens and Their Applications in the Diagnosis and Therapy of Cancer*, 35 Acta. Oncol. 287, 287–95 (1996), filed as Ex. 64 (ECF No. 24-64)). Dr. Blaiss speculated that gangliosides have structural similarities to tetanus toxoid sufficient to spark a molecular mimicry-driven cross reaction after antibody production. *Id.* (citing H. Louch et al., *Identification of a Binding Site for Ganglioside on the Receptor Binding Domain of Tetanus Toxin*, 41 Biochem. 13644, 13644–52 (2002), filed as Ex. 67 (ECF No. 24-6)).

B. Respondent's Experts

1. *Dr. Vinay Chaudhry* – Dr. Chaudhry prepared one written report for Respondent. Report, dated December 21, 2024, filed as Ex. C (ECF No. 21-26) ("Chaudhry Rep.").

Dr. Chaudhry is the James F. Howard, Jr. Distinguished Professor of Neurology at the UNC Chapel Hill School of Medicine. Curriculum Vitae, filed January 3, 2025, (ECF No. 21-61) at 2. Prior to this role, Dr. Chaudhry was a Professor of Neurology at Johns Hopkins University School of Medicine. *Id*. Dr. Chaudhry received a Bachelor of Medicine and Bachelor of Surgery from the All India Institute of Medical Sciences. *Id.* at 1. He is board certified in Neurology, Neuromuscular Diseases, Electrodiagnostic Medicine, and Clinical Neurophysiology. *Id*. Dr. Chaudhry has an active clinical practice and, along with evaluating patients, is involved in clinical research with over 120 publications. *Id.* at 5–24; Chaudhry Rep. at 1.

Dr. Chaudhry's report included a summary of the relevant medical history of Petitioner. Chaudhry Rep. at 2–5. Dr. Chaudhry agreed with Petitioner's diagnosis of right-sided facial nerve palsy on January 25, 2022, and that she was appropriately treated for Bell's palsy. *Id*. at 6 (citing M. Ronthal & P. Greenstein, *Bell's Palsy: Pathogenesis, Clinical Features, and Diagnosis in Adults,* UpToDate (2025), filed as Ex. C-11 (ECF No. 21-27) ("Ronthal & Greenstein")). But he was only willing to opine that Petitioner had experienced a "GBS-like syndrome," and he seemed to differentiate the Bell's palsy from it. *Id*. at 7, 15. In so maintaining, he noted the lack of studies and testing in the medical record consistent with efforts to evaluate GBS as a potential diagnosis. *Id*. at 9. Petitioner had several telemedicine visits, but they were not occasions to test her reflexes, and he also noted Petitioner's treatment for B12 deficiency. *Id*. In addition, a nerve conduction study to confirm GBS was never performed, the MRI of the spinal cord was limited, and spinal fluid was never tested for inflammation. *Id*. At most, Dr. Chaudhry admitted that Petitioner's acute monophasic course, combined with areflexia, was suggestive of GBS. Chaudhry *Id.*

Acute facial palsy, Dr. Chaudhry noted, has two well-known causes: herpes simplex virus or herpes zoster infections. Chaudhry Rep. at 6. (citing D. Gilden, *Clinical Practice. Bell's Palsy*, N. Engl. J. Med. 1323, 1323–133 (2004) Ex. C-2 (ECF No. 21-28) ("Gilden"); N. Holland & G. Weiner, *Recent Development in Bell's Palsy*, 329 BMJ 553, 553–57 (2004) filed as Ex. C-3 (ECF No. 21-29) ("Holland")). Herpes simplex virus is thought to lead to Bell's palsy in one to two-

thirds of all cases, with varicella zoster virus being the second most common cause of acute facial palsy. Chaudhry Rep. at 6 (citing Ronthal & Greenstein at 4; Gilden at 1330; Holland at 553; N. Hato et al., *Steroid and Antiviral Treatment for Bell's Palsy*, 371 The Lancet 1818, 1818–20 (2008), filed as Ex. C-10 (ECF No. 21-36)).

Additionally, Dr. Chaudhry discussed noninfectious mechanisms for causing Bell's palsy, with a focus on pregnancy. Chaudhry Rep. at 7 (citing 13, 14). Bell's palsy presents almost exclusively in the third trimester, and is well described in the literature as presenting with a hypertensive disorder. Chaudhry Rep. at 7 (citing *ACOG Practice Bulletin. Diagnosis and Management of Preeclampsia and Eclampsia. Number 33, January 2002. American College of Obstetricians and Gynecologists*, 77 Int. J. Gynaecol. Obstet. 67, 67–75 (2002), filed as Ex. C-14 (ECF No. 21-40); R. Hilsinger, K. Adour, & H. Doty, *Idiopathic Facial Paralysis, Pregnancy, and the Menstrual Cycle*, 84 Ann. Othol. Rhinol. Laryngol. 433, 433–42 (1975), filed as Ex. C-13 (ECF No. 21-39)).

Dr. Chaudhry briefly addressed whether the Tdap vaccine could cause Bell's palsy, and concluded it cannot. Chaudhry Rep. at 8 (citing A. Rowhani-Rahbar et al., *Immunization and Bell's Palsy in Children: A Case-Centered Analysis*, 175 Am. J. of Epidemiology 878, 878–85 (2012), filed as Ex. C-17 (ECF No. 21-43)). Rather, he maintained Petitioner's Bell's palsy was caused by either herpes simplex virus or Ramsay Hunt syndrome.[8] *Id.* (citing D. Shmorgun, W. Chan, & J. Ray, *Association Between Bell's Palsy in Pregnancy and Pre-Eclampsia*, 95 QJM: Monthly J. Assoc. Physicians 359, 359–62 (2002), filed as Ex. C-12 (ECF No. 21-38); Holland at 553). While the record lacked documentation of some characteristics of a herpes simplex virus infection, such as a rash, Dr. Chaudhry emphasized the absence of documentation of a skin examination in the records. *Id*. He also noted Petitioner had been treated with an antiviral drug, and was documented to be improving on this treatment with no weakness in the extremities until after her C section on February 3, 2022. *Id*.

That pregnancy (complicated by hypertension) was also a likely alternative explanation for Petitioner's subsequent symptoms. Chaudhry Rep. at 8, 9. One study found GBS has an increased incidence during the postpartum period of pregnancy. *Id.* at 9 (citing L. Chan et al., *Guillain-Barré Syndrome in Pregnancy*, 83 Acta. Obstet. Gynecol. Scand. 319, 319–25 (2004), filed as Ex. C-27 (ECF No. 21-53) ("Chan")). Given that association, Dr. Chaudhry deemed it likely that Petitioner originally had Bell's palsy (probably due to a herpes infection of some kind); underwent a C-section; and then developed lower extremity weakness which was diagnosed as GBS and treated

[8] Ramsay Hunt Syndrome is defined as a herpes zoster infection affecting the "facial and vestibulocochlear nerves, often associated with transitory ipsilateral facial paralysis and herpetic vesicles of the external ear or tympanic membrane." *Ramsay Hunt syndrome,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111266&searchterm=Ramsay+Hunt+syndrome (last visited June 22, 2026). Symptoms can include tinnitus, vertigo, and hearing disorders. *Id.*

accordingly, but was more likely attributable to the pregnancy (complicated by her preeclampsia). *Id.* at 10.

Dr. Chaudhry then briefly noted the literature related to the prevalence of GBS after the reception of a Tdap vaccine. Chaudhry Rep. at 10. Several reliable, large-scale studies all pointed against a relation between the vaccine and GBS. *See, e.g.* Tuttle at 2047; R. Baxter et al., *Lack of Association of Guillain-Barré Syndrome with Vaccinations*, 57 Clin. Infect. Dis. 197, 201–03 (2013), filed as Ex. C-32 (ECF No. 21-58) ("Baxter 2013"); Nordin at 1; R. Baxter et al., *Recurrent Guillain-Barre Syndrome Following Vaccination*, Clin. Infect. Dis. 800, 800–04 (2012), filed as Ex. C-34 (ECF No. 21-60) ("Baxter 2012") (assessing recurrent GBS in post-vaccination patients between the years of 1995 and 2006 from Kaiser Permanente Northern California databases and finding no cases of recurrent GBS after a flu vaccine, or within six weeks of any vaccine)).

Finally, Dr. Chaudhry addressed the propositions set forth in Dr. Jeret's First Report. Chaudhry Rep. at 11. He dismissed Dr. Jeret's diagnosis (that Petitioner had experienced a "classical case" of GBS) because the distribution of weakness was in fact not the classical ascending pattern of weakness, and some treatment modalities were not typical of GBS. *Id.* Additionally, Dr. Chaudhry noted the lack of EMG test results that would confirm GBS, and the alternative diagnoses available. *Id.* Dr. Chaudhry also addressed Dr. Jeret's discussion of causality between Tdap vaccines and GBS, opining that the sources relied upon (like case reports) did not actually purport to establish causality. *Id.* at 11–12 (2012 IOM Rep.). And Dr. Chaudhry maintained that Petitioner's Bell's palsy was separate from her post-partum symptoms. *Id.* at 13.

2. *Dr. J. Lindsay Whitton* – Dr. Whitton provided two written reports for Respondent. Report, dated January 3, 2025, filed as Ex. A (ECF No. 21-1) ("First Whitton Rep."); Report, dated April 23, 2025, filed as Ex. E (ECF No. 23-1) ("Second Whitton Rep.").

Dr. Whitton is an immunologist who received his Ph.D. from the University of Glasgow in herpesvirus transcription. Curriculum Vitae, filed January 3, 2025, (ECF No. 21-12) at 1. After receiving his Ph.D., Dr. Whitton served as a Professor at Scripps Research Institute in La Jolla, CA, from 1998 to 2023. *Id.* Afterwards, he became an Emeritus Professor in the Department of Immunology and Microbiology. *Id.* Dr. Whitton has contributed to two hundred publications and has served as Editor for two medical journals, Microbiology & Immunology and Viral Immunology. *Id.* at 2–13. Additionally, he is a member of a variety of professional societies, including the Royal College of Pathologists, the American Association of Immunologists, and the American Society of Microbiology. *Id.* at 1.

*First Report*

Dr. Whitton began his first report with a summary of the clinical and pathological features of GBS, before turning to its likely pathogenic mechanisms. First Whitton Rep. at 3–4. GBS is considered by most to be an autoimmune disease, and it has been proposed that some subtypes of GBS are triggered by molecular mimicry. *Id*. at 4. The immunological agents involved are likely "antibodies whose target molecules are thought to be host gangliosides that are present in peripheral nerves." *Id.* (citing P. van Doorn, L. Ruts & B. Jacobs, *Clinical Features, Pathogenesis, and Treatment of Guillain-Barre Syndrome*, 7 Lancet Neurol. 939, 939–50 (2008), filed as Ex. A-1 (ECF No. 21-2); H. Willison, *The Immunobiology of Guillain-Barré Syndromes*, 10 J. Peripher. Nerv. Syst. 94, 94–112 (2005), filed as Ex. A-2 (ECF No. 21-3); B. van der Berg et al., *Guillain-Barre Syndrome: Pathogenesis, Diagnosis, Treatment and Prognosis*, 10 Nat. Rev. Neurol. 469, 469–482) (2014), filed as Ex. A-7 (ECF No. 21-8)). Despite unsuccessful attempts to confirm the effects of these antibodies, their role in certain types of GBS is accepted. *Id.* (citing S. Rinaldi & H. Willison, *Ganglioside Antibodies and Neuropathies*, 21 Curr. Opin. Neurol. 540, 540–546 (2008), filed as Ex. A-10 (ECF No. 21-11)). In two thirds of cases, signs of an infection would precede GBS onset. *Id*.

Dr. Whitton turned next to his assessment as to whether a causal relationship between tetanus toxoid-containing vaccines and GBS can be preponderantly demonstrated. First Whitton Rep. at 4. The Institute of Medicine's ("IOM") initial evaluation of the risk of developing GBS after receiving a tetanus-toxoid containing vaccine heavily relied on one paper published in 1978: the Pollard & Selby case report referenced by Petitioner's experts. *Id.* (citing Committee to Review Adverse Effects of Vaccines: Evidence and Causality 59–60 (K. Stratton et al., eds., 1994), filed as Ex. A-11 (ECF No. 21-12) (the "1994 IOM Rep.")). Based on that paper, the IOM concluded the evidence favored a causal relation between the vaccine and the development of GBS. *Id.* (citing 1994 IOM Rep. at 89.) In response, however, a large-scale study conducted in 1997 found no significant association between the Tdap vaccine and GBS. *Id.* at 4–5 (citing Tuttle at 2047). Subsequent studies reached the same conclusion. *Id.* at 5. *See, e.g.,* Nordin at 1; Baxter 2012 at 803; Baxter 2013 at 201–03.

Dr. Whitton spent the remainder of his first report responding to other aspects of Dr. Jeret's opinion. First Whitton Rep. at 6. For example, Dr. Whitton assessed the sources provided by Dr. Jeret, finding some of the links to be dysfunctional or to lack necessary substantiation. *Id*. at 6–7. Dr. Whitton opined that many of the sources relied upon by Dr. Jeret were, in fact, ultimately dependent on Pollard & Selby, even though its conclusions had been reasonably called into question. *Id.* at 7. The Boostrix package insert, for example, relied on the 1994 IOM review which itself relied on Pollard & Selby. *Id.* (discussing 2012 IOM Rep.). Dr. Whitton also more generally disagreed with Dr. Jeret drawing conclusions based on case reports, which Dr. Whitton opined

"cannot be used to imply causality." *Id*. And Dr. Whitton noted the lack of detail in Dr. Jeret's proposed mechanism of causation, which made it difficult to assess its reliability. *Id*. at 10.

Similarly, Dr. Whitton deemed the Vaccine Adverse Events Reporting System ("VAERS") to be weak proof in support of causation. First Whitton Rep. at 8. The VAERS system identifies reported adverse events following vaccination, but the VAERS website itself states it is not designed "to determine if a vaccine caused a health problem." *Id.*; *About Us*, VAERS, https://vaers.hhs.gov/about.html (last visited June 4, 2026). Thus, any conclusion drawn from VAERS assessing causality is inherently unreliable. First Whitton Rep. at 8.

The Tdap vaccine also could not have constituted a risk factor when administered in the context of pregnancy. This vaccine is often given to women during pregnancy to boost maternal antibodies. First Whitton Rep. at 9 (citing *Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women—Advisory Committee on Immunization Practices (ACIP)*, 62 MMWR Morb. Mortal. Kly. Rep. 131, 131–135 (2013), filed as Ex. A-21 (ECF No. 21-22)). Given the frequency of Tdap vaccine administration during pregnancy, coupled with the rarity of GBS during pregnancy, it was unlikely the two factors heightened the risk of GBS (as studies specific to this possibility observed). *Id.*; J. Layton et al., *Prenatal Tdap Immunization and Risk of Maternal and Newborn Adverse* Events, 35 Vaccine 4072, 4072–73 (2017), filed as Ex. A-22 (ECF No. 21-23) ("Layton") (assessing whether there was an association between prenatal Tdap vaccination and adverse birth outcomes and finding no such association); L. Clark & D. Johnson, *Safety and Clinical Benefits of Adacel and Adecel-Polio Vaccination in Pregnancy: A Structured Literature* Review, 12 Infect. Dis. Ther. 1955, 1955–2003 (2023), filed as Ex. A-23 (ECF No. 21-24).

*Second Report*

Dr. Whitton's Second Expert Report responded in the main to Dr. Blaiss's initial report. Dr. Whitton began by opining that Dr. Blaiss did not properly address all comments made by Respondent's neurologic expert, Dr. Chaudhry. Second Whitton Rep. at 2. Dr. Blaiss had disregarded some of the comments made by Dr. Chaudhry, such as the potential involvement of a herpes viral infection in Petitioner's treatment. *Id*.

Next, Dr. Whitton assessed the sources used to corroborate Dr. Blaiss's contentions about GBS's relationship to a variety of vaccinations. Second Whitton Rep. at 2. Ullah, for example, did not study Tdap but instead a rarely-used rabies vaccine. *Id*. at 3 (citing Ullah at 1). Additionally, Dr. Whitton noted Dr. Blaiss's "indirect referencing" of other studies that did not support his contentions. *Id.* (citing P. Haber et al., *Vaccines and Guillain-Barre Syndrome*, 32 Drug Saf. 309, 309–323 (2009), filed as Ex. E-1 (ECF No. 23-2)) (concluding that there is "little evidence to support a causal association *with most vaccines*" and GBS (emphasis added)).

Dr. Whitton also addressed the use of case reports by Dr. Blaiss to establish causality between the Tdap vaccine and GBS. Second Whitton Rep. at 3–4. Case reports cited by Dr. Blaiss included Pan and Dhadwad. *See id.*; s*ee also* Pan at 1–2; Dhadwad at 13. But case reports cannot be used to imply causality. Second Whitton Rep. at 4. Additionally, Dr. Whitton noted that Dr. Blaiss over relied on temporal associations, noting that "the presence of such a relationship does not imply causation." *Id*.

Dr. Whitton maintained there was simply no reliable data to support the contention that Tdap can cause GBS. Second Whitton Rep. at 5. He emphasized, for example, that in Nordin the rate ratio "straddles" the null value of 1.0. *Id.* (citing Nordin at 1). Hence, its authors concluded there was no evidence the Tdap vaccine is associated with GBS within six weeks of vaccination. *Id.* (citing Nordin at 1). And the antibody-inoculated mice studied in Inic-Kanada did not develop any signs of neurological disease, leading Dr. Whitton to question its relevance (since the cross-reactivity with β2-GP1 observed was not ultimately pathogenic). *Id.* at 6 (citing Inic-Kanada at 46–47). Moreover, the homologic amino acid sequence provided by Dr. Blaiss was lacking corroboration in the materials cited. *Id.* at 6–7 (citing First Blaiss Rep. at 11). And Dr. Blaiss's claim that pro-inflammatory cytokines contribute to GBS was misguided, according to Dr. Whitton, since such cytokines are not considered *specific* to GBS's development. *Id.* at 7 (citing First Blaiss Rep. at 11).

## III. Procedural History

This case was initiated in January 2022. Respondent's filed his 4(c) Report on March 26, 2024 and supplemented his report on June 14, 2024, at my direction. Parties submitted their expert reports, the last of which was submitted by Petitioner on June 30, 2025. I subsequently set a schedule for briefing the claim via ruling on the record, and that process was completed in November 2025. The matter is now ripe for resolution.

## IV. Parties' Arguments

It is important to note that the dispute between these parties centers around both diagnosis and causation. Petitioner and Respondent agree that the injury at issue is not Bell's palsy, but rather GBS, and thus they contest whether the Petitioner had GBS caused by the Tdap vaccine. Br. at 7–8; Opp. at 9. But Petitioner maintains that her facial drooping (diagnosed as Bell's palsy) could have been an initial presenting symptom of GBS, while Respondent contends it was unrelated to her later symptoms, and/or caused by other factors. Br. at 8; Opp. at 9.

*Petitioner*

Petitioner maintains that all three causation prongs established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005), are satisfied herein. Br. at 8–19.

First, Petitioner argues she has satisfied *Althen* prong one by causally connecting her GBS to the Tdap vaccine she received, based on the mechanism of molecular mimicry. Br. at 9–15. With the support of Dr. Blaiss, Petitioner contends that she experienced GBS given the diagnostic criteria set forth by Shahrizalia & Yuki—and that it can be triggered by molecular mimicry. *Id.* at 9 (citing Shahrizalia & Yuki at 3–4). These criteria are: (i) the establishment of an epidemiological association between the infectious agent and the immune-mediated disease; (ii) the identification of T-cells or antibodies directed against the patient's target antigens; (iii) the identification of microbial mimics of the target antigen; and (iv) reproduction of the disease in an animal model. *Id.* (citing Shahrizalia & Yuki at 3–4). GBS is, according to the authors of the cited study, the first true model of molecular mimicry to fulfill all four criteria. *Id.* (citing Shahrizalia & Yuki at 2).

Vaccines, moreover, may be triggers for molecular mimicry. Br. at 9. According to Petitioner, it is well established that "it is biologically plausible that injection of an inactivated virus, bacterium, or live attenuated virus" could induce an autoimmune response. *Id*. In support of the assertion that the Tdap vaccine could trigger molecular mimicry, Petitioner relies on a variety of articles. *Id.* at 10–12. One implicates tetanus toxoid, a component of the Tdap vaccine, in molecular mimicry because of the similarity between tetanus toxoid and several sera proteins. *Id.* at 10 (referencing Inic-Kanada). A separate study demonstrates β2-GPI can interact with certain gangliosides, which could lead to the formation of immune complexes and promote an inflammatory response in the peripheral nervous system. *Id.* (citing Goodfellow & Willison). These articles provide validation, according to Petitioner, for Dr. Blaiss's proposition that the interaction between β2-GPI and pathogens can contribute to the development of GBS. *Id*. at 10–12 (referencing Goodfellow & Willison at 3; Nakos at 6; Islam at 10).

Petitioner concludes her assessment under *Althen* prong one by noting the case reports presented by Dr. Blaiss which memorialized serious adverse events following receipt of a Tdap vaccine. Br. at 12 (citing Cohen at 4, Dhadwad at 1). Although case reports may not prove causation alone, they can contribute valuable information to the establishing of a causal link. *Id*. Additionally, Petitioner highlights that the Advisory Committee on Immunization Practices (ACIP), relying on the 1994 Institute of Medicine Report, acknowledged that GBS can follow the administration of a tetanus toxoid-containing vaccine. *Id.* at 14. Despite the differences between the 2012 IOM Report and the 1994 IOM Report, Petitioner posits that the 2012 IOM Report did not explicitly reject the initial findings from the earlier report. *Id.* (citing 2012 IOM Rep.).

Second, Petitioner contends *Althen* prong two is satisfied because she has presented a sequence of cause and effect showing the Tdap vaccine was the likely reason for the development of her GBS. Br. at 15–18. According to Petitioner, a clinical course "consistent with the proposed mechanism, coupled with a different etiology, satisfies this prong." *Id.* at 16. The question is not whether there is direct proof of a mechanism, but whether the medical records show a clinical course consistent with the mechanism (i.e., molecular mimicry) within the time frame in which the injury can occur following a vaccination. *Id.* at 15–16. Petitioner cites the World Health Organization's causality assessment criteria referenced in Collet, which states that if a clinical event within a reasonable time in relation to vaccine administration cannot be explained by a concurrent disease or drugs, it is probable it was caused by the vaccination. *Id.* at 16 (citing Collet at 4).

Attempts by Respondent's expert Dr. Chaudhry to explain the GBS as a result of other factors are unsuccessful. Br. at 16–18. Dr. Chaudhry relied on Petitioner receiving antiviral treatment to stand for the proposition that her facial palsy was caused by a herpes virus, but the medical records failed to substantiate this possibility. *Id.* at 16. Additionally, pregnancy alone cannot be implicated in the development of Petitioner's GBS. The study cited by Dr. Chaudhry to support this contention found no significant difference in incidence of GBS between pregnant women and the general population. *Id.* at 17 (citing Chan at 1). Finally, studies referenced by Dr. Chaudhry to relate Petitioner's GBS to her C-section surgery were inconsistent with Petitioner's circumstances (i.e., she had experienced no antecedent infection, and onset of lower limb paresthesia occurred prior to her procedure, with leg weakness only one day post-partum). *Id.* (citing M. Chen et al., *Postpartum Guillain-Barre Syndrome: A Case report and Literature Review,* 16 Cureus 1, 3–4 (2024), filed as Ex. C-29 (ECF No. 21-55)). The absence of any evidence of prior neurological diseases or alternative causes, the timing of onset of the symptoms, and Petitioner's experts all support vaccine causation, thereby satisfying her burden of demonstrating a logical sequence of cause and effect. *Id.* at 18.

Petitioner lastly asserts she has shown by the preponderance of the evidence a medically acceptable timeframe for the onset of her symptoms post-vaccination. Br. at 18–19. Petitioner's expert, Dr. Jeret maintained that that neurological symptoms (whether the initial Bell's palsy or later symptoms) began within the "'typical'" 3–42 days after an inciting event. *Id.* at 19 (citing First Jeret Rep. at 7). And Respondent did not raise a specific issue with Petitioner's satisfaction of this *Althen* prong. *Id*.

*Respondent*

Respondent contends that the Petitioner has failed her requisite showing on all three *Althen* prongs. First, he maintains the initial *Althen* "can cause" prong is not met. Opp. at 10. The medical theory presented by a petitioner must be persuasive, and more than just plausible or possible. *Id*.

And it must be supported by a scientific explanation specific to her case. *Id.* at 11. But numerous prior Program decisions have rejected the theory that the Tdap vaccine could cause GBS via the mechanism of molecular mimicry. *Id.* (referencing *K.A. v. Sec'y of Health & Hum. Servs.*, No. 16-989V, 2022 WL 20213037 (Fed. Cl. Spec. Mstr. April 18, 2022), *mot. for rev. den'd*, 164 Fed. Cl. 98 (2023), *aff'd,* 2024 WL 2012526 (Fed. Cir. May 7, 2024) (Rule 36 Affirmance); *Dennington v. Sec'y of Health & Hum. Servs.*, No. 18-1303V, 2023 WL 2965239 (Fed. Cl. Spec. Mstr. March 23, 2023), *mot. for rev. den'd*, 167 Fed. Cl. 640 (2023), *appeal dismissed*, No. 2024-1214, 2024 WL 1255318 (Fed. Cir. Mar. 25, 2024)). Based on these previous decisions, Respondent argues, the theory presented herein warrants rejection as well. *Id*. at 12.

Further, Respondent asserts the evidence adduced in this case does not preponderate in favor of a finding that the Tdap vaccine can cause GBS. Opp. at 12. Specifically, Respondent notes the lack of large-scale studies establishing a causal association between the Tdap vaccine and GBS. *Id*. at 13. Alternatively, the studies set forth by Respondent indicate there is no association between heightened risk for GBS and the Tdap vaccine. *Id*. Tuttle, for example, involved approximately twenty-five million adults and children, and its authors concluded that there was no "association of public health significance" between tetanus-toxoid-containing vaccines and GBS. *Id.* (citing First Whitton Rep. at 5). Similarly, the Nordin study found no evidence that the Tdap vaccine is associated with an increased risk of GBS within six weeks of vaccination. *Id.* (citing First Whitton Rep. at 5; Chaudry Rep. at 10; Nordin at 1). The Baxter 2012 study and IOM reports had concurred in this finding. *Id.* at 13–14 (discussing Baxter 2012 at 1; 2012 IOM Rep. at 61).

Respondent argues that these studies have high probative value, undermining the theory that the Tdap vaccine can cause GBS. Opp. at 14. Petitioner's experts and referenced literature otherwise do not tip the scales in favor of causation. *Id.* at 15–17. Respondent rebuffs the predominant sources relied upon by Dr. Blaiss to establish molecular mimicry as not providing substantial support for his theory. *Id*. at 15. Thus, without stronger evidence, Petitioner did not preponderantly establish the Tdap vaccine cause GBS so as to satisfy *Althen* prong one. *Id.* at 17.

Respondent similarly contends that Petitioner did not provide enough evidence to preponderantly establish a logical sequence of cause and effect under *Althen* prong two. Opp. at 17. Respondent emphasizes the absence of reference to the Tdap vaccine in Petitioner's medical record, suggesting that treating physicians did not consider her GBS to have been vaccine-caused. *Id.* at 19 (citing Ex. 3 at 1041). At the same time, other evidence from the medical record undermined the possibility that the Tdap vaccine was causal. *Id*. For example, Respondent highlights Petitioner's treatment with valacyclovir while hospitalized in January 2022 as evidence of the likelihood that she was suffering from a viral infection (which could have triggered her Bell's palsy and/or GBS). *Id.* (citing Chaudhry Rep. at 7; Ex. 3 at 1236–37).

Respondent also highlights Petitioner's pregnancy as a potential trigger for her GBS, as noted by Dr. Chaudhry and the literature he referenced. Opp. at 19 (citing Chaudhry Rep. at 9; Chan at 1–2). Additionally, assertions by Dr. Jeret that Petitioner was predisposed to an abnormal response to the Tdap vaccine are not strongly supported. *Id.* at 20 (citing Br. at 17). Alternatively, the assertion that receiving the Tdap vaccine during pregnancy does not increase risk of GBS finds more support in the medical literature. *Id.* (First Whitton Rep. at 9–10; Layton at 1). In Layton, 150,000 women received the Tdap vaccine during or immediately after pregnancy, but did not suffer GBS. *Id.* (citing First Whitton Rep. at 9–10; Layton at 1, 3).

Lastly, Respondent contends Petitioner cannot preponderantly demonstrate that onset occurred in a medically acceptable timeframe. Opp. at 20 (citing Br. at 19; Ammar at 1-2). And because Petitioner did not demonstrate her Tdap vaccine could have caused GBS in the first place, no successful third prong showing was possible at all. *Id.* at 20–21.

## 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).[9] There is no Table claim for GBS caused by a tetanus or tetanus toxoid-containing 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

[9] 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).

[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 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*., 2022 WL 4869354 (Fed. Cl. Spec. Mstr. Aug. 31, 2022), *mot. for rev. den'd,* 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 Dept. 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 rev. 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*, 993 F.2d at 1528 ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

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

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

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

a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

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

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

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

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

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to

existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. 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").

E. *Determination to Resolve Case without a Hearing*

I have opted to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Toile v. Sec'y of Health & Human Servs.*, No. 15-85V, 2018 WL 1750619, at *2 (Fed. Cir. Apr. 12, 2018); *see also Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *See Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402–

03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417.

## ANALYSIS

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

GBS has been defined as an acute, monophasic peripheral neuropathy involving rapidly-progressive and ascending weakness and paralysis, and which is thought to have an autoimmune mechanism. Baxter 2012 at 800. It usually presents with pain, numbness, paresthesia, or weakness in the limbs, but can also present with pulse and blood pressure changes, or respiratory failure. *See* Chan at 320; Ammar at 2 tbl. 1; Shahrizaila & Yuki at 1–2.

Reliable scientific evidence supports the conclusion that GBS can be caused by *one* covered vaccine, the flu vaccine (although the risk from a wild flu *infection* is much greater). Bellanti & Rinaldi at 3. A large body of reasoned Program decisions[10] recognize an association between the flu vaccine and GBS (as well as other related peripheral neuropathies). Indeed, there is a Table claim for GBS due to receipt of a flu vaccine. 42 C.F.R. § 100.3.14. This means the Government accepts that sufficiently-probative and reliable science on the topic exists to justify conceding causation, at least for Program purposes. *Haskins v. Sec'y of Health & Hum. Servs.*, No. 18-1776V, WL 2020 1870279 (Fed. Cl. Spec. Mstr. Mar. 13, 2019). Even in cases where a Table element for such a claim cannot be met (for example, when onset is too short or too long to fit within the timeframe of 3–42 days set for the claim), any subsequent causation-in-fact analysis performed by the special masters rarely requires the claimant to offer proof in support of the first *Althen* prong, "can cause" element; instead, it is reasonably assumed to be satisfied already. *See Welch v. Sec'y of Health & Hum. Servs*. No. 18-494V, 2019 WL 349360 (Fed. Cl. Spec. Mstr. July 2, 2019).

Other vaccines have also been found causal of GBS, although there is disagreement among the special masters as to the preponderant strength of these proposed associations. *See, e.g.*, *Gross v. Sec'y of Health & Hum. Servs.*, No. 17-1075, 2022 WL 9669651, at *36–37 (Fed. Cl. Spec. Mstr. Sept. 22, 2022) (finding the pneumococcal vaccine caused GBS); *but see Trollinger v. Sec'y of Health & Hum. Servs.*, No. 16-473V, 2023 WL 2521912, at *30 (Fed. Cl. Spec. Mstr. Feb. 17, 2023), *mot. for rev. den'd*, 167 Fed. Cl. 127 (2023) (holding that the pneumococcal vaccine was not shown to cause GBS); *Bielak v. Sec'y of Health & Hum. Servs.*, No. 18-761V, 2022 WL

[10] Although prior decisions from different cases do not control the outcome herein, special masters may reasonably take into account, for guidance, the logic of such reasoned determinations. In fact, it is wise to do so, given how often similar causation theories or fact patterns arise in Vaccine Program cases.

18058244, at *3 (Fed. Cl. Spec. Mstr. Dec. 9, 2022) (same). It thus cannot be said that the Program has developed a consistent view as to what the science preponderantly "says" about causation of GBS when the flu vaccine is not involved. Instead, it appears that the outcome in such cases is mostly a function of the evidence before the special master (along with a special master's individual views about the applicability of causation theories to different vaccines), with no clear trend one way or the other.

Claims that the Tdap vaccine can cause GBS are also common, but it is not the case that causation in this specific context can be assumed from what is known about the flu vaccine association. In fact, and based on my reasoned and detailed consideration of the theory in several prior cases, it appears *unlikely* that the Tdap vaccine can cause GBS.[11] *Hiatt v. Sec'y of Health & Hum. Servs.*, No. 19-1363V, 2025 WL 3230494 (Fed. Cl. Spec. Mstr. Oct. 24, 2025), *mot. for review den'd,* 2026 WL 730718 (Fed. Cl. Feb. 5, 2026), *appeal docketed*, No. 2026-1621 (Fed. Cir. Apr. 7, 2026); *Kaczerowski v. Sec'y of Health & Hum. Servs.,* No. 21-758V, 2025 WL 2798865, at *29–38 (Fed. Cl. Spec. Mstr. Aug. 28, 2025); *Dennington*, 2023 WL 2965239 at *19–20; *K.A.*, 2022 WL 20213037, at *29-30; *Montgomery v. Sec'y of Health & Hum. Servs.*, No. 15-1037V, 2019 WL 2511352 (Fed. Cl. Spec. Mstr. May 21, 2019); *Tompkins v. Sec'y of Health & Hum. Servs.*, No. 10-261V, 2013 WL 3498652 (Fed. Cl. Spec. Mstr. June 21, 2013), *mot. for rev. den'd*, 117 Fed. Cl. 713 (2014); *Isaac*, 2012 WL 3609993 at 19.[12]

Prior Tdap-GBS cases have often involved causation theories nearly identical to what is offered here. I recently addressed in great detail the arguments for a Tdap vaccine-GBS association. *See generally Kaczerowski,* 2025 WL 2798865, at *3–10, 32–38. The expert offered by the petitioner in that case relied on numerous contentions and specific items of literature that have been offered in this case as well. *See, e.g.*, *Kaczerowski*, 2025 WL 2798865, at *2–10 (similarly filing, among other things, Ammar and Bakshi & Graves; Pollard & Selby; and Yih). But I deemed his showing not to meet the preponderant standard—despite the fact that the petitioner had filed four expert reports, allowing ample opportunity to refine his opinion in response to the critiques raised by Respondent's experts.

In particular, I noted the following deficiencies with the causation theory proposed in *Kaczerowski*:

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[11] I have also decided a few cases in which I determined that the petitioner failed to establish a causal association between the Tdap vaccine and CIDP—a different injury from GBS, although also still a peripheral neuropathy (and Program claimants frequently rely on GBS-specific evidence in arguing that a vaccine can cause CIDP). *See, e.g.*, *DeVaughn v. Sec'y of Health & Hum. Servs.*, No. 22-832V, 2025 WL 758128 (Fed. Cl. Spec. Mstr. Feb. 10, 2025); *Howard*, 2022 WL 4869354 at *26; *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 18-1012V, 2022 WL 1013264, at *1 (Fed. Cl. Spec. Mstr. Mar. 11, 2022).

[12] I recently decided another case involving the contention that the Tdap vaccine can cause GBS, but resolution turned on the third *Althen* prong, rendering that decision less valuable for guiding the present outcome. *Langert v. Sec'y of Health & Hum. Servs.,* No. 22-809V, 2025 WL 1892418 (Fed. Cl. Spec. Mstr. June 13, 2025).

- Scientific evidence associating the Tdap vaccine's antigenic/wild components with GBS is lacking;

- The Government has not conceded a GBS-Tdap vaccine association, even if it warns against a second Tdap vaccine exposure after GBS temporally develops in the wake of an earlier Tdap vaccine receipt;

- Reliance on case reports as evidence of causation is misplaced as it serves only as evidence of a temporal association;

- Independent studies that purport an association between the Tdap vaccine with GBS are unreliable or rebutted by better studies;

- Reliance on analogizing the Tdap vaccine to the flu vaccine is improper; and

- Petitioner's experts were unable to explain why the Petitioner did not previously develop GBS after Tdap boosters received in the past.

*Kaczerowski,* 2025 WL 2798865, at 43–51.

In *Isaac*, a petitioner proposed molecular mimicry as the causal mechanism. *Isaac*, 2012 WL 3609993, at *6. But the special master determined that the petitioner's expert had over-relied on a single case report (Pollard & Selby—also offered here) to prove causation, without adequately substantiating the mechanism. *Id.* at *20–21. This determination was affirmed on appeal at the Court of Federal Claims and Federal Circuit. In *Tompkins*, the special master denied entitlement in a case alleging that a number of vaccines received at the same time (including Tdap) caused a petitioner's GBS, but the causal theory put forward attempted to assert that the vaccines could also individually trigger the disease. *Tompkins*, 2013 WL 3498652, at *15. The petitioner's expert, however, relied heavily on VAERS passive surveillance data, and otherwise invoked a number of theories (molecular mimicry, or endotoxin in tetanus-containing vaccines) that were only cursorily substantiated. *Id.* at *19–23.

I acknowledge that some special masters have deemed causation to have been demonstrated in Tdap vaccine-GBS cases. *See Mohamad v. Sec'y of Health & Hum. Servs.*, No. 16-1075V, 2022 WL 711604, at *18 (Fed. Cl. Spec. Mstr. Jan. 27, 2022), *mot. for rev. den'd,* 2024 WL 4943421 (Fed. Cl. Nov. 12, 2024). In *Mohamad*, a special master ruled in a petitioner's favor in a Tdap-GBS case, but almost wholly based on the determination that the Government had effectively conceded the first *Althen* Prong. In particular, the special master observed that (a) in 2011, the IOM had noted a precaution to receipt of the Tdap vaccine in the future if an immunized individual had developed GBS within six weeks of a prior dose, and (b) this precaution note (along

with an acknowledgment of the possibility of encephalopathy in a seven-day timeframe) had been maintained in subsequent ACIP reports, despite interim findings that the tetanus-GBS link was not as well-established as previously thought. *Mohamad,* 2022 WL 711604, at *13–15. From this (and also due to credibility determinations specific to the experts who had testified in that case), the special master concluded that the first *Althen* prong was satisfied. *Id.* at *7, 15–18.

But the argument that the temporal sequence of governmental publications discussing GBS as a possible adverse event from receipt of the Tdap vaccine, coupled with treatment advice against giving it *again* to a person who previously also experienced Tdap vaccine-associated GBS, does not amount to persuasive proof that the Government "knows" there is causal association. *Kaczerowski,* 2025 WL 2798865, at *34. And efforts to broadly apply the same thinking applicable to the flu vaccine and GBS to all other covered vaccines are not sufficient either. Instead, a claimant seeking to prove the Tdap vaccine caused an individual's GBS needs to offer some overall combination of proof with *some specificity* to the Tdap vaccine's components, rather than analogizing to the flu vaccine. This showing must be *preponderantly* established—not simply that it is *biologically plausible* a vaccine could impact the immune system in such a way that it could lead to an autoimmune demyelinating disease, but that it *likely* does so.

Overall, then, I emphasize that I have repeatedly been confronted with causation theories endeavoring to preponderantly establish a Tdap vaccine-GBS association. But after careful, detailed analysis (exemplified most recently by *Kaczerowski*), I have concluded that the theories are not preponderantly supported—no matter how many individual items of literature offered, or the expert qualifications at issue. For me to find that a claimant had avoided the pitfalls that resulted in denials of entitlement in such prior matters, I would need to be presented with more than a different expert, or petitioner with a distinguishable medical history. Rather, I would need evidence not previously considered—in particular, some *more recent scientific or medical proof* that breathes new like into a theory so often rejected.

## II. Petitioner Has not Carried Her Prong One Burden of Proof

It is understood in the Vaccine Program that because claimants must preponderantly establish all three *Althen* prongs to receive damages, special masters need only evaluate those causation elements relevant to a denial of entitlement. *Dobrydnev v. Sec'y of Health & Hum. Servs*., 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). Here, I find the first *Althen* prong has not been satisfied (and that failure alone is grounds for denying entitlement).[13] Even if it were undisputed that Petitioner's Bell's palsy and subsequent symptoms amount to GBS, it has not been preponderantly shown the Tdap vaccine could have caused them.

[13] Respondent has also raised reasonable objections to Petitioner's prong two showing that would merit evaluation if my prong one determination is deemed erroneous. But because *all three* prongs must be met for entitlement to damages, my analysis here can reasonably focus solely on the first prong.

The theory offered in this case falls victim to the same kind of generally-deficient causation arguments I reviewed at length in *Kaczerowski.* There, as here, the Petitioner's experts argue that the Tdap vaccination is a trigger for molecular mimicry. Using modeling, Petitioner's experts argue that there is sufficient homology between tetanus toxoid to other sera proteins to trigger such an autoimmune reaction. But I have noted many times now that this argument is too general, and is not backstopped by reliable evidence suggesting either that antibodies necessary for a cross-reactive attack on nerve myelin are *likely* generated in response to the relevant Tdap vaccine's components (here, the tetanus toxoid, since that is the focus of Petitioner's experts), or that these antibodies do likely trigger GBS (as opposed to being potentially reactive or generated in the midst of an autoimmune disease process—not at its outset, as would be required if the vaccine were likely causal). The theory is one I can reasonably say, based on repeated prior exposure, to be no more than *plausible*, and lacking in sufficient reliable scientific or medical support.[14]

In addition, Petitioner's experts fall into many of the same "traps" in setting forth the links in their chain of reasoning that frequently have bedeviled other claimants seeking to prove a Tdap vaccine-GBS association. Thus, they rely on case reports and temporal associations—evidence that is exceedingly weak in supporting causation. Indeed, by the admission of Petitioner's experts, case reports better serve as signals for further study than as outright proof of causation. *See, e.g., Langert v. Sec'y of Health & Hum. Servs.,* No. 22-809V, 2025 WL 1892418, at *8 fn. 9 (Fed. Cl. Spec. Mstr. June 13, 2025). Drs. Jeret and Blaiss have also relied on numerous items of literature (*see, e.g.,* Pollard & Selby; Ammar; Bakshi & Graves; Yih) also filed in *Kaczerowski*, not to mention many other prior decisions, but which have been assessed as inadequate support for a preponderant finding of causation. And Respondent references some epidemiologic studies more directly contradicting the conclusion that the Tdap vaccine is associated with GBS. Baxter 2013 at 201-3.

Admittedly, a few items of literature involving studies have been offered that were not evaluated in prior cases, like Inic-Kanada or Goodfellow & Willison. But these as well do not amount to the evidentiary support that so often has not been provided in this context. As noted by Dr. Whitton, the Inic-Kanada paper is irrelevant to Petitioner's claim because the mice inoculated

[14] The practice of relying on prior determinations has sometimes been criticized by the Court, based on the view that it results in insufficient explanations for a special master's reasoning, or works an unfairness on claimants (who deserve the chance to fully litigate their claim no matter the special master's reasoned intuition about its likely success). *Radke v. Sec'y of Health & Hum. Servs*., No. 22-1384, 2026 WL 1132925, at *4–5 (Fed. Cl. Apr. 2, 2026); *Stewart-Robinson v. Sec'y of Health & Hum. Servs*., 173 Fed. Cl. 567, 576 (2024). However, the Court has also acknowledged that special masters correctly and reasonably take into account the "on the job" expertise they develop in adjudicating Vaccine Act claims, and thus familiarity with commonly-asserted causation theories. *Eberline v. Sec'y of Health & Hum. Servs*., No. 23-655, 2026 WL 1746434, at *21–22 (Fed. Cl. May 29, 2026). In addition, the performance of a special master's duties also occurs within a specific context in which adjudication of claims is meant to be expedited and more informal than a usual trial setting. Comparable determinations should serve as persuasive guidance when a special master is confronted with a theory they have been exposed to many times before.

with tetanus toxoid in that study did not develop signs of neurological disease. Second Whitton Rep. at 6 (discussing Inic-Kanada). Even if the relevant antibodies theorized to interact with a target self glycoprotein were generated in response to animal subjects first inoculated with tetanus toxoid, there was no concrete evidence of those antibodies interacting with gangliosides to create an autoimmune reaction and neurologic complications, and it was an overgeneralization to assume the antibodies would be pathogenic in the specific manner required to initiate GBS. *Id.* at 6-7; *see also* Goodfellow & Willison at 5 (discussing anti-GQ1b IgG, anti-GM1, anti-GD1a, andti-GT1a anti-ganglioside antibodies in relationship to GBS, and concluding that there is a likely pathogenic pathway only for *C. Jejuni*-associated GBS). If anything, Dr. Blaiss married the Inic-Kanada and Goodfellow & Willison articles to create a hypothesis, but together they did not amount to reliable evidence supportive of a causal relationship.

I cannot say with any degree of certainty that it could *never* be established (and by the "more likely than not" preponderant standard applicable to Vaccine Act claims) that the Tdap vaccine could cause GBS. But the evidence offered most often in these cases reflects an effort to apply what is known about the flu vaccine's association to a disparate context. And the evolution of the Government's understanding of a relationship over time only serves to widen the causal gap. At present, it is simply more likely than not that GBS occurring in the temporal wake of receipt of a Tdap vaccine is more likely attributable to chance (perhaps a function of more individuals receiving Tdap boosters). Some new and compelling research filling in the numerous missing links in the theory of a causal association will be required if entitlement is to be found in these cases.

## CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[15]

**IT IS SO ORDERED**.

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

[15] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.