In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1363V

ANGELA HIATT,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: October 24, 2025
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Richard Gage, Law Offices of Richard Gage, Cheyenne, WY, for Petitioner.

Mary Holmes, U.S. Department of Justice, Washington, DC, Respondent.

ENTITLEMENT DECISION[1]

On September 6, 2019, Angela Hiatt 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 the tetanus-diphtheria-acellular-pertussis ("Tdap") and human papillomavirus ("HPV") vaccines on February 16, 2017. Petition (ECF No. 1) at 1. She has since narrowed her claim to focusing solely on the Tdap vaccine. Petitioner's Brief, filed Feb. 25, 2025 (ECF No. 77) ("Br.") at 6–7.

I determined that this matter could be fairly resolved via ruling on the record, and both sides filed briefs in support of their positions. *See* Br.; Respondent's Opposition, filed Mar. 26, 2025 (ECF No. 80) ("Opp."); Petitioner's Reply, filed Apr. 2, 2025 (ECF No. 81) ("Reply"). The

[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).

matter is now ripe for resolution. For the reasons set forth in more detail below, I hereby deny entitlement. Petitioner has not preponderantly established that the Tdap vaccine can cause GBS, or did so to her.

I. Factual Background

Ms. Hiatt received both the Tdap and HPV vaccines on February 16, 2017, at the office of her primary care provider ("PCP"). Ex. 1 at 44–46. She was 45 years old at the time. There is no medical record evidence indicating that she experienced any unusual reaction to the vaccines in the week immediately after.

On February 27, 2017 (now eleven days post-vaccination), Petitioner went to the emergency department ("ED") of McKay Dee Hospital in Ogden, Utah, with complaints of chest and back pain that she reported had begun earlier that morning. Ex. 5 at 95. She also reported left-sided jaw pain, which she associated with a recent sinus cold. *Id.* Evaluation for cardiac issues revealed nothing of concern, and she was treated with antacids and discharged with a diagnosis of non-cardiac chest pain. *Id.*

That same day Petitioner went to see her PCP for further evaluation of the pain symptoms that had caused her to visit the ED. Ex. 1 at 42. She also reported symptoms of upper respiratory infection with facial pressure and ear pain. *Id.* Her PCP assessed her with an upper respiratory infection with non-cardiac chest and thoracic back pain, and directed her to follow up if her symptoms did not improve. *Id.* at 42–43. Petitioner returned to the ED later that same day, however, due to her concerns about worsening chest pain. Ex. 5 at 29. She was reevaluated for cardiac issues, and also underwent a lung scan to test for pulmonary emboli, but the work-up was negative, and she was discharged again with pain medication and antihistamines. *Id.*

Three days later (March 1, 2017), Ms. Hiatt went back to her PCP for evaluation of ongoing chest pain plus weakness and hand/foot/tongue numbness. Ex. 1 at 39. She now reported that she was experiencing nausea, vomiting, and "stomach flu" symptoms in the days before her chest pain started (something Petitioner had not informed treaters at either of the February 27th medical encounters, although this was deemed possibly to reflect prior gastric band surgery she had experienced). *Id.* Her PCP's impression was epigastric abdominal pain, chest pain, anemia, weakness, and fatigue, and blood testing was ordered, along with a cardiac stress test (which resulted in no significant findings). *Id.* at 40, 41.

Because of Petitioner's ongoing symptoms, she was admitted to South Ogden Regional Medical Center based upon a three-day history of progressive weakness and a one-week history of back pain. Ex. 9 at 55. At this time she specifically reported a preceding gastrointestinal illness with nausea, vomiting, and diarrhea the week prior. *Id.* Exam now revealed an absence of deep tendon reflexes, weakness, and sensory deficits in her legs and arms. *Id.* at 59. And a thoracic spine

MRI yielded normal findings, but she tested positive for elevated protein levels in her cerebrospinal fluid. *Id.* at 26; 123.

Based upon her overall presentation, a consulting neurologist proposed that Petitioner had GBS preceded by gastrointestinal flu-like illness. Ex. 9 at 26–27 ("this increase in protein by 20 over the upper range of protein for CSF as well as the cell count being normal with given history is probably consistent with Gillain-Barre [sic] syndrome and warrant treatment for this"). She was admitted to the intensive care unit because of respiratory distress, and within days required intubation and ventilatory assistance. *Id.* at 65. While hospitalized, Petitioner received a five-day course of IVIG, and after some gradual improvement was transferred to Northern Utah Rehabilitation Hospital on March 15, 2017. *Id.* at 3–4, 118.

By April 13, 2017, Petitioner was able to walk and perform personal tasks independently, and was discharged from rehab at that time. Ex. 6 at 40–41. She continued thereafter to experience neurologic sequelae of her GBS, however. Ex. 4 at 8–10. She required some physical therapy that summer, and continued to experience balance issue and limb weakness and numbness into the fall. Ex. 1 at 21, 45; Ex. 4 at 2–4, 5–7. Other evidence of Petitioner's medical treatment in 2018 does not bear on causation, and I therefore do not include discussion of it herein.[3]

II. Expert Reports

A. *Petitioner's Expert – Dr. Carlo Tornatore*

Dr. Tornatore is a neurologist, and he prepared a single written report in this case. *See* Report, dated Feb. 7, 2024, filed as Ex. 36 (ECF No. 56-1) ("Tornatore Rep.").

Dr. Tornatore graduated from Cornell University with a Bachelor of Arts and Sciences in Neurobiology, and attended Georgetown University Medical Center, where he received a Master of Science in Physiology. He subsequently graduated from medical school at Georgetown University School of Medicine, completing a residency in the Department of Neurology at Georgetown University Hospital. Tornatore Rep. at 1. Dr. Tornatore also completed a fellowship in Molecular Virology at the National Institute of Health in Bethesda, Maryland. *Id*. He has published multiple articles addressing demyelinating disorders and their pathology. *Id*. at 2. Currently, Dr. Tornatore serves as a Professor and Chairman of the Department of Neurology at Georgetown University Medical Center, Chairman and Neurologist-in-Chief of the Department of Neurology at Medstar Georgetown University Hospital in Washington, D.C., and Medstar Health's

[3] Petitioner also filed multiple personal and witness statements that described onset and Petitioner's state after vaccination. *See* Affidavit, dated Apr. 26, 2021, filed as Ex. 14 (ECF No. 27-1); Affidavit, dated Apr. 26, 2021, filed as Ex. 15 (ECF No. 27-2); Affidavit, dated Apr. 26, 2021, filed as Ex. 16 (ECF No. 27-3); Affidavit, dated Apr. 26, 2021, filed as Ex. 17 (ECF No. 27-4); Affidavit, dated Sep. 27, 2022, filed as Ex. 32 (ECF No. 46-1); Affidavit, dated Nov. 1, 2022, filed as Ex. 33 (ECF No. 47-1); Physician Letter, dated Nov. 1, 2022, filed as Ex. 34 (ECF No. 47-2). However, because this case turns on general causation, I forgo including a discussion of those documents.

Regional Director Neurology. *Id.* at 1. Throughout his clinical career, Dr. Tornatore has cared for several hundred patients with acute and post-acute GBS. *Id.* at 2.

Dr. Tornatore's report began with a detailed review of Petitioner's medical history, although he stressed certain aspects of it over others. Tornatore Rep. at 2–8. For example, he observed that her first medical encounter eleven days post-vaccination featured complaints of back pain, which he noted could be a presenting symptom of GBS. *Id.* at 2–3, 20. This evolved not only to radiating pain in the chest and jaw, but finger tingling and numbness. *Id.* at 3. Treaters over time, and based upon additional exams and lab findings, embraced a GBS diagnosis, and Dr. Tornatore found no reason to question it himself. *Id.* at 4–6, 8–9.

Dr. Tornatore next provided a brief explanation of GBS. He deemed it an "autoimmune demyelinating neuropathy" impacting the peripheral nervous system, and understood to be instigated by antigens from either a viral/bacterial infection or (in some limited cases) vaccination. Tornatore Rep. at 9. A cross-reactive attack on nerve myelin by autoantibodies produced in response to the stimulating foreign antigens would drive GBS. Its symptomatic features include extremity weakness and numbness, and it could also cause facial weakness. *Id*.

The cross-reactivity of the autoantibodies driving GBS would occur as a result of molecular mimicry between the presenting foreign antigens and self-tissue myelin structures. Tornatore Rep. at 9–10; R. Hughes & D. Cornblath, *Guillain-Barré Syndrome,* 366 Lancet 1653, 1660 (2005), filed as Ex. 37 (ECF No. 56-2) ("Hughes & Cornblath"). The general concept of mimicry, or shared homology between amino acid sequences in viral/bacterial antigens and host structures, was well accepted in science—along with the fact that this could result in antibodies produced in reaction to a foreign antigen to mistakenly attacking self. *Id.* at 9. But Dr. Tornatore acknowledged that medical science had not identified a specific cross-reactive antibody likely causal for *most* patients suffering from the common form of GBS, acute inflammatory demyelinating polyneuropathy ("AIDP"). *Id*. at 10–11; Hughes & Cornblath at 1659.

Nevertheless, Dr. Tornatore maintained that components of the Tdap vaccine could likely trigger an autoimmune process leading to GBS from molecular mimicry. Tornatore Rep. at 11–12. In support of this contention, he began with a review of government publications or notifications that he deemed to concede this possibility. The website of the "Centers for Disease Control" (the "CDC"), for example, notes that "certain vaccines" have been associated with GBS (although the screenshot provided in Dr. Tornatore's report says nothing about Tdap specifically, let alone GBS risk due to any of its wild infectious components).[4] Dr. Tornatore also referenced a document

[4] Petitioner, however, only listed the URL to the CDC's website in his report, but did not file anything as it relates to this particular reference. *See* Centers for Disease Control and Prevention, *Guillain-Barré Syndrome,* (May 15, 2024) https://www.cdc.gov/campylobacter/guillain-barre.html [https://web.archive.org/web/20240515063152/https://www.cdc.gov/campylobacter/guillain-barre.html] (last visited October 22, 2025).

published in 2017 by the "Advisory Committee on Immunization Practices (the "ACIP"), which advised treaters to take care in administering tetanus-containing vaccines to individuals who had previously experienced GBS within six weeks of receipt of a prior dose of tetanus-containing vaccine. Tornatore Rep. at 11–12 (citing E. Ezeanolue et al., "Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)," *General Best Practice Guidelines for Immunization,* https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf (2017) (last visited Oct. 22, 2025), filed as Ex. 38 (ECF No. 56-3) ("Ezeanolue"), at 54). He also noted this precaution was repeated in the CDC "Morbidity and Mortality Weekly Report" from 2018. J. Liang et al., "Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," 67 *Morbidity and Mortality Weekly Report* 1 (2018), filed as Ex. 39 (ECF No. 56-4).

Medical science provided a reliable reason to associate Tdap vaccine antigenic components with GBS, Dr. Tornatore contended. Tornatore Rep. at 12–17. He pointed to existing medical and scientific support for the idea that a specific wild bacterial infection (*Campylobacter jejuni*) has been associated with GBS mediated by cross-reacting autoantibodies that (as a result of mimicry between the antigens of the bacterial infection and nerve structures) mistakenly attacked self. *Id.* at 12. But much of Dr. Tornatore's causation theory focused not on Tdap but upon the distinguishable influenza ("flu") vaccine. In support, he offered some items of literature commonly seen in Program cases, but mainly relevant to the flu vaccine or its variants. *Id.* at 12, 13–17.[5]

Nevertheless, Dr. Tornatore opined that Tdap antigens could prompt a similar cross-reaction despite their differences from the flu vaccine components, due to molecular mimicry. Many animal model experiments had observed that neuropathic symptoms could be induced by flu virus or vaccine components due to amino acid sequential homology with myelin basic protein ("MBP")[6] in live subjects.[7] Tornatore Rep. at 13–16. Thus, "viruses/vaccines bearing such

[5] I do not include these citations or a discussion of them—both because they are far more often than not referenced in Program cases involving GBS, and because they are primarily relevant to the flu vaccine. *See, e.g.*, L. Schonberger et al., *Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976–1977,* 110 Am. J. Epid. 105 (1979), filed as Ex. 42 (ECF No. 56-7) ("Schonberger").

[6] MBP is defined as "a basic protein (MW 18,000) that constitutes about 30 per cent of myelin proteins; elevated levels of MBP occur in acute exacerbation of multiple sclerosis and acute cerebral infarction." *Myelin Basic Protein,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=100535 (last visited Oct. 22, 2025).

[7] Dr. Tornatore also briefly referenced another kind of mechanism that could explain an autoimmune process prompted by a foreign antigen—"degeneracy" of T and B cells nonspecific to the presenting antigen. Tornatore Rep. at 13; D. Mason, *A Very High Level of Crossreactivity is an Essential Feature of the T Cell Receptor,* 19 Immunol. Today 395 (Sept. 1998), filed as Ex. 45 (ECF No. 56-10). But he did not provide details as to how this kind of nonspecific activation was likely vaccine-sparked, and overall relied more heavily on the standard kind of molecular mimicry mechanism (cross-reactivity driven by autoantibodies generated by antigenic mimics) usually featured in Program cases.

[homologous] peptides may contribute to the pathogenesis of autoimmune inflammatory CNS activity"—and it was "unlikely that [only] a single viral peptide is responsible for the induction of autoimmune inflammatory CNS disease." *Id.* at 15.

In order to connect existing scientific support for an autoimmune mechanism for GBS in the context of the flu vaccine to the circumstances of this case, Dr. Tornatore noted that additional research had proposed another GBS target antigen. Tornatore Rep. at 17–18; H. Inglis et al., *Antibody Responses to Peptides of Peripheral Nerve Myelin Proteins P0 and P2 in Patients with Inflammatory Demyelinating Neuropathy,* 78 J. Neurol. Neurosurg. Psych. 419 (2007), filed as Ex. 51 (ECF No. 57-5) ("Inglis") (finding sample of GBS patients displayed increased antibody reactivity to "P2" peripheral myelin protein). This P2 protein had "significant homology" with the tetanus toxin, and Dr. Tornatore relied on his own BLAST search[8] to substantiate the contention. Tornatore Rep. at 18–19. In effect, because "epitopes from tetanus toxin bear resemblance" to a peptide relevant to experimentally-induced forms of CNS and peripheral neuropathies, then it was likely the same kind of mimicry could occur, and drive GBS, in the context of a Tdap vaccine's administration. *Id.* at 20.

Dr. Tornatore did, however, endeavor to offer some literature specific to the putative association between the Tdap vaccine and GBS. For example, he cited to an article that evaluated VAERS[9] passive surveillance data. N. Souayah et al., *Guillain-Barré Syndrome After Vaccination in United States: Data from the Centers for Disease Control and Prevention/Food and Drug Administration Vaccine Adverse Event Reporting System (1990-2005),* 11 Neuromusc. Dis. 1 (2009), filed as Ex. 22 (ECF No. 20-8) ("Souayah"). Souayah noted a number of other vaccines that might also be associated with GBS, although (a) a flu vaccine association was the most commonly-observed, and (b) tetanus-containing vaccines came in third place in term of how often

[8] According to its own website, the "Basic Local Alignment Search Tool" (BLAST) "finds regions of local similarity between sequences. The program compares nucleotide or protein sequences to sequence databases and calculates the statistical significance of matches. BLAST can be used to infer functional and evolutionary relationships between sequences as well as help identify members of gene families." https://blast.ncbi.nlm.nih.gov/Blast.cgi (last visited Oct. 22, 2025). It is common in the Program for immunology experts to utilize BLAST searches when arguing about whether a vaccine's protein components mimic self-structures.

[9] The Vaccine Adverse Event Reporting System ("VAERS") is a national warning system designed to detect safety problems in U.S.-licensed vaccines. *See About VAERS*, VAERS, https://vaers.hhs.gov/about.html (last visited October 22, 2025). It is managed by both the CDC and the FDA. VAERS monitors and analyzes reports of vaccine related injuries and side effects from both healthcare professionals and individuals. But it has been observed in the Program that VAERS data is not particularly probative of causation, unless supplemented with other reliable evidence—since a VAERS report only establishes a temporal, post-vaccination occurrence, and does not independently confirm the reported adverse event either. *See also Vig v. Sec'y of Health & Human Servs.*, No. 01–198V, 2013 WL 6596683, at *17 (Fed. Cl. Spec. Mstr. Nov. 14, 2013) ("VAERS is a stocked pond, containing only reports of adverse events after vaccinations but no data about the number of vaccines administered or the occurrence of the same adverse event in individuals who have not been vaccinated").

post-vaccination GBS was reported. Souayah at 2 tbl. 1, 3. Souayah's authors also acknowledged the limitations on reliance on uncorroborated VAERS report data. *Id.* at 5.

Another such article is a case report—and it often surfaces in cases in which claimants allege GBS to have been caused by the Tdap vaccine. Tornatore Rep. at 12 (citing J. Pollard & G. Selby, *Relapsing Neuropathy Due to Tetanus Toxoid: Report of a Case,* 37 J. Neurol. Sci. 113 (1978), filed as Ex. 43 (ECF No. 56-8) ("Pollard & Selby"). Pollard & Selby, however, is a 47 year-old case report—and it involved an individual who experienced three documented instances of relapse of neuropathic symptoms after receipt of a tetanus toxoid vaccine—a fact pattern distinguishable from this Petitioner's experience (and as noted below, there are other reasons to question Pollard & Selby's probative value in this case).

Dr. Tornatore also emphasized an article that observed the aforementioned relapse risk of GBS symptoms in individuals previously diagnosed with GBS but who had received a tetanus toxoid-containing vaccine. R. Hughes et al., *Risk of Relapse of Guillain-Barré Syndrome or Chronic Inflammatory Demyelinating Polyradiculopathy,* 73 Muscle & Nerve 1230, 1231 (Sep. 1996), filed as Ex. 56 (ECF No. 57-10) ("Hughes") (describing case series reports of 110 patients with GBS or CIDP over 12-year period; identifying only two instances of a temporal relationship to vaccination, but stressing (from an "overcautious" position) the risk of receiving a second vaccine if a person experienced a symptoms relapse within 12 weeks of a prior dose). Hughes, however (like Pollard & Selby) is far more probative of relapse risk in existing patients than to the present circumstances).

Otherwise, Dr. Tornatore maintained that an eleven-day, post-vaccination onset was medically acceptable, although he relied on a study specifically relevant to the flu vaccine for support.[10] Tornatore Rep. at 21–22. And he deemed it "highly improbable" that Petitioner's gastrointestinal symptoms explained her GBS, since a *Campylobacter jejuni* infection was never confirmed, and the kind of GBS associated with such a bacterial infection was usually axonal in nature (as opposed to AIDP, which Petitioner likely experienced). *Id.* at 22.

B. *Respondent's Experts*

1. Kourosh Rezania, M.D. – Dr. Rezania, a neurologist, offered a single expert report for Respondent. Report, dated Dec. 20, 2024, filed as Ex. A (ECF No. 72-1) ("Rezania Rep.").

Dr. Rezania received his medical degree from Tehran University School of Medicine. Curriculum Vitae, filed as Ex. B (ECF No. 72-2) ("Rezania CV"), at 2. He then completed an

[10] *See* Schonberger at 112 fig. 5.

internship in Internal Medicine at New York Hospital, followed by his residency in Adult Neurology at Mount Sinai Medical Center. *Id.* Thereafter, Dr. Rezania completed fellowships in Neurophysiology and Neuromuscular Medicine at the University of Chicago. *Id.* He is currently a professor of Neurology, as well as the Director of the Neuromuscular Fellowship Program and the ALS Multidisciplinary Clinic at the University of Chicago Pritzker School of Medicine. Rezania Rep. at 1. Dr. Rezania is board certified by the American Board of Psychiatry and Neurology in Adult Neurology and Psychiatry, and Neuromuscular Medicine, in addition to Electromyography by the American Board of Neuromuscular and Electrodiagnostic Medicine. Rezania CV at 2. He has published over 60 peer-reviewed publications, with a primary focus on various neuromuscular diseases, and has evaluated and treated numerous patients with GBS over the course of his clinical career. Rezania Rep. at 1.

Dr. Rezania accepted Petitioner's GBS diagnosis. Rezania Rep. at 3–4. He also conceded that its onset likely occurred on February 27, 2017, as evidenced by Petitioner's complaints of "severe thoracic radicular pain." *Id.* at 4. But Dr. Rezania gave more weight to the possibility that it was attributable to a prior, or intercurrent, infection than did Dr. Tornatore. Her nausea and vomiting were reported (at Petitioner's February 27, 2017 ED visit) to have begun a few days earlier (but after vaccination), and it was reasonable to assume a viral infection was more likely explanatory. *Id.* Because Petitioner was never tested for possible "viral suspects," however, it could not be ascertained what might have been a credible alternative causal explanation—but regardless, in almost half of all GBS cases only an idiopathic (and hence unidentified) cause can be offered. *Id.* at 6; B. van den Berg et al., *Guillain-Barre Syndrome: Pathogenesis, Diagnosis, Treatment and Prognosis* 10 Nat. Rev. Neurol 469, 469 (2014), filed as Ex. A-3 (ECF No. 73-3) (stating that [t]wo-thirds of patients report symptoms of a recent respiratory or gastrointestinal tract infection before the onset of GBS" … but "[i]n about half of patients with GBS, a specific type of receding infection can be identified.").

By contrast, Dr. Rezania doubted the Tdap vaccine could have been causal of Petitioner's GBS. For starters, the risk of GBS after such a vaccine was much lower than the risk associated with the flu vaccine (and even the updated version of that vaccine posed less of a risk than the one associated with GBS during the swine flu epidemic in the 1970s). Rezania Rep. at 4; D. Salmon et al., *Association Between Guillain-Barre Syndrome and Influenza A (H1N1) 2009 Monovalent Inactivated Vaccines in the USA: a Meta-Analysis*. 381 Lancet 1461, 1461 (2013), filed as Ex. A-8 (ECF No. 73-8) (suggesting only a "small increased risk" of GBS associated with the influenza A (H1N1) 2009 monovalent inactivated vaccine). At most, some case reports speculated that there could be an association with the Tdap vaccine, but they did not constitute especially persuasive evidence.

Dr. Rezania questioned the probative value of other items of evidence cited in Dr. Tornatore's Report. Ezeanolue, for example, not only settled on the less-impactful use of the word

"precaution" (rather than "contraindication"), but it also suggested the absence of "strong evidence of a significant association" between GBS and Tdap. Rezania Rep. at 4; Ezeanolue at 56. And Souayah relied on passive surveillance data intended for use as "signal detection," and thus was not reliable proof of causation. Rezania Rep. at 5 ("VAERS data may be incomplete, imprecise, incidental, or unable to be substantiated, and it should not be used independently to ascertain vaccine-related adverse events"). In addition, Dr. Rezania challenged the probative value of evidence offered by Dr. Tornatore specific to the flu vaccine—not only because such evidence involved a different vaccine, but also due to the fact that the articles in question often did not actually support causation meaningfully. *Id.* at 5–6.

Dr. Tornatore's attempt to establish homologic similarity between the tetanus component of Tdap and MBP nerve elements was also unsuccessful, in Dr. Rezania's estimation. Rezania Rep. at 6. Dr. Tornatore's own personal findings (from desktop computer research) could not be relied upon in the first place, since they did not reflect peer-reviewed and published determinations. *Id.* Inglis aside, "the target antigen in the majority of AIDP (the GBS variant the petitioner had) cases is yet unrecognized, and there is no clear evidence of molecular mimicry between specific pathogens and components of myelin or Schwann cells in the majority of AIDP patients." *Id;* N. Shahrizaila et al., *Guillain-Barre Syndrome,* 397 Lancet 1214, 1218 (2021), filed as Ex. A-24 (ECF No. 73-24) (indicating that autoantibodies against myelin proteins are not detected in individuals with AIDP, and that anti-neurofascin antibodies are quite rare); H. Koike et al., *Emerging Infection, Vaccination, and Guillain-Barre Syndrome: A Review.* 10 Neurol. Ther. 523, 523 (2021), filed as Ex. A-25 (ECF No. 73-25) (concluding that "mimicry between specific pathogens and myelin or Schwann cell components has not been clearly demonstrated in AIDP"). Homology alone also was not predictive of an autoimmune cross-reactive event. And Dr. Tornatore's BLAST research did not also include evidence suggesting what cross-reactivity would lead to—antibody *or* T cells—furthering the degree to which he speculated as to the negative impact stemming from the putative existence of homology. Rezania Rep. at 6.

2. Olajumoke Fadugba, M.D. – Dr. Fadugba is a medical and academic immunologist, and she prepared one written report. *See* Report, dated Dec. 16, 2024, filed as Ex. C (ECF No. 72-3) ("Fadugba Rep.").

Dr. Fadugba attended the University of Delaware for her undergraduate degree, and Vanderbilt University School of Medicine for her medical degree. Curriculum Vitae, filed as Ex. D (ECF No. 72-4) ("Fadugba CV"), at 1. She then completed an internship and residency in Internal Medicine at Washington University School of Medicine, followed by a fellowship in Allergy and Immunology at Vanderbilt University School of Medicine. *Id.* She currently is an Associate Professor of Clinical Medicine at the University of Pennsylvania School of Medicine, as well as the Fellowship Program Director and Chief of the Allergy and Immunology Section at the University of Pennsylvania. *Id.*; Fadugba Rep. at 1. Dr. Fadugba is board certified by the American Board of Internal Medicine and the American Board of Allergy and Immunology.

Fadugba CV at 1–2. She is involved in evaluating and treat vaccine responses in both a clinical and immunologic setting, as well as vaccine reactions reported by his adult patients. Fadugba Rep. at 1.

The initial section of Dr. Fadugba's report featured an overview of Petitioner's relevant medical history. Fadugba Rep. at 2–6. She also provided a brief description of GBS, emphasizing that it is usually a post-infectious condition (especially related to prior gastrointestinal or respiratory symptoms). *Id.* at 6–9; R. Bellanti & S. Rinaldi, *Guillain-Barré Syndrome: A Comprehensive Review*, 31 Eur. J. Neurol. 1, 1 (Aug. 2024), filed as Ex. C-1 (ECF No. 73-28) ("Bellanti & Rinaldi"). GBS is associated with a number of specific infections (although not with any of the Tdap vaccine's component analogs). Bellanti & Rinaldi at 3. Dr. Fadugba acknowledged that medical science hypothesized the existence of a "humoral mechanism" (meaning mediated by antibodies) for how GBS might occur, but noted that specific "anti-myelin antibodies have yet to be identified" (although she also allowed that certain ganglioside-specific autoantibodies were associated with at least one variant form of GBS). Fadugba Rep. at 7, 8. Indeed, almost half of all GBS patients did not test positive for any known autoantibodies even putatively associated with the condition. *Id.*

Dr. Fadugba did not accept Dr. Tornatore's causation theory as evidentiarily-established, and she specifically took issue with several of his contentions. First, she denied the significance of certain government publication statements about the risks of GBS in association with the Tdap vaccine. Fadugba Rep. at 8–9. The ACIP precaution about administration of the Tdap vaccine to individuals who had previously *both* experienced GBS *and* after prior Tdap vaccination itself noted the insufficiency of evidence of causality (pro or con) with respect to the two, and that passive surveillance data had not suggested otherwise. Fadugba Rep. at 9; Ezeanolue at 56. Thus, the precaution against a second administration of the vaccine to individuals who previously incurred GBS after vaccination was not itself strong evidence of causation.

Second, Dr. Fadugba deemed unpersuasive the evidence cited by Dr. Tornatore as suggesting that molecular mimicry was a likely mechanism for how "autoimmune neurologic conditions like GBS" occur. Fadugba Rep. at 9. Evidence specific to cross-reactivity occurring in the wake of a *Campylobacter jejuni* infection, she noted, was far more robust than evidence of the same kind of reaction after receipt of the Tdap vaccine. *Id.* at 9–10. Indeed, since the time of the 1970s swine flu epidemic (and resulting studies showing an association between the flu vaccine in use at that time and GBS), subsequent studies had more often than not *failed* to show such a link. *See, e.g.*, A. Babazadeh et al., *Influenza Vaccination and Guillain–Barré Syndrome: Reality or Fear*, 7 J. Trans. Intern. Med. 137, 140 (2019), filed as Ex. C-4 (ECF No. 73-31) ("Babazadeh") (stating that "[i]n fact [the] 1976 H1N1 influenza vaccine in New Jersey is the only proven

association of GBS and influenza vaccination").[11] Dr. Tornatore, however, could only cite to a number of fairly-old studies involving animal model experiments which were not only applicable primarily to the flu vaccine, but could not be deemed strong evidence of how a human would react to an analogous vaccine stimulus. Fadugba Rep. at 10–11. And other studies suggesting T cell recognition of MBP could not reasonably be understood to also mean that this lead to autoimmune disease (especially in the disparate context of a tetanus-containing vaccine). *Id.* at 11–12.

Dr. Fadugba similarly took issue with the argument advanced by Dr. Tornatore that (based on his own BLAST search) homology could be demonstrated between the P2 protein (which other studies had suggested could be an antigenic target for neuropathic autoimmune conditions) and tetanus toxin—allowing the analogy that if the flu vaccine could react against that protein, so too could the Tdap tetanus component. Fadugba Rep. at 12. She noted in reaction that a mere showing of sequential homology as not enough to establish that the homologous antigen is likely to cause an autoimmune-mediated disease process. *Id.* Rather, medical science understood that *several* criteria needed to be satisfied. L. Peterson & R. Fujinami, *Molecular Mimicry, in* Autoantibodies 13–19 (2nd ed. 2007), filed as Ex. C-9 (ECF No. 73-36). But those had not been met in this case. Dr. Tornatore's showing of epitope similarity was too "nonspecific," with no independent evidence showing that the tetanus toxin was believed to have similarity with relevant host nerve sequences, no evidence that Petitioner possessed cross-reactive antibodies that could have prompted a pathogenic response, no independent epidemiologic evidence[12] that the Tdap vaccine likely causes GBS, and no reproducible animal model results supporting the theory either. Fadugba Rep. at 13–14. Otherwise, Dr. Tornatore over-relied on case reports of studies interpreting passive surveillance data—weak proof of causation. *Id.* at 14.

While there was overall, Dr. Fadugba opined, insufficient direct proof that the Tdap vaccine could cause GBS, there existed sound epidemiologic evidence for the contrary position. Fadugba Rep. at 14–15. One large-scale study involving thousands of Kaiser Permanente managed

[11] Dr. Fadugba also in this context briefly questioned the persuasive value of Dr. Tornatore's contention that immune "degeneracy" (in which "a single T cell receptor may recognize thousands of different peptide sequences") explained how many vaccines could result in the same aberrant response known to occur for one, despite their differences. Fadugba Rep. at 10. Were this true, she reasoned, one would expect to see "an unquantifiable prevalence of autoimmune disease in the general population"—as well as any number of different environmental triggers for GBS—yet this was not so. *Id.*

[12] I fully recognize that the Program *itself* never requires claimants to offer epidemiologic evidence affirmatively supporting their causation theory. I also note that the criteria that medical professionals or scientists might apply in evaluating whether molecular mimicry has a persuasive explanatory basis for a given autoimmune condition is not congruent with the Program's causation prongs or evidence used to support them. Nevertheless—and as I have ruled in other cases—the fact that these kind of criteria are what experts consider important in analyzing the applicability of molecular mimicry to a given disease or illness is something a special master can reasonably consider, in evaluating overall if it is "more likely than not" that molecular mimicry has explanatory value when affirmatively offered in a Vaccine Act case to explain how or why a vaccine could have caused a particular injury. *Cerrone v. Sec'y of Health & Hum. Servs.*, No. 17-1158V, 2023 WL 3816718 (Fed. Cl. Spec. Mstr. June 1, 2023), *mot. for review den'd,* 168 Fed. Cl. 745 (2023), *aff'd*, 146 F.4th 1113 (Fed. Cir. 2025).

care program participants identified no association between the Tdap vaccine and GBS. R. Baxter et al., *Lack of Association of Guillain-Barré Syndrome with Vaccinations*, 57 Clin. Infect. Dis. 197 (July 2013), filed as Ex. C-13 (ECF No. 73-40) ("Baxter"). During the study period, only 415 cases of GBS were confirmed (out of x>30 million person-years), and the calculated risk for developing GBS after a tetanus vaccine between the observed six-week interval and the prior 12 months for tetanus diphtheria combination was 1.4—which both the authors of the study and Dr. Fadugba interpreted as not supportive of an association between the Tdap vaccine and GBS. *Id.* at 197; Fadugba Rep. at 15. Baxter's authors maximized the validity of their results by incorporating methods that allowed them to control confounders that can render uncontrolled studies invalid, such as only using confirmed cases of GBS, and employing a case-centered design with a comparison group. Baxter at 197.[13]

Dr. Fadugba concluded with a discussion of Petitioner's onset and its medical acceptability, measured from the date of vaccination. Fadugba Rep. at 15–16. Dr. Tornatore offered literature specific to the flu vaccine for this aspect of his opinion, and did not identify comparable literature specific to tetanus-containing vaccines. *Id.* at 15. She admitted, however, that an 11-day onset was otherwise "biologically plausible." *Id.* Dr. Fadugba also proposed that the medical record better supported the conclusion that a concurrent or preexisting infection explained Petitioner's GBS, since Petitioner's treatment history established evidence of both "viral upper respiratory tract symptoms" and gastrointestinal issues before or around the time of her hospitalization. *Id.* at 16.

III. Procedural History

The Petition was filed more than six years ago. The matter remained in "pre-assignment review" for eight months, while Petitioner endeavored to obtain and file records relevant to the claim. It was thereafter assigned to a different special master in the spring of 2020, and the parties spent nearly three years attempting to settle the claim (culminating in an unsuccessful alternative dispute resolution effort). Respondent's Rule 4(c) Report opposing compensation was at long last filed in April 2023 (ECF No. 53), and the parties next engaged in expert discovery through the end of 2024. The matter was reassigned to me in the winter of 2025, and at that time I set a schedule for ruling on the record, with briefing completed in April of this year. The claim is now ripe for resolution.

IV. Parties' Arguments

Petitioner

[13] Dr. Fadugba also referenced a comparable study focusing on the HPV vaccine but finding no link. Fadugba Rep. at 15 (citing T. Boender et al., *Risk of Guillain-Barré Syndrome after Vaccination Against Human Papillomavirus: A Systematic Review and Meta-Analysis, 1 January 2000 to 4 April 2020*, 27 Euro. Surveill. 4:2001619 (Jan. 2022), filed as Ex. C-14 (ECF No. 73-41). However (and as noted above), because Petitioner's causation contentions focus only on the Tdap vaccine, I do not include analysis of the causal role, if any, of the HPV vaccine.

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, 10, 16–17.[14] First, she argues that the "can cause" prong is met. *Id.* at 17–22. In so contending, Petitioner maintains that the Program has effectively "accepted" a causal association between tetanus toxoid-containing vaccines and GBS. Br. at 22. To support this proposition, she notes that a number of older Program cases recognized an association, relying on prior governmental publications akin to what Dr. Tornatore invokes or independent case reports like Pollard & Selby. *Id.* at 17–19. A 2011 "Institute of Medicine" publication on vaccine-associated adverse events later downplayed the strength of evidence on the association. But it seemed to require a level of proof approaching certainty that does not apply in Vaccine Act cases. *Id.* at 19–20.

Subsequent decisions in the Program expressly recognized that the Government had likely conceded causation over time, even if superseding publications did not expressly so state. Br. at 20–21; *Mohamad v. Sec'y Health & Hum. Servs*., 2022 WL 711604 (Fed. Cl. Spec. Mstr. Jan. 27, 2022), *mot. for review den'd*, No. 16-1075V, 2024 WL 4943421 (Fed. Cl. Nov. 12, 2024). And some subsequent publications, like Ezeanolue, bulwarked that conclusion. Br. at 21. In addition, more often than not Tdap-GBS cases are settled—and from that Petitioner noted "the obvious implication is that settling so many cases seems to be an admission that Respondent accepts the association between tetanus vaccines and GBS." *Id.* at 22.

Petitioner also argues that Dr. Tornatore's causation theory was preponderantly established. Br. at 22–23. Dr. Tornatore observed (referencing Hughes & Cornblath) that GBS's pathogenesis likely implicates molecular mimicry as its mechanism, and that the homology demonstrated by Dr. Tornatore between the tetanus toxin and the P2 protein established the possibility of an autoimmune cross-reaction. *Id.* at 23. Petitioner's contentions regarding the second and third prongs are more succinct. *Id*. at 23–25. In effect, she maintains both are met (although she only references Dr. Tornatore's opinion with respect to the third prong in so contending). *Id.* at 24.

On Reply, Petitioner insists that the tetanus vaccine can cause GBS, and in fact should be on the Vaccine Injury Table, given the strength of evidence supporting the association. Reply at 1–2. Petitioner again points to prior decisions from Special Masters where entitlement was found in favor of Petitioner for tetanus-GBS claims, and where Respondent settled over seventy cases for tetanus-GBS claims. *Id.* (discussing *Harris v. Sec'y of Health & Hum. Servs.*, No. 18-944V,

[14] Petitioner also devoted much of her brief to the proposition that she need only demonstrate a "biologically plausible theory," rather than meet the preponderant, "more likely than not" standard that facially governs causation claims. Br. at 8, 9–16. But to the extent there was previously any doubt about this question, it was disposed of by the Federal Circuit as of this past summer. *Cerrone*, 146 F.4th at 1121 (a petitioner's assertion that *Althen* prong one requires only a showing of plausibility "understates the burden [a petitioner] bears under the first factor in the *Althen* formulation"). I therefore do not address those aspects of Petitioner's brief that mischaracterize her legal obligations.

2023 WL 2583393 (Fed. Cl. Feb. 21, 2023); *Mohamad*, 2022 WL 711604. Further, Petitioner argues that Respondent cannot carry his burden of establishing the existence of a causal "factor unrelated," since no alternatively-causal virus has been identified. *Id.* at 3–7.

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 11–14. Although Dr. Tornatore asserts that the Government has conceded a causal role of the Tdap vaccine in GBS, the "precaution" warning in Ezeanolue did not include reliable findings of a causal relationship, and thus constituted only a conservative warning about limited circumstances, based on a few case report instances as well. *Id.* at 11–12. And it otherwise was inapplicable to Ms. Hiatt, who had not been shown to have previously experienced post-Tdap vaccine GBS. *Id.* at 12.

More specifically, the theory that the Tdap vaccine could spark an autoimmune cross-reaction via autoantibodies created due to mimicry between the vaccine's tetanus component and self-nerve tissues was speculative and dependent on evidence relating to other vaccines or non-analogous infections, or studies that actually did not demonstrate pathogenic effects from molecular mimicry's causation of autoantibodies. Opp. at 12–13. The very concept of molecular mimicry has widespread acceptance in the medical and scientific community—and yet no "reliable or reproduceable evidence in the literature of tetanus vaccine causing GBS" had been offered in this action. *Id.* at 13. Instead, outdated case reports (like Pollard & Selby) or studies considering VAERS data, like Souayah, were referenced—weak support for causation. *Id.*

Petitioner also failed to meet the other two *Althen* prongs, Respondent argued. Her primary contemporaneous treaters never accepted the Tdap vaccine as causal—while proposing a preceding gastrointestinal illness may have been. Opp. at 14 (*citing* Ex. 9 at 26–27). Actual treatment evidence, like lab work, supported this conclusion—and it was consistent with Dr. Tornatore's concession that most individuals who experienced GBS did so after a prior infection. Tornatore Rep. at 11. Thus, the "did cause" prong was unmet. The timeframe prong also had not been satisfied, since (given that prong one causation had not been demonstrated), it could not also be shown that there was *any* possible medically-acceptable timeframe for onset. Opp. at 16.

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).[15] There is no Table claim for GBS caused by a tetanus-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 [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

[15] 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).

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) (petitioner's 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 review 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 review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

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

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir.

1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras*, 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 review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

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

App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

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

There is no dispute in this case as to the propriety of the GBS diagnosis. *See, e.g.*, Opp. at 11. But some discussion of the condition's features will still be helpful in resolving causation. 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. Bellanti & Rinaldi at 5. It usually presents with "pain, numbness, paraesthesia, or weakness in the limbs." Hughes & Cornblath at 1661; Bellanti & Rinaldi at 5.

Reliable scientific evidence supports the conclusion that GBS can be vaccine-caused—specifically by the flu vaccine (although the risk from a wild flu *infection* is much greater). Bellanti & Rinaldi at 3. Consistent with this, a large body of reasoned Program decisions[16] 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. Secretary of Health &*

[16] 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.

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 review 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 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.

This is definitely true for claims that the Tdap vaccine can cause GBS. Several cases decided in the past ten years (some of which I authored) found no causal association between the two.[17] *See, e.g.*, *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 v. Sec'y of Health & Hum. Servs.*, No. 18-1303V, 2023 WL 2965239 (Fed. Cl. Spec. Mstr. Apr. 17, 2023), *mot. for review den'd*, 167 Fed. Cl. 640 (2023), *appeal dismissed,* No. 2024-1214, 2024 WL 1255318 (Fed. Cir. Mar. 25, 2024); *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 review den'd*, 117 Fed. Cl. 713 (2014); *Isaac*, 2012 WL 3609993 at 19.[18]

[17] 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).

[18] 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).

Prior Tdap-GBS cases have often involved causation theories comparable to what is offered here. In my recent *Kaczerowski* decision, a petitioner employed Dr. Tornatore, as here. And in that case, Dr. Tornatore 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. But I deemed his showing not to meet the preponderant standard—even though the petitioner filed four reports from Dr. Tornatore, allowing him ample opportunity to refine his opinion in response to the critiques raised by Respondent's experts.

In *Isaac*, a petitioner proposed molecular mimicry as the causal mechanism. *Issac*, 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.

Admittedly (and as vociferously stressed by Petitioner), some special masters have deemed causation demonstrated in Tdap vaccine-GBS cases. *See Harris*, 2023 WL 2583393; *Mohamad*, 2022 WL 711604, at *18. 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.

As I have noted in other cases, however, 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.

II. Petitioner Has not Carried Her 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).

First, I do not find that it has been shown that the Government has conceded a Tdap-vaccine causal association. As noted in *Kaczerowski,* that kind of reasoning was actually rejected by a prior special master in the *Tompkins* decision, issued in 2013—nearly 10 years before *Mohamad. Kaczerowski*, 2025 WL 2798865, at *34 (referencing *Tompkins,* 2013 WL 3498652, at *26). It certainly could be ascertained that Government publications have not affirmatively stated that there is *no possible* Tdap vaccine-GBS relationship—and I do not conclude that either. But clearly and over time, commentary on GBS as a possible adverse effect of receipt of a Tdap vaccine moved away from the view that the association was well-founded to a more neutral position. While the issue may be legitimately disputed in the context of a Vaccine Program claim, the Government cannot be said to have conceded the point entirely.

What of the more recent publications discussing treatment precautions about the use of the Tdap vaccine? Those precautions apply solely to circumstances not relevant to this case, since Petitioner never had GBS before after receipt of a prior Tdap vaccine dose. Moreover (and as Dr. Fadugba persuasively established), the precaution is *itself* weak proof of causation, and documents offered to substantiate it contain equivocal statements about the strength of any purported association. Fadugba Rep. at 9. I do not deny that this precaution provides *some* support for Petitioner's causation theory—but it is ultimately too flimsy and irrelevant to the facts of this case to aid Petitioner all that much.

Second, Respondent's willingness to settle petitions alleging GBS after receipt of a Tdap vaccine is not itself reliable proof that the causation theory advanced herein has preponderant support. I have addressed the exact same contention in other cases where I denied entitlement. *See, e.g*., *Howard,* 2022 WL 4869354, at *22–23. No matter how many times Respondent may have resolved cases involving the same theory or injury, the choice by a litigant to settle a case does not

stand as evidence that the causal theory underlying such claims is correct, preponderantly-established, or reflects reasoning the Respondent shares (and of course the decision to settle *any* case is not evidence of the strength of one side's position that can be deemed persuasive authority by as judicial neutral). Only *reasoned decisions* by other special masters (which do exist—and which admittedly in some instances are favorable to Petitioner herein) deserve any consideration as guidance. A list of cases in which petitioners "won" is not proof of causation.

Finally, there are too many substantive deficiencies in Dr. Tornatore's theory as specifically crafted herein for me to find that it has been preponderantly established. As noted above, the theory was largely consistent with what Dr. Tornatore offered in *Kaczerowski*—a recent case in which I also found the Tdap vaccine-GBS association not to have been preponderantly established, and which provides useful guidance here as well (since the theories presented in both cases were so similar). To summarize:

- While there is evidence suggesting that *flu vaccine components* could cause an autoimmune-cross reaction with MBP sufficient to spark GBS, that evidence cannot be applied in blanket fashion to the Tdap vaccine (or other disparate vaccines for that matter);

- The wild-analogs to the TDAP vaccine components have not been shown to be associated with GBS (for example, a tetanus wild bacterial infection);

- Passive surveillance data or case reports are weak proof of causation, and only demonstrate a naked temporal association with vaccination;

- Existing epidemiologic evidence better supports the conclusion that the Tdap vaccine is not likely associated with GBS; and

- Naked showings of putative amino acid sequential homology between antigens *compared* to tetanus toxin and MBP-like proteins are speculative and/or insufficient alone to prove an autoimmune cross-reaction between Tdap vaccine and the identified self-antigen is "more likely than not" to lead to GBS.

See Kaczerowski, 2025 WL 2798865, at *33–38.

Dr. Tornatore made no additional causation arguments that distinguish the opinion he offered in this case from what he proposed in *Kaczerowski*, and identified no more recent studies bulwarking the putative vaccine association, while relying on numerous items of literature (Pollard & Selby; Souayah; Ezeanolue; Hughes & Cornblath) also filed in this matter. Respondent, however, referenced herein two epidemiologic studies more directly contradicting the conclusion that the Tdap vaccine is associated with GBS. Babazadeh at 3; Baxter at 197. As a result, I have

been provided with no evidence in this case that would suggest I should diverge from my determination in *Kaczerowski.* It has not been preponderantly demonstrated that "more likely than not" the Tdap vaccine can cause GBS. Indeed, if anything the showing in this case (in which Dr. Tornatore prepared a single report, not the *four* discussed in *Kaczerowski*) was even less well-substantiated.

As a final point, I acknowledge that the special masters are not in agreement on the question of Tdap vaccine causation of GBS, and this may lead to inconsistent outcomes. But this is understood always to be possible in the Vaccine Program—often because the personal medical/health circumstances of each allegedly injured party can impact the aberrant capacity of a vaccine, as well as due to differences in the evidence offered from case to case. Special masters are no more compelled to follow each other's decisions than any trial judge would be in a district court. Having now ruled in many Tdap-GBS cases, I can reasonably observe that overall the evidence suggesting that there is a causal relationship between the two is quite thin.

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.[19]

IT IS SO ORDERED.

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

[19] 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.