

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-752V

Filed: February 20, 2026

* * * * *

NICHOLAS GILLON, *

Petitioner, *

No. 21-752V

v. *

Special Master Gowen

SECRETARY OF HEALTH AND *
AND HUMAN SERVICES, *

Respondent. *

* * * * *

Leah V. Durant, Law Offices of Leah V. Durant, PLLC, Washington, D.C., for petitioner.
Naseem Kouros, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT¹

On January 15, 2021, Nicholas Gillon (“petitioner”) filed a claim under the National Vaccine Injury Compensation Program (“the Program” or “Vaccine Program”).² Petition (“Pet.”) (ECF No. 1); *see* 42 U.S.C. § 300aa-1 *et seq.* (the “Vaccine Act”). Petitioner alleges that, as a result of receiving the tetanus-diphtheria-acellular pertussis (“Tdap”) vaccine on June 5, 2019, he developed Guillain-Barré syndrome (“GBS”), as well as associated sensory deficits. *See* Pet. at ¶¶ 3-4; Petitioner (“Pet’r”) Exhibit (“Ex.”) 6 at ¶¶ 2-6 (ECF No. 7).

¹ Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this decision contains a reasoned explanation for the action in this case, it is required to be posted on the website of the United States Court of Federal Claims. The court’s website is at <http://www.uscfc.uscourts.gov/aggregator/sources/7>. **This means the decision will be available to anyone with access to the Internet.** Before the decision is posted on the court’s website, each party has 14 days to file a motion requesting 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). “An objecting party must provide the court with a proposed redacted version of the decision.” *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court’s website without any changes.** *Id.*

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter “Vaccine Act” or “the Act”). Hereinafter, individual section references will be made to 42 U.S.C. § 300aa of the Act.

In a prior ruling,³ now withdrawn, the undersigned found that petitioner established his claim by a preponderance of the evidence. Respondent thereafter moved for reconsideration, asserting errors of fact and law. Respondent (“Resp’t”) Motion (“Mot.”) (ECF No. 50). The undersigned granted that motion and has carefully reviewed the issues raised, as well as petitioner’s response in opposition and his additional items of medical literature that were concurrently filed. Order dated Feb. 18, 2026 (ECF No. 57); *see also* Pet’r Response (“Resp.”) (ECF No. 52); Pet’r Exs. 39-44 (ECF No. 53).

For the reasons discussed in the order addressing the issues raised by respondent’s motion, certain clarifications of the Ruling were made. *See* Order dated Feb. 18, 2026. Nevertheless, after crediting respondent’s arguments and petitioner’s response thereto, the outcome of the prior determination remains unchanged. Pursuant to Vaccine Rule 3(b), the undersigned finds, that petitioner has established by preponderant evidence that he is entitled to compensation.

I. Procedural History

Petitioner filed his claim for compensation on January 15, 2021, and filed medical records and an accompanying affidavit⁴ to support his claim on April 22 of that year. Pet.; Pet’r Exs. 1-5 (ECF No. 7); Pet’r Affidavit (“Aff.”) (ECF No. 7). On October 8, 2021, the case was assigned to my docket. *See* Notice of Reassignment (ECF No. 12).

Early in the matter, respondent indicated being “amenable to informal resolution.” Status Report at 1 (ECF No. 16). The parties engaged in several rounds of settlement discussions, documenting their efforts in three joint status reports, (ECF Nos. 17-19), but ultimately, negotiations “reached an impasse.” Status Report at 1 (ECF No. 20).

Respondent thereafter submitted a Rule 4(c) report on July 7, 2022, wherein the Division of Injury Compensation Programs (“DICP”) concluded that the matter was not appropriate for compensation under the Vaccine Act. Rule 4(c) Report at 1 (ECF No. 21). Accordingly, respondent requested that the petition be dismissed for insufficient proof. *Id.*

On July 7, 2022, the parties were ordered to provide expert reports. Petitioner submitted an expert report from Dr. David M. Simpson,⁵ accompanied with the medical literature supporting his opinions. Pet’r Ex. 10 (ECF No. 25); Pet’r Exs. 12-19 (ECF No. 26). In turn,

³ Ruling on Entitlement (“Ruling”) (withdrawn) (ECF No. 48).

⁴ Petitioner’s affidavit was revised on November 4, 2021. Pet’r Revised Aff. (ECF No. 14).

⁵ Dr. David Simpson serves as a professor of neurology at the Icahn School of Medicine at Mount Sinai and as an attending physician at Mount Sinai Medical Center, where he directs the Neuro-AIDS Program, the Neuromuscular Diseases Division, and the Clinical Neurophysiology Laboratories. Pet’r Ex. 11 at 2 (ECF No. 25). Certified by both the American Board of Psychiatry and Neurology (ABPN) and American Board of Electrodiagnostic Medicine (ABEM), Dr. Simpson has published more than 260 articles. *Id.* at 23-36.

respondent provided an expert report from Dr. Brian C. Callaghan,⁶ along with the medical literature referenced therein. Resp't Ex. A (ECF No. 27); Resp't Exs. A.1-5 (ECF No. 27).

The undersigned held a Rule 5 status conference on May 22, 2023, after which petitioner was ordered to transmit a demand to respondent. Rule 5 Order (ECF No. 29). As respondent alerted the Court of another "impasse in settlement discussions," petitioner was directed to provide updated medical records and a supplemental expert report on August 24, 2023. Status Report at 1 (ECF No. 31). Petitioner complied by submitting additional medical records on October 10, 2023; a supplemental report by Dr. Simpson, together with the medical literature he cited, were filed on November 9, 2023. Pet'r Ex. 21 (ECF No. 33); Pet'r Exs. 22-33 (ECF No. 35). Respondent filed a second expert report by Dr. Callaghan on January 22, 2024. Resp't Ex. C (ECF No. 37).

A second Rule 5 status conference convened on August 29, 2024, after which the undersigned ordered petitioner to update his affidavit and transmit a revised demand to respondent. Second Rule 5 Order (ECF No. 39). Petitioner complied with the scheduling order on September 12, 2024. Pet'r Aff. (ECF No. 40).

On October 18, 2024, the parties reported that they "remain very far apart" in their respective assessments of the case and requested leave to brief the issue of entitlement. Joint Status Report at 1-2 (ECF No. 42). On December 20, 2024, petitioner filed a third expert report by Dr. Simpson, supporting medical literature, and a motion for a ruling on the record. Pet'r Exs. 35-38 (ECF No. 44); Pet'r Brief ("Br.") (ECF No. 45). Respondent filed a response to petitioner's brief on February 19, 2025. Resp't Br. (ECF No. 47).

As the matter was ripe for resolution, a ruling on entitlement was issued on December 16, 2025. Ruling. On January 6, 2026, respondent moved for reconsideration, asserting errors of fact and law. Resp't Mot. This motion was granted to the extent that it had requested that the Ruling be withdrawn. *See* Order dated Jan. 7, 2026. A ruling determining whether respondent was entitled to any additional relief, such as a substantive change in outcome, was deferred to allow for further review and for time allowing petitioner to respond. On January 20, 2026, petitioner filed a response supporting the Ruling and addressing respondent's asserted errors. Pet'r Resp. Having addressed those errors in a subsequent order, the undersigned now addresses issues concerning entitlement. Order dated Feb. 18, 2026.

II. Legal Standard

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as

⁶ Dr. Brian Callaghan is the Eva L. Feldman Professor of Neurology at the University of Michigan, where he also serves as an associate program director for research and a co-director for its Neuromuscular Division. Resp't Ex. B at 1-2 (ECF No. 27). His clinical responsibilities include serving as a staff physician in the Department of Neurology at the Veterans Affairs Ann Arbor Health System and directing its Amyotrophic Lateral Sclerosis Clinic. *Id.* at 2. ABPN and ABEM certified, Dr. Callaghan has published more than 130 articles and has seen an estimated 50 patients with GBS. Resp't Ex. A at 1.

a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” *Rooks v. Sec’y of Health & Hum. Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner bears the burden of proving his claim by a preponderance of the evidence. § 13(a)(1). 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 v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Concrete Pipe & Prods. of Cal., Inc. v. Construction Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993) (brackets in original)).

To receive compensation through the Program, petitioner must prove either (1) that he suffered a “Table Injury”—*i.e.*, an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. *See* §§ 11(c)(1), 13(a)(1)(A); *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that he suffered a Table Injury, he must prove that a vaccine he received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury (“*Althen* prong one”); (2) a logical sequence of cause and effect showing that the vaccine was the reason for his injury (“*Althen* prong two”); and (3) a showing of a proximate temporal relationship between the vaccine and his injury (“*Althen* prong three”). § 13(a)(1); *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). In *Kottenstette*, the Federal Circuit reiterated that proof of causation does not “require identification and proof of specific biological mechanisms[.]” *Kottenstette v. Sec’y of Health & Hum. Servs.*, 861 Fed.Appx. 433, 441 (Fed. Cir. 2021) (citing *Knudsen*, 35 F.3d at 549). Causation “can be found in vaccine cases... without detailed medical and scientific exposition on the biological mechanisms.” *Knudsen*, 35 F.3d at 549. It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the alleged injury, as long as he can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *See Moberly*, 592 F.3d at 1325.

Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including “any... conclusion, [or] medical judgment . . . which is contained in the record regarding... causation.” § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties’ proffered experts and rule in petitioner’s favor when the evidence weighs in his favor. *See Moberly*, 592 F.3d at 1325-26 (“Finders of fact are entitled—indeed, expected—to make determinations as to

the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence”); *Althen*, 418 F.3d at 1280 (noting that “close calls” are resolved in petitioner’s favor).

In Vaccine Program cases, expert testimony may be 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 also *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)). In such cases, the *Daubert* analysis has been used in the weighing of scientific evidence that was actually proffered and heard, rather than as a tool for the pre-trial exclusion of expert testimony. *Davis v. Sec’y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (Fed. Cl. 2010), *aff’d*, 420 Fed.Appx 973 (Fed. Cir. 2011) (noting that “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 determine the persuasiveness and/or reliability of expert testimony in Vaccine Program cases has routinely been upheld. See, e.g., *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742-45 (2009). 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”).

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280 (holding that Congress created a system in which “close calls regarding causation are resolved in favor of injured claimants”); *Knudsen*, 35 F.3d at 551 (“[i]f the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded”).

III. Summary of Evidence Submitted

a. Medical Records

Petitioner, a 43-year-old male, was generally healthy prior to vaccination with no history of autoimmune or neurological disorders or of any demyelinating neurologic injury. Pet. at ¶¶ 1, 4. At a Memorial Day barbeque on May 27, 2019, petitioner accidentally cut his left ring finger with his pocketknife while opening a package of chicken. Pet’r Ex. 2 at 53 & 79. Out of concern for increased swelling and redness at the laceration site, petitioner sought care for the wound on June 5, 2019. *Id.* at 79. Outside of the swelling to his injured finger and its slightly limited range of motion, his exam was unremarkable. *Id.* at 55. He was diagnosed with cellulitis, given a course of antibiotics, and advised to follow-up with his primary care physician in 48 hours. *Id.* at 56. Before discharge, a nurse administered the Tdap vaccine in petitioner’s left deltoid. Pet’r Ex 1, 51; Pet’r Ex. 2 at 56; Pet’r Ex. 7 at 1.

Although petitioner has not produced contemporaneous documentation confirming receipt of any Tdap vaccinations prior to the one at issue, his medical records reference a Tdap “due date” of February 3, 2001, without indicating whether the vaccination was administered or, if so, whether he tolerated it well. Pet’r Ex. 2 at 5.

On June 21, 2019, petitioner felt “a little bit numb” after surfing and “somewhat worn out” after visiting a trampoline park. Pet’r Ex. 2 at 79. These initial sensory symptoms began approximately sixteen days post-vaccination. He then took a trip to New Orleans, where he did a “tremendous amount of walking” and began experiencing “some tingling in his feet.” *Id.* At the time, petitioner attributed the tingling to having had fractured his right distal fibula on January 28, 2019, and sprained his left ankle on an unidentified date. *Id.* at 39, 79. By June 26, 2019, petitioner “start[ed] to get weak.” *Id.* at 63. While exercising about three days later, he rapidly fatigued after two pull-ups when, prior to his vaccination, he could generally do twelve repetitions before reaching muscular failure. *Id.*

On approximately June 20, 2019, about one day before the onset of symptoms, petitioner experienced a two-day episode of mild, self-limiting diarrhea. *Id.* at 63-64. Petitioner denied having symptoms associated with systemic infection, such as vomiting, cramping, or fever. *Id.* There is no evidence that he sought medical treatment during the episode or that laboratory testing was performed to identify a specific infectious agent, such as *Campylobacter jejuni* (“*C. jejuni*”), a pathogen known to precede some cases of GBS. *See generally*, Resp’t Exs. A.3-4.

Petitioner’s first medical encounter following the vaccination was on June 30, 2019, approximately three weeks post-vaccination. Pet’r Ex. 2 at 63-64. Petitioner presented at an urgent care facility, where Certified Physician Assistant (“PA-C”) Christine N. Stanfield recorded his chief complaint as the sudden onset of muscle weakness and bilateral tingling that began in his feet, ascended to his shins, jumped to the lateral aspects of his palms, and extended to his fifth digits. *Id.* The motor examination revealed areflexia bilaterally in the biceps, brachioradialis, triceps, patellae, and ankles, and sensation was decreased over the plantar aspect of both feet. *Id.* at 65. Although petitioner exhibited normal tone without drift or adventitious movements, PA-C Stanfield observed diffuse weakness in all extremities, with 4/5 strength in his quadriceps, hip flexors, and shoulder shrug. *Id.* While petitioner was able to stand up without using his arms, he demonstrated a wide-based gait. *Id.*

After consulting with the on-call neurologist, Dr. Guterrez, and another physician, Dr. Sean T. Baxter, PA-C Stanfield admitted petitioner to the Clinical Decision Unit. *Id.* at 66. The care team’s differential diagnosis included GBS, thought to be secondary to “dysentery” versus “reaction” to the Tdap vaccination. *Id.* at 67. No diagnostic evaluation for dysentery was undertaken, and no objective clinical findings support this proposed etiology beyond petitioner’s own report of a brief diarrheal episode. To confirm the working diagnosis of GBS, several studies were ordered. *Id.*

Petitioner underwent a lumbar puncture. *Id.* at 67-68. Dr. Guterrez had advised that intravenous immunoglobulin (“IVIG”) therapy would be indicated if the protein level in

petitioner's cerebrospinal fluid ("CSF") sample exceeded 100 mg/dL.⁷ *Id.* at 66. Because petitioner's CSF protein was only mildly elevated at 49 mg/dL, he was not treated with IVIG therapy. *Id.* at 77. Moreover, Dr. Gutierrez cautioned that the "CSF protein [was] not high enough to confidently rule in GBS," as about seventy-five percent of patients have protein levels exceeding 100 mg/dL by the third week of symptoms. *Id.* at 67. Accordingly, petitioner was discharged with instructions to follow up as an outpatient. *Id.* at 77.

Magnetic resonance imaging ("MRI") studies of the spine were done on July 4, 2019, approximately one-month post-vaccination. *Id.* at 67. The MRI showed no abnormal enhancement, demyelination, or inflammation, and no stenosis or impingement involving the spinal cord, cauda equina, or nerve roots. *Id.* at 187-96. Overall, the findings were normal and revealed no abnormalities consistent with GBS or other neurological pathology.

The next day, petitioner kept his follow-up neurology appointment and met with his treating neurologist, Dr. David W. Schmidt. *Id.* at 79. Though he reported feeling better, petitioner still had demonstrable weakness, particularly in his bilateral triceps. *Id.* at 80-81. Deep tendon reflexes remained absent in his biceps, brachioradialis, triceps, patellae, and ankles. *Id.* at 81. Dr. Schmidt concluded that there was "sufficient clinical evidence to warrant the diagnosis of [GBS]" and ordered MRI studies of the brain, which were unremarkable, and a five-day course of IVIG therapy. *Id.* at 81, 195-96; Pet'r Ex. 8 at 2. No suspected etiology other than reaction to the Tdap vaccine was identified.

After completing the final day of IVIG therapy on Friday, July 12, 2019, petitioner experienced nausea, vomiting, and headaches. Pet'r Ex. 2 at 115. He reported to an urgent care and was treated for a "severe migraine," which was attributed to the IVIG therapy. *Id.* at 117. His provider discharged him, finding no indication for further evaluation, intervention, or admission to the hospital. *Id.* at 118.

On February 25, 2020, at his next appointment with Dr. Schmidt, petitioner stated that he had achieved "about 85% recovery" but was still experiencing numbness in his feet and intermittent tingling in the fingers, predominantly in the C8 dermatomes. Pet'r Ex. 2 at 141. He described an "unnerving" sensation accompanied by decreased strength, which interfered with his activities of daily living ("ADLs") to varying degrees and diminished his enjoyment of life. *Id.* Upon examination, his deep tendon reflexes were absent in the right upper extremity, hypoactive in the left upper extremity, and hypoactive at the knees and ankles, with downgoing toes. *Id.* at 141-42. Dr. Schmidt's impression was that petitioner had GBS that responded to IVIG therapy and was nearly resolved. *Id.* at 142. The neurologist advised petitioner to return for a follow-up in July, at which time nerve conduction studies could be ordered if any deficits persisted. *Id.*

On June 17, 2020, just over a year post-vaccination, petitioner kept his follow-up appointment with Dr. Schmidt. *Id.* at 157-58. Petitioner reported feeling that "things [were] progressing," explaining that he felt increasingly unsafe and less capable performing instrumental ADLs. *Id.* at 157. He noted that the tingling in his feet and numbness in his hands

⁷ PA-C Stanfield documented in a subsequent note that Dr. Guitierrez would have advised IVIG therapy had the CSF protein been 80 mg/dL or higher. Pet'r Ex. 2 at 67.

were almost constant, interrupting his sleep and leaving him fatigued. *Id.* On examination, Dr. Schmidt observed that petitioner remained hyporeflexive bilaterally in both upper and lower extremities. *Id.* He opined that petitioner “seems to have evidence of bilateral carpal tunnel syndrome and bilateral cubital tunnel syndrome,” adding that “compressive neuropathies are not uncommon after someone already has an underlying neuropathy.” *Id.* at 158. Dr. Schmidt provided wrist splints and recommended electromyography (“EMG”) and nerve conduction velocity (“NCV”) testing. *Id.*

Roughly six months later, on January 15, 2021, petitioner filed a claim for compensation under the Vaccine Program, stating that he “continue[d] to suffer sequela as a result of his GBS.” Pet. at ¶ 4. On April 22, 2021, approaching the two-year anniversary of his vaccination, and again on November 4, 2021, petitioner described an ongoing “sensation of numbness and strangeness in [his] hands and feet.” Pet’r Aff. at ¶ 2; Pet’r Revised Aff. at ¶ 2. He further explained that when he touches his wife and family, he cannot feel them: “My hands touch them, but my palms don’t feel it, as if I always have thick gloves on.” Pet’r’ Aff. at ¶ 6; Pet’r Revised Aff. at ¶ 6.

Early the following year, on January 13, 2022, petitioner sought a remote video consultation with Dr. Schmidt. *See* Pet’r Ex. 8. No EMG/NCV studies had been performed in the interim. *Id.* at 2. Petitioner described a “plateauing of [his] recovery,” hindered by chronic numbness, tingling, pain, and loss of sleep. He reported that loss of strength also persisted, but his balance, coordination, and proprioception had improved through participation in soft martial arts. *Id.*; *see also* Pet’r Ex. 9. Dr. Schmidt recommended EMG testing and repeat MRI studies of the brain and cervical spine. Pet’r Ex. 8 at 3.

On August 8, 2022, petitioner saw Dr. Kevin P. Kolostyak for his EMG/NCV testing. Pet’r Ex. 21 at 37-49. The EMG/NCV was interpreted as normal, showing no evidence of large-fiber polyneuropathy, radiculopathy, myopathy, or median or ulnar entrapment neuropathies at the wrists or elbows. The report noted that electrodiagnostic testing may occasionally yield false-negative results in cases of very mild or intermittent compression. *Id.* Petitioner was advised to follow up with his treating neurologist. *Id.* at 39.

Petitioner supplemented the contemporaneous medical records with an affidavit on September 12, 2024, more than five years after vaccination. Pet’r Aff. 34. He reported experiencing daily symptoms during the first three years following vaccination, with periodic flare-ups of more acute sensory disturbances. *Id.* at ¶ 3. He further stated that he continues to experience episodes of GBS-related symptoms approximately once per month, and that during the most severe episodes, “it... hurts to be hugged or touched in any way.” *Id.* at ¶¶ 4-5. According to petitioner, these flare-ups affect his ability to engage safely in woodworking, disrupt his sleep and work, limit physical activities, and strain family interactions, contributing to “intense and prolonged distress, depression, frustration, and anxiety.” *Id.*

Taken together, the contemporaneous medical records and petitioner’s affidavits document the onset of neurologic symptoms approximately sixteen days after vaccination, followed by a confirmed diagnosis of GBS, and more than six months of related symptoms.

These records form the factual basis for evaluating whether petitioner's vaccination was the cause-in-fact of his subsequent illness.

b. Petitioner's Expert, Dr. David M. Simpson, MD, FAAN

Petitioner relies on the expert opinion of Dr. Simpson, initially set forth in his March 6, 2023 report and supplemented by reports dated November 5, 2023, and December 16, 2024. Pet'r Exs. 10, 22, 35. Dr. Simpson reviewed petitioner's medical records and stated that petitioner had no significant past medical history. Pet'r Ex. 10 at 1; *see* Pet'r Exs. 1-9, 21. In all three reports, Dr. Simpson concluded that petitioner's Tdap vaccination was more likely than not the cause-in-fact of his GBS. Pet'r Ex. 10 at 6; Pet'r Ex. 22 at 5; Pet'r Ex. 35 at 3.

Dr. Simpson opined that petitioner developed new neurological symptoms, specifically ascending sensory disturbance of the limbs and subjective weakness, within approximately two weeks of vaccination. Pet'r Ex. 10 at 5. He made note that at petitioner's first medical encounter post-vaccination, clinicians documented mildly elevated CSF protein, diffuse 4/5 weakness, decreased distal sensation, areflexia, and a wide-based gait. *Id.* In Dr. Simpson's view, these findings were fully consistent with the treating providers' suspected diagnosis of GBS, and he opined that "[t]here are no logical alternative potential causes of the illness... other than receipt of the Tdap vaccine." *Id.*

Relying on *Asbury and Cornblath's* classical criteria for GBS,⁸ Dr. Simpson placed petitioner's condition within the broader category of inflammatory demyelinating polyneuropathy and, more specifically, within the GBS spectrum, which encompasses several recognized variants. Pet'r Ex. 10 at 4. He explained that petitioner's progressive weakness in more than one limb, universal areflexia or hyporeflexia, symmetry of involvement, rapid deterioration reaching its nadir by the fourth week of illness, and subsequent substantial recovery all closely mirrored the established clinical course of GBS. Pet'r Ex. 23 at 1-2.

Dr. Simpson distinguished petitioner's constellation of symptoms from those attributed to small fiber neuropathy ("SFN"). Pet'r Ex. 22 at 2. He explained that petitioner's acute onset, together with the objective finding of areflexia, pointed to large-fiber demyelination. In contrast to SFN, which involves small-fibers and typically presents without objective weakness or reflex changes, petitioner's course was most consistent with acute inflammatory demyelinating polyneuropathy ("AIDP"), the most common form of GBS. *Id.* at 1-2.

Petitioner's rapid progression over several weeks, followed by recovery rather than relapse, also weighed against chronic inflammatory demyelinating polyneuropathy ("CIDP"). *Id.* at 2. Dr. Schmidt, petitioner's treating neurologist, documented near-complete recovery by February 25, 2020, approximately eight months after symptom onset, which is consistent with monophasic AIDP. *Id.*; *see* Pet'r Ex. 2 at 141. Petitioner's EMG/NCV studies performed August 8, 2022, and described as normal, the results provided additional data to corroborate the

⁸ A.K. Asbury & D.R. Cornblath, *Assessment of Current Diagnostic Criteria for Guillain-Barré Syndrome*, 27 Ann. Neurol. S21 (1990). [Pet'r Ex. 23].

diagnosis. Pet'r Ex. 22 at 2; *see* Pet'r Ex. 21 at 39. No evidence of intermittent deterioration, a feature of CIDP, was identified.

Petitioner filed his final affidavit on September 12, 2024, stating that although his symptoms improved markedly after the first three years post-vaccination, he continues to experience intermittent sensory symptoms, including monthly flare-ups of numbness in the hands and feet. Pet'r Ex. 34 at ¶¶ 2-4. Dr. Simpson explained that such fluctuations are common residual sequelae following GBS and do not suggest ongoing demyelination or new pathology. Pet'r Ex. 22 at 2; *see* Pet'r Ex. 2 at 157. He cited medical literature, including *Bernsen et al.*⁹ and an article by *Dornonville de la Cour & Jakobsen*,¹⁰ that documents significant rates of long-term sensory disturbances among GBS patients, underscoring that residual symptoms of the type reported by petitioner are not novel. Pet'r Ex. 35 at 2-3.

Dr. Simpson opined that petitioner's history and pattern of residual symptoms were most consistent with GBS/AIDP and, correspondingly, most suggestive of a vaccine-related etiology. *Id.* He explained that GBS is understood to be an immune-mediated disease arising from aberrant immune cross-reactivity that damages peripheral nerves. Pet'r Ex. 10 at 4. In his view, antigenic components of the Tdap vaccine provoked such an aberrant response through a biologic mechanism that was more likely than not molecular mimicry. *Id.* 4-5. To support his opinion, Dr. Simpson submitted medical literature that recognizes this process as capable of producing immune-mediated demyelinating neuropathy.

Dr. Simpson cited *Levin et al.*,¹¹ which outlined how immune cross-reactivity can lead to neurologic injury, albeit in the context of patients with human T-lymphotropic virus type I who subsequently developed central nervous system ("CNS") damage. Pet'r Ex. 14. The article defined molecular mimicry as a mechanism by which "an immune response mounted against an environmental antigen cross-reacts with a host antigen, which in turn leads to autoimmunity, organ-specific damage, and possibly disease." *Id.* at 8.

*Donofrio*¹² likewise investigated similar pathophysiology. Pet'r Ex. 12. The author found that antibodies generated against a pathogen's membranous molecules may mistakenly target the membranes of host motor axons, causing demyelination. *Id.* at 11. Although the article does not address Tdap specifically, the author emphasized that GBS has been linked to numerous antecedent antigenic exposures and that no single pathogenic epitope or myelin biomarker has been identified to definitively identify the cause of GBS. *Id.*

⁹ R.A. Bernsen et al., *Long-Term Sensory Deficit after Guillain-Barré Syndrome*, 248 J. Neurol. 483 (2001). [Pet'r Ex. 36].

¹⁰ C. Dornonville de la Cour & J. Jakobsen, *Residual Neuropathy in Long-Term Population-Based Follow-Up of Guillain-Barré Syndrome*, 64 Neurol. 246 (2005). [Pet'r Ex. 37].

¹¹ M.C. Levin, et al., *Neuronal Molecular Mimicry in Immune-Mediated Neurologic Disease*, 44 Ann. Neurol. 8798 (1998). [Pet'r Ex. 14].

¹² P.D. Donofrio, *Guillain-Barré Syndrome*, 23 Continuum (Minneapolis, Minn.) 1295 (2017). [Pet'r Ex. 12].

Dr. Simpson opined that the absence of a unique epitope or biomarker does not foreclose molecular mimicry; rather, demyelinating neuropathy may arise from immune responses to a variety of antigens, including Tdap's antigenic components. Pet'r Ex. 10 at 4-5. Using this framework, Dr. Simpson referenced *Safranek et al.*,¹³ which found an increased risk of GBS among adults within six weeks after vaccination. *Id.* at 4. The article supports the broader concept that post-vaccinal immune activation may precipitate demyelination even when the precise triggering antigen cannot be pinpointed. *See id.*

In a supplemental report, Dr. Simpson affirmed that petitioner's Tdap vaccination precipitated petitioner's GBS and that molecular mimicry remains the most likely mechanism connecting the cause with the injury. Pet'r Ex. 22 at 4. He cited *Pollard*,¹⁴ a case report of a patient who developed acute idiopathic polyneuropathy (a descriptive term corresponding to the eponym GBS) on three separate occasions following tetanus-containing vaccination. *Id.* at 4-5. The authors concluded that the repeated temporal association strongly suggested a vaccine-triggered immune susceptibility, noting that "there is little doubt that the three clinical episodes of demyelinating neuropathy resulted from the administration of tetanus toxoid," and that the "only other common factor" preceding each episode was a minor laceration. Pet'r Ex. 31 at 5.

Dr. Simpson further noted that national advisory bodies have recognized a potential relationship between tetanus-containing vaccines and GBS. Pet'r Ex. 22 at 5. He highlighted that the Advisory Committee on Immunization Practices ("ACIP") designates a prior episode of GBS occurring within six weeks of a tetanus-containing vaccine as a "precaution"¹⁵ against subsequent dosing and therefore signals a recognized potential risk of immune-mediated recurrence. *Id.*; *see also* Pet'r Ex. 32 at 63-64; Pet'r Ex. 33 at 23. Dr. Simpson also pointed to the Institute of Medicine ("IOM"), which concluded that the evidence is "inadequate to accept or reject"¹⁶ a causal relationship between tetanus toxoid-containing vaccines and GBS, indicating that while causation has not been established by the IOM, neither has the IOM ruled it out. Pet'r Ex. 19 at 586-87.

Beyond this immunologic explanation, Dr. Simpson found no credible alternative cause for petitioner's development of GBS. Pet'r Ex. 10 at 5-6. Although petitioner recalled a brief,

¹³ T.J. Safranek et al., *Expert Neurology Group. Reassessment of the Association Between Guillain-Barré Syndrome and Receipt of Swine Influenza Vaccine in 1976-1977: Results of a Two-State Study*, 133 *Am. J. Epidemiol.* 94095 (1991). [Pet'r Ex. 14].

¹⁴ J.D. Pollard & G. Selby, *Relapsing Neuropathy Due to Tetanus Toxoid. Report of a Case*, 37 *J. Neurol. Sci.* 113125 (1978). [Pet'r Ex. 16].

¹⁵ A.T. Kroger et al., *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 55 *MMWR Recomm. Rep.* 1 (2006). [Pet'r Ex. 32]; K. Kretsinger et al., *Preventing Tetanus, Diphtheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine—Recommendations of the Advisory Committee on Immunization Practices (ACIP) and Recommendation of ACIP, Supported by the Healthcare Infection Control Practices Advisory Committee (HICPAC), for Use of Tdap Among Health-Care Personnel*, 55 *MMWR Recomm. Rep.* 1 (2006). [Pet'r Ex. 33].

¹⁶ Committee to Review Adverse Effects of Vaccines, Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality* (Nat'l Acads. Press 2011). [Pet'r Ex. 19].

self-limited diarrheal episode preceding the onset of neurologic symptoms, Dr. Simpson characterized this episode as nonspecific and “signif[ying] very little,” noting the frequency of noninfectious causes of gastrointestinal (“GI”) upset. Pet’r Ex. 22 at 3. He underscored that *C. jejuni* is the only infectious agent with well-established epidemiologic support for triggering GBS and that petitioner’s medical records contain no evidence of such an infection.¹⁷ *Id.*; see Pet’r Ex. 2 at 63-64. At most, he opined, a short-lived GI disturbance might have rendered petitioner transiently more susceptible to an aberrant immune response following vaccination. Pet’r Ex. 10 at 5-6.

Dr. Simpson further explained that petitioner’s clinical course unfolded in a manner that complemented his conclusions. See Pet’r Ex. 10 at 5. Petitioner first experienced neurologic symptoms, which included reduced stamina during physical activity and fatigue with walking, approximately sixteen days after receiving the Tdap vaccine. *Id.* at 1; see also Pet’r Ex. 2 at 79. Notably, petitioner reported no comparable symptoms prior to vaccination, a detail that Dr. Simpson regarded as “telling” of a vaccine-induced process rather than an unrelated antecedent cause. *Id.*

To support the medical reasonableness of this latency, Dr. Simpson cited several published case reports documenting GBS or GBS-like presentations developing shortly after tetanus toxoid-containing vaccination. *Bakshi* reported neurologic symptoms four days after tetanus-diphtheria vaccination;¹⁸ *Schlenska* gave an account of neurologic symptoms, including myelopathy and encephalopathy, five days after vaccination with tetanus toxoid;¹⁹ *Newton* described signs of GBS-onset nine days after receipt of a pure tetanus toxoid injection;²⁰ and *Ammar* presented a case report of a GBS patient whose symptoms began approximately two weeks after Tdap vaccination.²¹ Pet’r Ex. 10 at 6; Pet’r Ex. 22 at 4. He further opined that an approximately two-week interval falls within the expected window for immune-mediated demyelination following vaccination. See *id.*

Soon after onset, petitioner experienced a rapid deterioration of sensory and motor symptoms, albuminocytologic dissociation in CSF, and subsequent improvement with IVIG therapy. Dr. Simpson described these developments as following the classical course of GBS. Pet’r Ex. 22 at 1, 5; see also Pet’r Ex. 28 at 1-2 (patient experienced a significant worsening of GBS symptoms approximately three days following symptom onset); Pet’r Ex. 29 at 1 (patient

¹⁷ I. Nachamkin, B.M. Allos, & T. Ho, *Campylobacter Species and Guillain-Barré Syndrome*. 11 Clin. Microbiol. Rev. 555 (1998). [Pet’r Ex. 26].

¹⁸ R. Bakshi & M.C. Graves, *Guillain-Barré Syndrome after Combined Tetanus-Diphtheria Toxoid Vaccination*, 147 J. Neurol. Sci. 201 (1997). [Pet’r Ex. 20].

¹⁹ G.K. Schlenska, *Unusual Neurological Complications Following Tetanus Toxoid Administration*, 215 J. Neurol. 299 (1977). [Pet’r Ex. 28].

²⁰ N. Newton & A. Janati, *Guillain-Barré Syndrome after Vaccination with Purified Tetanus Toxoid*, 80 Southern Med. J. 1053 (1987). [Pet’r Ex. 27].

²¹ H. Ammar, *Guillain Barré Syndrome after Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine: A Case Report*. 5 J. Med. Case Reports 502 (2011). [Pet’r Ex. 29].

experienced a significant worsening of GBS symptoms approximately one week following symptom onset). Petitioner’s near-complete recovery, aided by IVIG therapy, only further bolstered Dr. Simpson’s confidence that petitioner’s experience adheres to the recognized temporal progression of GBS/AIDP. Pet’r Ex. 22 at 1-2; *see also* Pet’r Ex. 27 at 1 (approximately two months post vaccination, patient was deemed appropriate for discharge and “was given an exercise program for the mild motor weakness of the left leg”); Pet’r Ex. 28 at 2 (patient experienced a rapid improvement with cortisone interval treatment and some residual GBS symptoms for at least the subsequent eleven months); Pet’r Ex. 29 at 2 (“patient was treated with [IVIG therapy] and his muscle strength improved. Three months later he continued to have tingling in his hands and feet and use a walker intermittently”).

Dr. Simpson presented a coherent theory that Tdap can precipitate GBS, consistent with theories advanced in other Program cases that ultimately resulted in compensation.²² He reasonably relied on petitioner’s contemporaneous clinical course of monophasic GBS/AIDP and appropriate timing as support for a vaccine-triggered process. It is worth noting, however, that portions of his report overstated the conclusions of the 2012 IOM report. The IOM did not “accept” a 42-day period as biologically meaningful; rather, it adopted an epidemiologic window for standardization. Pet’r Ex. 10 at 5. Nor did the IOM “favor acceptance” of a causal relationship between tetanus toxoid-containing vaccines and GBS; it concluded that the evidence is “inadequate to *accept or reject*” causation. Pet’r Ex. 22 at 5; *see also* Pet’r Ex. 19 at 586-87 (emphasis added).

Based on the published literature and petitioner’s medical records, Dr. Simpson concluded his reports reiterating his opinion that the June 5, 2019 Tdap vaccination was more likely than not the cause-in-fact of petitioner’s GBS. Pet’r Ex. 10 at 5-6; Pet’r Ex. 22 at 5; Pet’r Ex. 35 at 3.

c. Respondent’s Expert, Dr. Brian C. Callaghan, MD, MS

Respondent relies on the expert opinion of Dr. Callaghan, as set forth in a May 1, 2023 report and a January 22, 2024 supplemental report. Resp’t Exs. A & C, ECF Nos. 27& 37. In these reports, Dr. Callaghan concluded that petitioner’s GBS was more likely attributable to a GI illness than to his June 5, 2019 Tdap vaccination. Resp’t Ex. A at 5; Resp’t Ex. C at 2.

²² In the Vaccine Program, a number of petitioners, who alleged that a tetanus toxoid-containing vaccine caused their GBS, have been awarded a monetary sum pursuant to a ruling finding entitlement to compensation. *See e.g.*, *Mohamad v. Sec’y of Health & Hum. Servs.*, No. 16-1075V, 2022 WL 711604 (Fed. Cl. Spec. Mstr. Jan. 27, 2022) (finding that petitioner was entitled to compensation for GBS caused by the Tdap vaccine); *Swaiss v. Sec’y of Health & Hum. Servs.*, No. 15-286V, 2019 WL 6520791 (Fed. Cl. Spec. Mstr. Nov. 4, 2019) (finding that petitioner was entitled to compensation for SFN, a variant of GBS, caused by Tdap vaccination); *Harris v. Sec’y of Health & Hum. Servs.*, No. 18-944V, 2023 WL 2583393 (Fed. Cl. Spec. Mstr. Feb. 21, 2023) (finding that petitioner was entitled to compensation for GBS caused by Tdap vaccination); and *Coons v. Sec’y of Health & Hum. Servs.*, No. 20-1067V, 2024 WL 1741619 (Fed. Cl. Spec. Mstr. Mar. 29, 2024) (finding that petitioner was entitled to compensation for SFN caused by a tetanus diphtheria toxoid vaccine).

Dr. Callaghan agreed with Dr. Simpson that petitioner was correctly diagnosed with GBS; the diagnosis is not in dispute. Resp't Ex. C at 1. Dr. Callaghan likewise found that the record does not suggest that petitioner suffered from SFN. He stated that petitioner's August 8, 2022 EMG/NCV studies, which were characterized as "normal," reflect a "dramatic recovery" and argue against CIDP. *Id.* Beyond these areas of agreement, the experts diverge in their interpretation of the medical literature and in their views on the antecedent event that triggered petitioner's GBS.

Dr. Callaghan opined that no epidemiologic, mechanistic, or clinical evidence establishes a causal relationship between Tdap vaccination and GBS. Resp't Ex. A at 4. He emphasized that the 2012 IOM report had concluded that the evidence was "inadequate to accept or reject" a causal association between tetanus toxoid-containing vaccines and GBS. Resp't Ex. C at 2; *see* Pet'r Ex. 30 at 587. He noted that no subsequent studies have altered that conclusion, though respondent submitted three articles that may be construed as supporting the hypothesis that certain influenza vaccines may be involved with GBS.²³ *Id.*; Resp't Exs. A.1 at 4; A.2 at 6; & A.4 at 6.

He observed that Dr. Simpson proposed several theoretical mechanisms, including molecular mimicry, without, he argued, presenting vaccine-specific biologic evidence demonstrating that these mechanisms operate in connection with Tdap. Resp't Ex. A at 4. Although he acknowledged that molecular mimicry has been implicated in *C. jejuni*-associated GBS, Dr. Callaghan stated that no evidence shows that Tdap contains homologous antigens capable of inducing GBS through such a pathway. Resp't Ex. C at 2. However, proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Kottenstette v. Sec'y of Health & Hum. Servs.*, 861 Fed.Appx. 433, 441 (Fed. Cir. 2021) (citing *Knudsen*, 35 F.3d at 549). Causation "can be found in vaccine cases... without detailed medical and scientific exposition on the biological mechanisms." *Knudsen*, 35 F.3d at 549.

Addressing the case reports cited by Dr. Simpson, including *Bakshi*, *Newton*, *Schlenska*, *Ammar*, and *Pollard*, Dr. Callaghan recognized that they describe GBS or related neurologic syndromes following tetanus-containing vaccination. Resp't Ex. C at 1-2. He took issue, however, with their persuasive value. As Dr. Simpson himself noted, epidemiologic data are limited and may not detect rare events such as vaccine injuries, Pet'r Ex. 22 at 4, but in Dr. Callaghan's view, these "isolated case reports" may be offered to demonstrate only temporal proximity in specific individuals and "are not useful" for identifying a reliable, vaccine-specific mechanism that could trigger GBS. Resp't Ex. C at 2. It is worth noting that it is not necessary for petitioner to point to conclusive evidence in the medical literature linking a vaccine to the alleged injury, as long as he can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *See Moberly*, 592 F.3d at 1325.

²³ J.S. Marks & T.J. Halpin, *Guillain-Barré Syndrome in Recipients of A/New Jersey Influenza Vaccine*, 243 JAMA 2490 (1980). [Resp't Ex. A.1]; L.H. Martín Arias et al., *Guillain-Barré Syndrome and Influenza Vaccines: A Meta-Analysis*, 33 Vaccine 3773 (2015). [Resp't Ex. A.2]; F. Galeotti et al., *Risk of Guillain-Barré Syndrome after 2010-2011 Influenza Vaccination*, 28 Eur. J. Epidemiol. 433 (2013). [Resp't Ex. A.4].

Dr. Callaghan did not dispute that petitioner's approximately sixteen to eighteen-day onset falls within intervals reported in these case reports, nor that such a latency is medically sound for immune-mediated demyelination. *See* Resp't Ex. A at 5. Nevertheless, he maintained that temporal proximity alone is insufficient to establish causation and reiterated that no reliable evidence links Tdap specifically to GBS. *Id.*; Resp't Ex. C at 1-2.

Turning to alternative etiologies, Dr. Callaghan opined that petitioner's GBS was more logically connected to a GI illness occurring shortly before petitioner's symptom onset. Resp't Ex. A at 5. In summarizing petitioner's presentation, he wrote: "About 15 days after the Tdap vaccination, he developed a non-specific GI illness with diarrhea. Three days later, or 18 days after Tdap vaccination, he developed GBS." *Id.* at 3.

The contemporaneous records, however, reflect a slightly different sequence. Petitioner reported that the brief diarrheal episode occurred on or about Thursday, June 20, 2019. Pet'r Ex. 2 at 79. The following day, he felt "a little bit numb," and "his body felt somewhat worn out." *Id.* He then traveled to New Orleans between June 21 and June 25, recalling "some tingling in his feet." *Id.* Petitioner initially attributed this sensation to earlier orthopedic injuries; he had fractured his right distal fibula on January 28, 2019, and sprained his left ankle on an unidentified date. *Id.* at 39, 79. Petitioner's initial sensory symptoms therefore began approximately sixteen days after the June 5, 2019 Tdap vaccination and within about 24 hours of the GI upset, placing onset earlier than indicated in Dr. Callaghan's summary.

In Dr. Callaghan's view, a GI illness represented a more likely antecedent event than the vaccination. He wrote that "given the strong epidemiologic evidence linking GI illness with GBS, there is a clear non-vaccine cause." Resp't Ex. C at 2. He cited three articles,²⁴ which he interpreted as showing "strong support for an association between any GI illness and GBS," even when no pathogen is identified, and as reflecting an association that is "more robust" than that seen for vaccine-related causes. Resp't Ex. A at 5; Resp't Ex. C at 2; *see also* Resp't Ex. A.3, A.5.

Responding to Dr. Simpson's view that *C. jejuni* is the only GI pathogen with an established link to GBS, Dr. Callaghan countered that the literature demonstrated an association with a GI infection generally, irrespective of specific pathogen, and that causative organisms are often not tested for or identified. Resp't Ex. C at 2. He further noted that petitioner was not evaluated for the diarrheal illness at the time it occurred, making absence of a documented pathogen unsurprising. *Id.* Given this sequence and the broader epidemiologic literature showing that many GBS patients report preceding GI symptoms, he concluded that "greater evidence" supports a non-vaccine cause, namely a GI infection, than a vaccine-related cause. Resp't Ex. A at 5; Resp't Ex. C at 2.

²⁴ C. Grave et al., *Seasonal Influenza Vaccine and Guillain-Barré Syndrome: A Self-Controlled Case Series Study*, 94 *Neurology* e2168 (2020); F. Galeotti et al., *Risk of Guillain-Barré Syndrome after 2010-2011 Influenza Vaccination*, 28 *Eur. J. Epidemiol.* 433 (2013); S. K. Greene et al., *Guillain-Barré Syndrome, Influenza Vaccine, and Antecedent Respiratory and Gastrointestinal Infections: A Case-Centered Analysis in the Vaccine Safety Datalink, 2009-2011*, 8 *PLoS One* e67185 (2013).

In sum, the experts part ways not on the diagnosis, but on etiology and the relative weight to assign the competing medical literature. Dr. Callaghan provided a careful review of the available studies and accurately described the limitations of epidemiologic evidence and the inability of case reports to establish causation. However, aspects of his analysis appeared to apply a more demanding standard than the Vaccine Act requires, giving dispositive emphasis to the limitations of epidemiology to link Tdap specifically to GBS. Such a posture is inconsistent with Federal Circuit precedent, which makes clear that petitioners are not required to produce conclusive or epidemiologic evidence to satisfy the preponderance standard. *See, e.g., Knudsen*, 35 F.3d at 548-49 (medical certainty is more demanding than the preponderance standard).

The undersigned now turns to an analysis of the entire record, including these competing opinions, under the legal standards governing entitlement.

IV. Analysis

a. Diagnosis

Federal Circuit precedent establishes that, in certain cases, it is appropriate to determine the nature of an injury before engaging in *Althen* analysis. *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). Although earlier status conferences raised questions as to whether petitioner's symptoms were more consistent with CIDP, the parties agreed that petitioner's treating neurologist diagnosed GBS. Pet'r Ex. 10 at 3; Pet'r Ex. 22 at 2; Resp't Ex. A at 2; Resp't Ex. C at 1; *see generally*, Pet'r Ex. 2 at 81. The parties' experts likewise concurred with this diagnosis and did not dispute that both petitioner's clinical presentation and diagnostic testing support it. Pet'r Ex. 10 at 6; Resp't Ex. A at 5. Drs. Callaghan and Simpson agreed that petitioner had near-complete recovery within seven to eight months post-vaccination and that for a period thereafter continued to suffer symptoms in his hands and legs. Pet'r Ex. 35 at 2; Resp't Ex. A at 2; *see* Pet'r Ex. 8 at 1-3. The central disagreement in this case, then, is not *what* the condition is, but *why* it occurred.

Based on the record as a whole, the undersigned finds that petitioner has proven by preponderant evidence that he suffered from GBS, that his Tdap vaccination was the cause-in-fact of his injury, and that the effects of this injury lasted beyond six months.

b. Causation

1. *Althen* Prong One

Petitioner has shown by preponderant evidence a sound and reliable medical theory explaining how the Tdap vaccine can cause GBS.

Under *Althen* prong one, petitioner must provide a “reputable medical theory,” demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Such theory must only be “legally probable, not medically or scientifically certain.” *Knudsen*, 35 F.3d at 548-49. Petitioner may satisfy the first *Althen* prong without resorting to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *See 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). However, a “petitioner must provide a ‘reputable medical or scientific explanation’ for [petitioner’s] theory.” *Boatmon v. Sec’y of Health and Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Moberly*, 592 F.3d at 1322). While the theory need not be medically or scientifically certain, “it must still be ‘sound and reliable.’” *Id.* (quoting *Knudsen*, 35 F.3d at 548-49). The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” *Knudsen*, 35 F.3d at 548-49. Causation “can be found in vaccine cases...without detailed medical and scientific exposition of the biological mechanisms.” *Id.*

Special masters evaluate reliability by examining whether the theory is consistent with accepted immunologic mechanisms, the medical community recognizes the mechanism as sound and reliable, the expert’s reasoning is grounded in scientific literature and the contemporaneous medical records, and the expert applies the theory to the petitioner. Epidemiologic confirmation is not required, nor may respondent demand scientific certainty. *Capizzano*, 440 F.3d at 1325-26.

Respondent and respondent’s expert, Dr. Callaghan, attributed the illness to an antecedent diarrheal episode, whereas petitioner and his expert, Dr. Simpson, affirmed that the Tdap vaccine was the most likely precipitating event. Pet’r Ex. 10 at 6; Resp’t Ex. A at 5. For the reasons discussed below, the undersigned finds that petitioner has provided by preponderant evidence a sound and reliable theory explaining how the Tdap vaccine can cause GBS, therefore, satisfying *Althen* prong one.

Evoking the theory of molecular mimicry, which has been previously accepted in the Program, Dr. Simpson stated that the Tdap vaccine can induce GBS through immune-mediated processes, leading to an attack on peripheral nerve myelin. *See* Pet’r Ex. 10 at 4; *see also e.g.*, *Swaiss*, 2019 WL 6520791 at 12, 28, n28 (finding that molecular mimicry was a sound and reliable medical theory); *Coons*, 2024 WL 1741619 at 24 (finding that molecular mimicry was a sound and reliable medical theory). Dr. Simpson opined that petitioner’s GBS more likely than not arose from such aberrant immune cross-reactivity that damaged his peripheral nerves. Pet’r Ex. 10 at 4. Though petitioner had a near-complete recovery, Dr. Simpson attributes petitioner’s ongoing symptoms to his having experienced an acute phase of GBS. Pet’r Ex. 35 2-3. To support his opinion, Dr. Simpson submitted medical literature that recognizes tetanus toxoid-containing vaccines as capable of producing immune-mediated demyelinating neuropathy. *See e.g.*, Pet’r Ex. 36.

Although the experts rely, in part, on overlapping bodies of medical literature, they differed in emphasis in how they interpret certain portions that bear on potential triggering

mechanisms for GBS. Dr. Simpson offered medical literature identifying a vaccine-associated risk of triggering GBS through abnormal immunologic responses, of which he opined molecular mimicry was the most likely mechanism causing petitioner's injury. Pet'r Ex. 10 at 4; Pet'r Ex. 22 at 4-5; *see also* Pet'r Exs. 19, 31, 32, 33. He likened this risk to the potential for Tdap components to have antigenic effects, pointing to evidence that showed GBS following tetanus toxoid-containing vaccination. Pet'r Ex. 10 at 4-5; *see also* Pet'r Exs. 13, 16, 19, 20.

Dr. Simpson described the components of Tdap as capable of provoking an autoimmune response through molecular mimicry, stating "it is generally accepted in the medical community that vaccinations may serve as a causal antecedent to the occurrence of GBS." Pet'r Ex. 10 at 5. While he may have overstated the IOM's conclusions by interpreting its finding of "insufficient evidence" more favorably than warranted, Dr. Simpson's central mechanism remains reliable and grounded in immunologic principles. His characterization affects the weight of this portion of his testimony, but not admissibility or overall persuasiveness. Indeed, special masters are not required to deny compensation when the IOM takes a neutral stance. *Mohamad*, 2022 WL 711604 at *17 (citing *Estep v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 664, 668 (1993), that the Vaccine Act "does not require [a special master] to accept the IOM Report as dispositive" (alteration in original), *app. dismissed*, No. 93-5192 (Fed. Cir. Oct. 29, 1993) and *Raymo v. Sec'y of Health & Hum. Servs.*, No. 11-0654V, 2014 WL 1092274, at *21 (Fed. Cl. Feb. 24, 2014) that "it is apparent that the IOM requires a very high standard before concluding that there is a causal relationship between vaccines and an injury").

Dr. Callaghan, in turn, noted that published data exist that may be offered, whether persuasively or not, in support of an association between certain influenza vaccines and GBS. Resp't Ex. A at 4. He found published literature describing this possible connection between certain influenza vaccines and GBS, adding that "the influenza vaccine and Tdap are quite distinct." *Id.* He wrote:

There is published data to support an association of certain influenza vaccines with an increased chance of GBS, such as the 1976 swine influenza vaccine (Marks), possibly the H1N1 2009 vaccine (Martin Arias), and perhaps the seasonal influenza virus (Martin Arias). However, the most recent investigation to look into an association between the seasonal influenza vaccine and GBS did not reveal a significant association (Grave).²⁵

Id. (emphasis added) (footnotes omitted). He also found two case reports, *Bakshi* and *Pollard*,²⁶ of GBS following tetanus-diphtheria vaccination. *Id.* He opined that a case report "only

²⁵ While Dr. Callaghan's contention may be correct that a more recent epidemiological investigation into an association between the seasonal influenza vaccine and GBS did not reveal a significant association, GBS occurring within three to forty-two days after receipt of seasonal influenza vaccines has been generally accepted in the Program as a Table Injury. 42 C.F.R. § 100.3 ¶ XIV.D.

²⁶ In his response to the motion for reconsideration, petitioner characterized Dr. Callaghan's statement regarding the limited number of case reports resulting from his literature review as "extraordinarily misleading" and concurrently filed additional items of medical literature that, according to petitioner, referenced "97 such case reports." Pet'r Resp. at n.2. The undersigned notes that these materials were not previously part of the record, were not reviewed by either party's expert, and were not relied upon in the original entitlement analysis. In any event, the entitlement

suggests a proximate temporal relationship between tetanus-diphtheria vaccination and GBS *in one individual.*” Resp’t Ex. A at 4 (emphasis added). He added that “a proximate temporal relationship alone is insufficient to show causation.” *Id.* He concluded that Dr. Simpson “fail[ed] to provide... support for any mechanism... leading from Tdap to GBS,” including through the pathway of molecular mimicry. Resp’t Ex. C at 2.

The Vaccine Act does not require that evidence be medically or scientifically certain. *Knudsen*, 35 F.3d at 548-49. Petitioner does not need to prove scientific certainty for his petition to be granted. The Vaccine Program does not require such a showing, and imposing it would improperly raise petitioner’s burden. “[T]he purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Althen*, 418 F.3d at 1280. “[T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.” *Knudsen*, 35 F.3d at 549; see also *Andreu*, 569 F.3d at 1378 (citing *Capizzano*, 440 F.3d at 1325-36 (“Requiring ‘epidemiologic studies...or general acceptance in the scientific or medical communities... impermissibly raises a claimant’s burden under the Vaccine Act’”).

Case reports may be offered as evidence in support of a claim in the Vaccine Program. See *Paluck v. Sec’y of Health & Hum. Servs.*, 104 Fed. Cl. 457, 475 (2012) (quoting *Campbell v. Sec’y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011), *aff’d*, 786 F.3d 1373 (Fed. Cir. 2015)). “Case reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value compared particularly to formal epidemiological studies. Nonetheless, the fact that case reports can by their nature only present indicia of causation does *not* deprive them of all evidentiary weight.” *Campbell*, 97 Fed.Cl. at 668 (emphasis added).

Moreover, statements from the Secretary appear to be consistent with petitioner’s theory that a tetanus toxoid-containing vaccine can cause GBS. The ACIP, whose recommendations were adopted and published by HHS, classified GBS occurring within six weeks of tetanus toxoid-containing vaccines as a “precaution.” Pet’r Ex. 32 at 63-64; Pet’r Ex. 33 at 23. This classification reflects the Secretary’s acknowledgement that tetanus toxoid-containing vaccines may carry a low, albeit nonzero, risk of inducing GBS in rare cases.

Likewise, the IOM has not rejected a causal relationship links Tdap to GBS. Pet’r Ex. 13 at 586-87. In reviewing studies concerning the risk of GBS following administration of vaccines containing tetanus toxoid, diphtheria toxoid, and acellular pertussis antigens, the committee identified publications supporting temporality. *Id.* at 586. It also noted that autoantibodies, complement activation, immune complexes, T cells, and molecular mimicry may contribute to the development of GBS-associated symptoms, although the available publications did not establish a definitive mechanistic link to Tdap. *Id.* at 587. Ultimately, the committee concluded that the epidemiologic and mechanistic evidence was insufficient to either support or refute causation. *Id.* That determination does not undermine petitioner’s theory; rather, it reflects the committee’s scientific uncertainty and leaves open the plausibility of a causal relationship under *Althen* prong one.

determination does not depend on those materials, which had not been filed at the time of issuance, and the Court does not rely on them here.

Alternatively, Dr. Callaghan offered literature indicating that GI pathogens, such as *C. jejuni*, are among the most common triggers of GBS and are widely supported by the medical community. He read the relevant epidemiologic studies as showing higher risk of GBS after GI illnesses than after Tdap vaccination. *See* Resp't Ex. A.3-5. Because he found this literature to be more robust than Dr. Simpson's references, Dr. Callaghan opined that petitioner's clinical course was more evocative of an infection-related etiology. Proceeding from these premises, Dr. Callaghan concluded that petitioner's GBS was more likely than not precipitated by a GI infection as evidenced by a two-day, diarrheal episode occurring on approximately June 20, 2019. *See* Pet'r Ex. 2 at 63-64.

However, the record does not support a finding that petitioner's mild, self-limiting diarrhea was infectious. Petitioner denied having symptoms associated with GI infections, such as vomiting, cramping, or fever; moreover, his GI distress was not medically attended, so no assessment made by a contemporaneous medical provider can be offered to support the assertion that the episode was infectious. *Id.* The record reflects that petitioner more likely experienced a transient gastrointestinal disturbance of unknown cause.

Dr. Simpson's theory that petitioner suffered vaccine-induced GBS is well-supported by contemporaneous medical findings. Petitioner recounted having sensory symptoms on June 21, 2019, approximately sixteen days post-vaccination and only 24 hours after he began experiencing GI upset. Pet'r Ex. 2 at 79. Particularly important to the analysis of likely causation is the timing. As often argued in the Program, a one-day onset is too fast for an autoimmune response to occur. *See, e.g., Langert v. Sec'y of Health & Hum. Servs.*, No. 22-809V, 2025 WL 1892418 (Fed. Cl. Spec. Mstr. June 13, 2025) (finding a one-day interval was not medically acceptable). Sixteen days is fairly squarely in the range where the proliferation of antibodies to the Tdap vaccination would likely be at peak levels. *See* Pet'r Ex. 12 at 1 (stating that GBS often follows exposure to an antigen by ten to fourteen days); *cf.* 42 C.F.R. § 100.3(a) (listing seasonal influenza vaccines—Guillain-Barré syndrome onset within three to forty-two days).

Finally, petitioner's treating providers repeatedly memorialized vaccine-mediated etiology, and no strong suspicion of an alternative cause influenced the management of petitioner's symptoms. *See e.g.,* Pet'r Ex. 2 at 81, 195-96; Pet'r Ex. 8 at 2. Petitioner's treating neurologist signed a form, required by petitioner's employer to be exempted from flu vaccination, in the context of petitioner's history of GBS within six weeks of receiving a previous vaccine, which provides additional evidence to indicate that petitioner's injury was precipitated by the vaccine. Pet'r Ex. 21 at 74; *cf. Andreu*, 569 F.3d at 1376-77 (“[a] treating doctor’s recommendation to withhold a particular vaccination can provide probative evidence of a causal link between the vaccination and an injury a claimant has sustained”) (footnote omitted) (citing cases).

The Vaccine Act's preponderance standard intentionally accommodates cases involving rare vaccine injuries that may be scientifically difficult to study. *See Althen*, 418 F.3d at 1280. Where “even very large epidemiological studies may not detect or rule out rare events,” case reports may capture data of such rare events. *See* Pet'r Ex. 22 at 4 (endorsing an observation

offered by the Chair of the IOM Committee). Accordingly, the case reports linking tetanus toxoid-containing vaccines to GBS, in addition to the testimony of Dr. Simpson, his other items of medical literature, petitioner's recollections, and the observations and care plans of petitioner's treating providers, inform the undersigned's conclusions. Petitioner has offered a reputable medical theory based on a sound and reliable medical or scientific explanation and has demonstrated the legal probability of the proposed theory. Thus, petitioner has demonstrated *Althen* prong one by preponderant evidence. *See Althen*, 418 F.3d at 1280.

2. *Althen* Prong Two

Petitioner has established, by preponderant evidence, a logical sequence of cause and effect, demonstrating that the Tdap vaccine was the most likely cause of his GBS.

Under *Althen* prong two, petitioner must prove by a preponderance of the evidence that the vaccine caused the alleged injury with a logical and fact-specific sequence connecting vaccination to symptom onset. *Broekelschen*, 618 F.3d at 1345. "Petitioner must show that the vaccine was the 'but for' cause of the harm...or in other words, that the vaccine was the 'reason for the injury.'" *Pafford*, 451 F.3d at 1356 (internal references omitted). Petitioners need not eliminate all other possibilities. *See* § 13(a)(1)(B).

Proof of the sequence may be circumstantial and may rely on medical records, treating physician impressions, and reliable expert opinion. *Capizzano*, 440 F.3d at 1325-26. A petitioner need not make a specific type of evidentiary showing, *i.e.* "epidemiologic studies, rechallenge, the presence of pathological markers o/r genetic predisposition, or general acceptance in the scientific or medical communities" to satisfy his burden. *Id.* at 1325. In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating providers 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 trustworthy evidence, though they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the "diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court").

Petitioner has demonstrated by preponderant evidence a logical sequence of cause and effect establishing that the Tdap vaccine he received on June 5, 2019, was the cause of his developing GBS. Importantly, as discussed above, the undersigned found that petitioner established that he developed GBS within approximately sixteen days of his vaccination and that his symptoms continued at least six months beyond his June 5, 2019 vaccination. Additionally, petitioner proffered a sound and reliable mechanism of vaccine causation.

Importantly, petitioner's treating providers gave circumstantial evidence in support of a causal relationship between Tdap and GBS. At his first, post-vaccination medical encounter on June 30, 2019, petitioner was evaluated by PA-C Stanfield who recorded his chief complaint as a sudden onset of muscle weakness and tingling primarily in the feet, shins, and hands, with a

latency having lasted approximately sixteen days. Pet'r Ex. 2 at 63-64. The motor examination revealed that petitioner was areflexive bilaterally in his biceps, brachioradialis, triceps, patellae, and ankles. *Id.* at 65.

The on-call neurologist, Dr. Guterrez, and another physician, Dr. Baxter, interfaced with PA-C Stanfield at this time, and the care team's differential diagnosis favored GBS, thought to be secondary to "dysentery" versus "reaction" to the Tdap vaccination. *Id.* at 66-67. Their proposed work-up was endorsed in order to confirm the diagnosis. *Id.* No objective findings weighed more in favor of a pathogenic organism rather than the Tdap vaccine as the underlying cause for petitioner's symptoms.

Several studies were ordered and were considered collectively by petitioner's treating neurologist, Dr. Schmidt. *Id.* A lumbar puncture indicated that petitioner's CSF protein was mildly elevated at 49 mg/dL and therefore inconclusive; no subsequent lumbar puncture was performed. *Id.* at 67-68, 77. MRI studies of the spine were made approximately one-month post-vaccination and were normal. *Id.* at 67. Dr. Schmidt observed that there was "sufficient clinical evidence," including petitioner's areflexia, to warrant the diagnosis of GBS. *Id.* at 81. A subsequent, normal MRI of the brain, taken on July 11, 2019, did not uncover an alternative explanation for petitioner's symptoms. *Id.* at 195-96. On August 8, 2022, Dr. Kolostyak conducted EMG/NCV testing and reported normal results, cautioning that very mild or intermittent compression may yield false negatives. Pet'r Ex. 21 at 37-49.

Petitioner achieved about 85% recovery by February 25, 2020. Pet'r Ex. 2 at 141. His rapid progress plateaued thereafter, and petitioner continued to report neurologic symptoms beyond January 2022. Pet'r Ex. 8 at 2; *see also* Pet'r Aff. 34. Given Dr. Kolostyak's limitation regarding EMG/NCV testing, petitioner's "normal" results do not rule out a logical connection between Tdap and petitioner's ongoing symptoms. Pet'r Ex. 21 at 39. Moreover, petitioner's ability to return to baseline may have been limited due to delays in starting IVIG therapy. *See* Pet'r Ex. 8 at 2.

Here, petitioner experienced a clinically characteristic course of GBS, featuring appropriate latency; rapid sensory and motor changes as indicated by areflexia; albuminocytologic dissociation in the CSF, responsiveness to IVIG, near complete recovery, and ongoing neurologic symptoms. Petitioner's treating providers and both parties' experts agreed that petitioner had a classic case of GBS. This consensus, along with the fact that petitioner never experienced these symptoms prior to the events at issue, support a single, discrete antecedent event. Vaccine-induced GBS, then, is fully compatible with the sequence of events documented in the record.

Because petitioner has provided a sound and reliable explanation, which is supported by the medical literature, to explain how the Tdap vaccine could cause GBS; petitioner developed GBS symptoms, which rapidly worsened, responded to IVIG therapy, and were nearly resolved, in the manner described in the medical literature; and his treating providers associated his condition with his Tdap vaccination, petitioner has provided preponderant evidence of a logical sequence of cause and effect establishing that the Tdap vaccine caused his GBS. Accordingly, the undersigned finds that petitioner has satisfied *Althen* prong two.

3. *Althen* Prong Three

Petitioner has demonstrated that symptom onset occurred within a medically acceptable window for vaccine-induced GBS.

Althen prong three requires petitioner to show a “proximate temporal relationship” between his vaccination and alleged injury. *Althen*, 418 F.3d at 1281. That term has been defined as a “medically acceptable temporal relationship.” *Id.* Petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347 at 1352 (2008). The explanation for what is a medically acceptable interval is case-specific and depends upon the injury alleged and the mechanism proposed under *Althen* prong one. *Id.*; *see also Pafford*, 451 F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. *See e.g., Veryzer v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 344 at 356 (2011) (explaining that a “temporal relationship alone will not demonstrate a causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury”).

In the Vaccine Program, onset of an alleged vaccine injury is marked by the “first symptom or manifestation of onset.” *See* § 16(a)(2). Either a *symptom* or *manifestation of onset* can constitute the start of a disease process “even though a symptom could be nonspecific, or hard to link to what was later viewed as a full disease.” *Langert v. Sec’y of Health & Hum. Servs.*, No. 22-809V, 2025 WL 1892418, at *19 (Fed. Cl. Spec. Mstr. June 13, 2025) (citing *Markovich v. Sec’y of Health & Hum. Servs.*, 477 F.3d 1353, 1357-59 (Fed. Cir. 2007)). Here, petitioner was vaccinated on June 5, 2019, and reported sensory symptoms, which included feeling “a little bit numb” and “somewhat worn out,” beginning on approximately June 21, 2019. *See* Pet’r Ex. 2 at 79. His symptoms worsened, prompting him to seek medical attention on June 30, 2019; upon examination, he was areflexic bilaterally in the biceps, brachioradialis, triceps, patellae, and ankles, and sensation was decreased over the plantar aspect of both feet. *Id.* at 63-65. The record, then, reflects an onset of his GBS at approximately sixteen days post vaccination.

This conclusion has independent support. *See* Pet’r Ex. 12 at 2;²⁷ Resp’t Ex. A.2 at 1 (stating that GBS is “characterized primarily by muscle weakness and loss of reflexes”). Petitioner received the Tdap vaccine on June 5, 2019, and sought medical treatment on June 30, 2019, for neurologic symptoms that began around June 21, 2019. Pet’r Ex. 2 at 63-64, 79. Petitioner consistently reported this timeframe of symptom onset to his providers, who associated the onset of his motor and sensory symptoms to his Tdap vaccination. *See e.g., id.* at

²⁷ “GBS evolves over days, often beginning with *numbness* in the lower limbs and weakness in the same distribution. The progression of symptoms, *particularly weakness*, can be rapid, resulting in quadriplegia within a few days. Approximately 50% of patients achieve maximum weakness by 2 weeks, 80% by 3 weeks, and 90% by 4 weeks.” Pet’r Ex. 12 at 2 (emphasis added) (footnote omitted).

67-81. Such contemporaneous reporting by petitioner to his treating providers of what he deemed an urgent medical concern supports this onset.

Additionally, petitioner's and respondent's experts placed the onset of petitioner's GBS, within approximately two to three weeks post-vaccination. Pet'r Ex. 10 at 5; Resp't Ex. A at 1. Dr. Simpson stated that petitioner's first symptoms "occurred within a medically acceptable timeframe for the occurrence of demyelinating disease following vaccination." Pet'r Ex. 10 at 5. In support of this point, Dr. Simpson referenced the IOM's use of a 42-day interval in its *Adverse Effects of Vaccines: Evidence and Causality* (2012) report, stating that the IOM has "accepted" immune-mediated injury may occur throughout the six-week post-vaccination period. *Id.*

However, the IOM adopted this window as a criterion for methodological consistency rather than as an affirmative statement that immune-mediated injury is biologically likely to occur throughout that entire period. *See* Pet'r Ex. 8 at 42 (explaining that "for a case to factor into the [2012 IOM report], it had to include mention of... a specific and reasonable time interval... between vaccination and symptoms"). Still, the IOM's interval confirms that an onset of approximately two weeks is medically sound and consistent with GBS presentations recognized in medical literature. Importantly, as noted above, an onset of approximately sixteen days post vaccination would be well within the time period for an autoimmune response to the vaccine giving rise to GBS based on molecular mimicry; the one-day period from the transient gastrointestinal disturbance would not. The Vaccine Program generally accepts a three- to forty-two-day latency, and a one-day onset is generally thought to be too fast.

To support the medical appropriateness of this latency, Dr. Simpson also cited case reports documenting neurologic symptoms occurring within four, five, nine, and twenty-one days following tetanus toxoid-containing vaccination. Pet'r Ex. 10 at 6; Pet'r Ex. 22 at 4; *see also* Pet'r Exs. 20, 27-29. Notably, Dr. Callaghan listed published medical literature that may support a proximate temporal relationship between tetanus toxoid-containing vaccination and GBS with a similar onset; Dr. Callaghan added that "a proximate temporal relationship alone is insufficient to show causation." Resp't Ex. A at 4; *see also* Pet'r Exs. 16, 20. One of those studies, *Pollard*, which both experts discussed, documented a case in which a patient developed "acute idiopathic polyneuropathy (Landry-Guillain-Barré-Strohl syndrome)" on three separate occasions, "each of which followed an injection of tetanus toxoid." Pet'r Ex. 10 at 4-5; *see* Pet'r Ex. 16 at 1, 5-6. As Dr. Simpson observed, the documented timeframe is consistent with petitioner's course of GBS. *See* Pet'r Ex. 10 at 5. Petitioner's symptom onset and clinical course were consistent with published case reports describing the development of GBS within approximately four to twenty-one days post-vaccination.

Program precedent has likewise accepted symptom onset intervals that were similar to petitioner's experience in other cases also involving tetanus toxoid-containing vaccines. *See, e.g., Mohamad*, 2022 WL 711604 at *18 (finding an interval of approximately ten days as medically appropriate); *Swaiss*, 2019 WL 6520791 at *28 (finding an interval of approximately seven days as medically appropriate); *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-610V, 2012 WL 3609993 (Fed. Cl. Spec. Mstr. July 30, 2012) *aff'd*, 108 Fed.Cl. 743 (Fed. Cl. 2013) (finding an interval of approximately two weeks is medically acceptable, though dismissing the petition); *but see Langert v. Sec'y of Health & Hum. Servs.*, No. 22-809V, 2025 WL 1892418

(Fed. Cl. Spec. Mstr. June 13, 2025) (finding a one-day interval was not medically acceptable); *see also* 42 C.F.R. § 100.3(a) (listing seasonal influenza vaccines—Guillain-Barré syndrome onset within three to forty-two days). Moreover, the timing of petitioner’s symptom onset accords with the medical literature describing the delayed, immune-mediated nature of GBS and is consistent with the assessments of his treating providers. Accordingly, the undersigned finds that petitioner has demonstrated, by a preponderance of the evidence, a medically appropriate temporal relationship under *Althen* prong three.

c. Alternative Cause

Because petitioner has satisfied all three *Althen* prongs, the burden shifts to respondent to show that the GBS was “more likely” caused by a factor unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B). Respondent, however, has not met that burden. *See supra* § IV(b)(1). The alleged GI illness occurred within one day of symptom onset; the episode was never confirmed as infectious in nature; no GI pathogen was identified; and the mere possibility of infection is not enough to meet respondent’s burden.

Petitioner has demonstrated a reputable medical theory, a logical sequence of cause and effect, and an appropriate temporal relationship. Thus, petitioner has proven causation-in-fact by preponderant evidence, establishing all three *Althen* prongs. The undersigned therefore finds that petitioner’s GBS was more likely than not caused by the Tdap vaccination he received on June 5, 2019.

V. Conclusion

Petitioner’s experience post-vaccination is precisely the type of rare case the Vaccine Program was designed to address. While the claimed injury is uncommon and the published literature limited, the medical theory, clinical picture, and timing of onset align under the preponderance standard. Where the evidence is close, the Program resolves the matter in favor of the petitioner. *Althen*, 418 F.3d at 1280 (“close calls regarding causation are resolved in favor of injured claimants”).

In accordance with the above, petitioner has established by preponderant evidence that he is entitled to compensation, having demonstrated that the Tdap vaccine was the cause-in-fact of his GBS from which he suffered beyond six months.

Damages are addressed in a separate order.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master