

I. Factual Background

Petitioner's pre-vaccination history includes migraines, dizziness, nausea, eye and hand twitching, and numbness. *See generally* Ex. 3 at 3–4, Ex. 7 at 5, Ex. 14 at 13, and Ex. 16 at 61. In June 2019 (the year before the vaccination at issue), Petitioner had a new patient visit with internist Sharon Wasserstrom, M.D., for treatment of dizziness, fatigue, nausea, and headaches (with Petitioner noting that she had sought neurologic assistance in the past for persistent headaches). Ex. 3 at 3. She also reported that her left eye had been twitching “all the time” for the past three weeks, and that she noticed an “occasional left[-]hand twitch” and “bilateral hand numbness.” *Id.* at 3–4. Dr. Wasserstrom encouraged her to see a neurologist regarding her eye and hand twitching. *Id.* at 4.

Vaccination and Immediate Symptoms

On the late afternoon of October 14, 2020, Petitioner (then 39 years old) received a flu vaccine at a local CVS pharmacy. Ex. 1 at 3. Early the next morning (October 15th at approximately 12:30 AM) she went to the Advent Health Emergency Department, reporting that “shortly after” the vaccination she had begun to experience a headache plus vomiting. Ex. 4 at 98. The treating physician took note of Petitioner's history of migraines, but a neurological exam did not reveal any focal neurological deficits, and a CT scan also produced no evidence of acute intracranial abnormalities. *Id.* at 85, 133. Petitioner was treated with intravenous fluids and other medications, and discharged home after she reported that her symptoms had improved. *Id.* at 86–87.

That very afternoon, however, Ms. Pool returned to the Emergency Department, now reporting tingling in her extremities that was progressing, plus persistent headache. Ex. 2 at 55. To rule out Guillain-Barré syndrome (“GBS”), a lumbar puncture was performed, but it only revealed a high red blood cell count. *Id.* at 61, 179. Petitioner was eventually transferred to Advent Health East Orlando Hospital. *Id.* at 61. There, she underwent a physical examination that revealed decreased strength in her upper and lower extremities. Ex. 2 at 42.

Petitioner was admitted for observation and to evaluate the possibility of GBS. Ex. 2 at 43. On October 16, 2020, Petitioner had a consultation with neurologist Shafiuddin Ahmed, M.D. *Id.* at 44. Based on exam and initial testing results, Dr. Ahmed deemed GBS unlikely, instead diagnosing Petitioner with “[a]cute paresthesia secondary to possible additive agents of flu vaccination.” *Id.* at 45. Petitioner received some prescriptions and was discharged. *Id.*

Additional Fall 2020 Symptoms

Petitioner continued to seek emergency treatment on several more occasions that Fall for symptoms comparable to what she reported experiencing after vaccination.

For example, on October 20, 2020 (still less than one week from her vaccination), Petitioner went back to Dr. Wasserstrom with complaints of facial numbness and chest heaviness. Ex. 10 at 17. She again referenced her vaccination at this time, reporting that she developed a severe headache within an hour of receipt of the vaccine. *Id.* Dr. Wasserstrom proposed that Ms. Pool go back to the emergency department to be evaluated by a neurologist. In response, Petitioner again went to the Advent Health Emergency Department, now reporting tingling in her extremities that had spread to her face and tongue. Ex. 4 at 422. After a neurological examination revealed weakness in petitioner's upper and lower extremities, Petitioner was readmitted to the hospital for additional observation and treatment. *Id.* at 424, 426.

Petitioner remained hospitalized for only a few days. While there, she had a consultation with internist Mayra Abreu Fuentes, M.D., and Petitioner informed Dr. Fuentes of her immediate post-vaccination headache. Ex. 4 at 415. Petitioner was also evaluated by neurologist Walter Morgan, M.D. *Id.* at 417. Her examination revealed normal reflexes throughout her upper and lower extremities, but weakness in her extremities (especially pronounced in her lower limbs). *Id.* at 420. Dr. Morgan nevertheless opined that Petitioner's symptoms were "not consistent with [GBS]" given her normal reflexes and the short post-vaccination onset as well. *Id.* He instead expressed concern about a potential "cervical spine issue," and proposed that an MRI of Petitioner's spine be performed. *Id.* That MRI yielded normal results, and Petitioner was discharged again (although it was recommended she undergo an outpatient electromyography ("EMG")). *Id.*

Ms. Pool again saw Dr. Wasserstrom on October 26, 2020, for a follow-up appointment regarding her hospitalization. Ex. 10 at 14. She now reported that she was experiencing extreme dizziness and brain fog any time she got up and moved around. *Id.* Dr. Wasserstrom noted that petitioner had been experiencing "neuropathic[-]type pain since getting the flu shot," prescribed medication, and again recommended that petitioner be evaluated by a neurologist. *Id.*

In the second half of November, Petitioner visited the Advent Health Emergency Department for the fourth time that fall, reporting a bifrontal headache for the previous two days, along with . Ex. 5 at 18. She also reported that she had been experiencing "mild photophobia, blurry vision, dizziness, [and nausea/vomiting]." *Id.* Petitioner mentioned that she had continued to experience paresthesias since her hospitalization the previous month. *Id.* Petitioner's treating physician noted that petitioner did not display any neurological deficits upon examination. *Id.* at 21. She was discharged home with instructions to follow up with her PCP and neurology. *Id.*

Treatment in 2021 and MG Diagnosis

On January 8, 2021, Ms. Pool saw Dr. Wasserstrom again, complaining of continued tingling in her hands, feet, and face, as well as weakness in her arms and legs since getting her flu vaccine. Ex. 10 at 10. She mentioned that she had an appointment with a neurologist scheduled for February. *Id.* That telehealth appointment occurred on February 8, 2021, with neurologist Nivedita Jerath, M.D. (Petitioner’s causation expert). Ex. 7 at 33. At this time, Petitioner recounted her headaches plus a pins and needles sensation in her hands, arms, calves, feet, and face, as well as dizziness, blurry vision, and weakness after activity. *Id.* at 38. Dr. Jerath noted that Petitioner’s lumbar puncture and spinal MRI had yielded normal results, but also recorded her concern that Petitioner may have experienced some kind of “autoimmune reaction to the flu shot.” *Id.* at 39. And Dr. Jerath’s physical exam revealed the Petitioner had normal cranial nerve function and that she did not have ptosis.³ *Id.* at 19. Additional testing was performed at this time. Petitioner underwent an EMG to evaluate her for MG, and it revealed “borderline electrophysiological evidence of a possible neuromuscular junction disorder.” *Id.* at 39, 41. But an MG panel produced results within normal limits. *Id.* at 49.

Petitioner continued to see Dr. Jerath that spring, and was prescribed nerve pain medications. Ex. 7 at 31. After an April 2021 follow-up appointment (at which time Petitioner complained of facial, tongue, arm, and leg weakness), Dr. Jerath proposed that Petitioner had “most likely seronegative [MG]” and planned to start her on a prednisone trial. *Id.* at 23–24.

On May 22, 2021, Petitioner again sought urgent care at the Advent Health Emergency Department, reporting neck pain, headache, chest pain, photophobia, and nausea. Ex. 5 at 162. But a neurological examination did not reveal any focal neurological deficits, and Petitioner was prescribed medication for her nausea and discharged. *Id.* at 165. The Petitioner visited Dr. Jerath again in June complaining of headaches and expressing interest in seeing a headache specialist, for which Dr. Jerath provided a referral. Ex. 7 at 12–15. Later on that summer, in July (now nine months after vaccination), Ms. Pool saw neurologist Kayla Handy, M.D., at the Advent Health Neurology Headache Clinic, for treatment of her migraines (which she acknowledged were long-standing, predating the October 2020 vaccination). *Id.* at 5, 8, 10.

The records filed in this case for subsequent treatment reveal no potentially MG-associated symptoms or treatment until April 25, 2022, when Petitioner returned to Dr. Jerath reporting that her eyes were consistently twitching and drooping. Ex. 6 at 9. In July 2022, Dr. Jerath prepared a letter stating that Petitioner had a “clinical history of [MG],” and commenting that the flu vaccine had some temporal association with her MG symptoms onset. Ex. 8 at 1. Thereafter, the next time Petitioner obtained MG treatment was in March 2023, when she had a virtual appointment with

³ Ptosis is a “drooping of the upper eyelid” also known as blepharoptosis. *Ptosis*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=42014&searchterm=ptosis> (last visited Aug. 14, 2025).

Dr. Jerath. Ex. 15 at 12, 31. She now reported ongoing brain fog, eye twitching, muscle weakness, and fatigue. *Id.* at 12–13.

II. Expert Reports

A. *Petitioner’s Expert — Nivedita U. Jerath, M.D., M.S.*

Dr. Jerath, a neurologist/neuromuscular specialist and one of Petitioner’s treaters, offered two written reports in this matter. Report, dated June 17, 2024, filed as Ex. 18 (ECF No. 33-1) (“First Jerath Rep.”); Report, dated Dec. 19, 2024, filed as Ex. 28-1 (ECF No. 37-2) (“Second Jerath Rep.”).

Dr. Jerath completed her M.D. at the Mayo Medical School, in Rochester, MN and subsequently undertook an internship focusing in internal medicine at the University of Illinois. Curriculum Vitae, dated June 17, 2024, filed as Ex. 19 (ECF No. 34-2) (“Jerath CV”) at 1. From there, Dr. Jerath completed her residency in neurology at Harvard University, and then completed two Fellowships focusing in Neuromuscular Diseases and Clinical Neurophysiology at the University of Iowa. *Id.* Dr. Jerath is a board certified in neurology, neuromuscular, and electrodiagnostic medicine. She has practiced medicine for over a decade, and has treated hundreds of patients with inflammatory neuropathies and neuromuscular conditions. First Jerath Rep. at 1. She has also authored approximately three dozen articles relating to neurology. Jerath CV at 3–6. Dr. Jerath currently serves as the Neuromuscular Director at the AdventHealth Neuroscience Institute in Orlando, Florida, where she continues to conduct research relating to rare diseases such as hereditary neuropathies. First Jerath Rep. at 1–2.

First Report

Dr. Jerath’s first report began with an overview of her qualifications, along with a summary of Petitioner’s medical history (of which, as a contemporaneous treater, she had direct knowledge). *See generally* First Jerath Rep. at 1–3. She defined MG to be a rare “autoimmune condition characterized by weakness and fatigue,” and attributable to impairment of the nerve/muscle junction. *Id.* at 3. MG is believed to be mediated by autoantibodies. *Id.* at 4 (85 percent of all MG patients test positive for a specific autoantibody). Its symptoms include fatigue/weakness, plus, in many cases, eye-associated issues (drooping eyelids, double vision). *Id.* In addition to serologic testing for the associated autoantibody, MG can be diagnosed on the basis of EMG testing plus clinical presentation. *Id.* at 4.

Dr. Jerath opined that MG was an appropriate diagnosis for Petitioner’s symptoms. First Jerath Rep. at 7. Admittedly, and as the medical summary in the report acknowledged, an array of testing performed on Petitioner provided no insight as to the etiology of her symptoms. *Id.* at 2–3. Petitioner had also tested negative for any MG antibody. *Id.* at 3. But an EMG (performed February

8, 2021) “suggested possible evidence of a neuromuscular junction disorder.” *Id.* In addition, Dr. Jerath highlighted the fact that she had started Petitioner on a medication specific for treatment of MG, and it had greatly assisted her. *Id.*

As a result, the balance of this evidence suggested to Dr. Jerath that an MG diagnosis (seronegative) was appropriate. First Jerath Rep. at 3. That diagnosis was corroborated by Petitioner’s later symptoms. Thus, in the summer of 2021, Ms. Pool was experiencing double vision and fatigue, along with weakness, but the MG-specific treatments were helpful. *Id.* That grouping of symptoms continued into 2022 and 2023, but medication for MG continued to ameliorate Petitioner’s complaints. *Id.*

Dr. Jerath went on to propose how the flu vaccine could result in MG. First Jerath Rep. at 4–5. She noted that the flu vaccine could trigger an immune response resulting in the production of cross-reactive autoantibodies that (due to the fact that certain antigenic stimuli might mimic self-tissue protein structures) could in turn cause damage. *Id.* at 4. This was known to be possible with respect to instigation of GBS—but there were also case reports suggesting the same could be true for MG. F. Wang et al., *Laryngeal Myasthenia Gravis Following Influenza Vaccination: A Case Report and Literature Review*, 17 *Hum. Vaccines & Immunotherapeutics* 5529 (2021), filed as Ex. 20 (ECF No. 34-3) (“Wang”); M.C. Kang et al., *Myasthenia Gravis with Ocular Symptoms Following a ChAdOx1 nCoV-19 Vaccination: A Case Report*, 27 *A. J. Ophthalmology Case Rep.* 1 (2022), filed as Ex. 21 (ECF No. 34-4) (“Kang”).

Dr. Jerath provided a more detailed discussion of one article that she seemed to believe was especially probative of the putative causal association. V. Arumugham, *Vaccination with Bovine, Chick, Yeast Antigens Synthesizes Cross-Reactive Antibodies Targeting Human Acetylcholine Receptor and MuSK Protein to Cause Myasthenia Gravis: Confirmed by Natural Experiment (VAERS data), Bioinformatics, Case Reports, Animal Experiments and Titer Study*, (Sept. 2019), filed as Ex. 25 (ECF No. 34-8) (“Arumugham”). Arumugham appears to be an unpublished paper, and its source or derivation has not been identified in this case. It proposes that flu vaccines manufactured from chicken eggs could not only provoke an allergic reaction, but contain a specific protein (“AChR”) that was “ideally suited” to cross-react with a category of T cells, which in turn could lead to the production of the kind of AChR autoantibodies likely to cause MG.

Another possible flu vaccine-MG association, Dr. Jerath argued, was established by reference to the impact of a wild virus infection. First Jerath Rep. at 5. MG could be instigated, or at least worsened, by an influenza infection. And case reports established the vaccine could do so as well. Wang at 5529-30 (reviewing the potential link between MG and the influenza vaccine based on a single case of a fifty-eight year-old who developed laryngeal MG within five days of receiving a trivalent inactivated influenza vaccine).

Dr. Jerath concluded by contending that the other two causation prongs had been satisfied. First Jerath Rep. at 6. The record supported the conclusion that Petitioner's vaccination had caused her MG, since (a) she had no relevant medical history that would explain it (including no prior autoimmune diseases), and (b) she had demonstrated some kind of vaccination reaction immediately in its wake. *Id.* The latter had likely resulted in the production of the antibodies necessary for attacking the neuromuscular junction structures, leading to MG. *Id.* And the timeframe in which Petitioner's MG manifested was reflective of a vaccine-instigated pathologic process. An allergic reaction could occur within half an hour of vaccination, so Petitioner's immediate complaints were consistent with that timeframe. *Id.* And the development of an autoimmune disease like MG might often occur within one to two weeks of instigation, but could actually take up to three months later. *Id.*; B. Olivieri et al., *Vaccination and Autoimmune Diseases*, 9 *Vaccines* 1, 5 (2021), filed as Ex. 22 (ECF No. 34-5) ("Olivieri"); J. Kalita et al., *Myositis in H1N1 Infection Compounds to Myasthenic Crisis*, 72 *Neurology India* 148 (2024), filed as Ex. 24 (ECF No. 34-7) ("Kalita").

Second Report

Dr. Jerath's second report provided a more specific overview of Petitioner's clinical presentation and treatment (arising from Dr. Jerath's first-hand experience with her), in order to bulwark the contention that Petitioner had been accurately diagnosed with MG. Dr. Jerath noted that a subset of MG cases are seronegative, meaning without detectable antibodies associated with the condition. Second Jerath Rep. at 1. But the clinical symptoms for an individual experiencing this kind of MG would be "indistinguishable" from a case that was seropositive. *Id.*; C. Vinciguerra et al., *Diagnosis and Management of Seronegative Myasthenia Gravis: Lights and Shadows*, 13 *Brain Sci.* 1286, 1287 (Sept. 5, 2023), filed Ex. 29 (ECF No. 37-3) ("Vinciguerra"). (In so contending, however, Dr. Jerath included ocular muscle weakness symptoms, like ptosis or diplopia, as "key symptoms"—even though the record does not establish that Petitioner experienced these symptoms any time in the first four or more months after vaccination). Second Jerath Rep. at 2.

Petitioner's history reflected what would be expected for a seronegative form of MG, in Dr. Jerath's view, and she reiterated factors from that history consistent with this opinion. Petitioner first saw Dr. Jerath in February 2021, reporting "blurry vision" that Dr. Jerath deemed "an early sign of diplopia in MG." Second Jerath Rep. at 2. (Notably, however, Petitioner's primary complaints at this time, as reflected in the contemporaneous records, were "tingling in limbs and face," as well as post-exertion weakness, with blurry vision referenced only in the context of complaints about headaches and dizziness. *See* Ex. 7 at 38). By April 2021, Petitioner was experiencing more clear-cut symptoms of ptosis, like eye drooping or twitching (although the record referenced for this contention is from April 2022 (*see* Ex. 6 at 9)). Second Jerath Rep. at 2.

And she was displaying bulbar symptoms common to MG, like difficulty in chewing or swallowing. *Id.* at 2 (*citing* Ex. 7 at 19).

Dr. Jerath also re-emphasized her view that Petitioner’s responsiveness to certain medication corroborated the MG diagnosis. Second Jerath Rep. at 2–3. The same was true for the EMG testing, which “revealed a significant decrement in amplitude” consistent with MG. *Id.* at 3. (Dr. Jerath did not, however, provide any detailed comment on the points made by Dr. Bromberg about what Petitioner’s EMG actually showed).

B. *Respondent’s Expert — Mark B. Bromberg, M.D., Ph.D.*

Dr. Bromberg, a neurologist, prepared a single written report in this matter, and it only challenges the propriety of the MG diagnosis. Report, dated Sept. 3, 2024, filed as Ex. A (ECF No. 35-1) (“Bromberg Rep.”).

Dr. Bromberg received his Ph.D. in Neurophysiology from the University of Vermont in 1973 and subsequently undertook a National Institute of Health Postdoctoral Fellowship at the University of Washington’s Department of Physiology and Biophysics where he researched the peripheral nervous system. Curriculum Vitae, dated Sep. 3, 2024, filed as Ex. A Tab 3 (ECF No. 35-4) (“Bromberg CV”) at 1; Bromberg Rep. at 1. Afterwards, he pursued and obtained his M.D. from the University of Michigan, where he stayed to complete his residency in their Department of Neurology. Bromberg CV at 1. Dr. Bromberg has a lifelong certification in neurology from the American Board of Psychiatry and Neurology. Bromberg Rep. at 1. Currently, Dr. Bromberg is an academic neurologist teaching at the University of Utah’s Department of Neurology. where he performs clinical research focusing on neuromuscular disorders. Bromberg CV at 1; Bromberg Rep. at 1. Dr. Bromberg’s research has led him to author over one hundred scientific articles, book and journal chapters, and reviews relating to neurology. *See* Bromberg CV at 19–43.

Dr. Bromberg provided his own description of MG that was largely consistent with Dr. Jerath’s, but he outlined a few points about the “pattern of weakness” needed for the diagnosis. Bromberg Rep. at 9. In particular, he noted that “the most common initial site” for symptoms would be *ocular*. *Id.*; A. Jaretzki III et al., “Task Force of the Medical Scientific Advisory Board of the Myasthenia Gravis Foundation of America,” *Myasthenia Gravis: Recommendations for Clinical Research Standards*, 55 *Neurology* 16 (Jul. 12, 2000), filed as Ex. A Tab 1 (ECF No. 35-2) (“MGFA Task Force”), at 17. Thus, “the vast majority of patients” later displaying MG-associated weakness *first* present with eyelid ptosis and diplopia. Bromberg Rep. at 9. He also noted that diagnosing MG required consideration of clinical symptoms, but could be confirmed with one of two kinds of electrophysiologic tests. *Id.* And testing for specific autoantibodies relevant to the protein structures at the postsynaptic complex (the situs of the neuromuscular junction where MG would cause harm) was also important in diagnosis confirmation. *Id.* An

absence of the known involved antibodies would permit only the diagnosis of seronegative MG—in which case confirmation by electrodiagnostic testing would become more important. *Id.*

Relying on this understanding of MG, Dr. Bromberg proceeded to argue that the MG diagnosis did not fit Petitioner’s medical record or treatment course. He began with a full overview of her medical history. Bromberg Rep. at 2–8. Dr. Bromberg noted, for example, that in the two weeks following vaccination, Petitioner’s primary complaints involved GBS-like acute parasthesias, plus some nonspecific complaints (headache, vomiting), although she did also complain of generalized weakness. *Id.* at 2–3. Lab testing, however, soon ruled out GBS, and reports of blurry vision were generalized (rather than reflective of what the majority of MG cases would involve). *Id.* at 3–4. In addition (although uncontested by Petitioner), Ms. Pool had not tested positive for a primary antibody biomarker for MG. *Id.* at 12.

Dr. Bromberg also highlighted aspects of the results of EMG testing Petitioner underwent while in Dr. Jerath’s care in February 2021. Dr. Jerath had interpreted the results of the first EMG as providing “borderline evidence of a possible neuromuscular junction disorder.” Bromberg Rep. at 5 (*quoting* Ex. 6 at 46–50). But Dr. Bromberg read the results to be “within the normal range for changes in amplitude with repeated shocks to the motor nerves.” Bromberg Rep. at 10. In particular, he contended that amplitude reductions of 8 to 10 percent were within normal limits, and higher reductions should subsequently show “partial repair” when tested again immediately after (before returning to abnormal levels in later testing rounds). *Id.* at 10–11; J. Kouyoumdjian & E. de Paula Estephan, *Electrophysiological Evaluation of the Neuromuscular Junction: A Brief Review*, 81 Arq. Neuropsiquiatr. 1040, 1040 (Dec. 29, 2023), filed as Ex. A Tab 2 (ECF No. 35-3). Here, however, Ms. Pool’s testing revealed only a within-normal-range of 2.7 percent loss, and subsequent testing runs were inconsistent with the pattern of change expected for MG. Bromberg Rep. at 11–12. As a result, Dr. Bromberg opined that “neither muscle test meets criteria for a clear abnormality of neuromuscular transmission, and certainly not for MG.” *Id.* at 12.

In addition, Dr. Bromberg questioned whether Petitioner’s initial presentation to Dr. Jerath actually supported an MG diagnosis. That first treatment evaluation in early February 2021 “did not include clear descriptions” of usual MG symptoms (particularly the ocular-associated problems evident in the majority of MG cases). Bromberg Rep. at 9. Rather, she complained of parasthesias, weakness after activity (leading to her legs “giving out”), and headaches or brain fog. *Id.* at 5, 9. Dr. Bromberg felt it would be unusual to report this pattern of symptoms in MG, especially in the absence of ptosis or diplopia (neither of which were described or revealed in exam, although Petitioner complained of generalized “blurry vision”). *See* Ex. 6 at 43. No ocular-associated MG symptoms were reported or observed at later visits with Dr. Jerath either (at most, Petitioner complained of eye drooping in May 2021, but it was not discerned on exam). Bromberg Rep. at 10; Ex. 6 at 19–20. And cranial nerve exams did not confirm the presence of any issues. Bromberg Rep. at 10.

Dr. Bromberg further expressed doubt that the benefits of Dr. Jerath's treatment provided indirect evidence of the accuracy of the MG diagnosis. Bromberg Rep. at 12. Petitioner had received pyridostigmine, an MG-specific medication, in addition to steroids, and Dr. Jerath maintained it was likely responsible for Petitioner's improvement from the summer of 2021 onward. *Id.* at 10. But Dr. Bromberg proposed that pyridostigmine would only provide a short term improvement (a few hours) in strength before receipt of another dose. *Id.* And steroids should result in "substantial and enduring improvement in strength" for someone with MG, but this was not evident from Petitioner's actual medical history after steroids became part of her treatment regimen. *Id.*

III. Procedural History

The Petition was filed in December 2022, and a year later Respondent filed his Rule 4(c) Report challenging the propriety of an entitlement award. The parties thereafter filed the above-discussed experts reports, concluding the process at the end of 2024. I set a briefing schedule for the resolution of the matter, and the parties completed the filing of their respective briefs in the winter of 2025, making this claim ripe for resolution.

IV. Parties' Arguments

Petitioner

Petitioner argues that she has provided sufficient evidence to support her diagnosis of MG, and that it could be caused by the flu vaccine. First, she asserts that her medical records, clinical presentation, diagnostic testing, treatment response, and expert opinions show that she suffers from MG, specifically seronegative MG. Br. at 8. Seronegative MG is a particularly difficult disease to diagnose, especially since it lacks detectable antibodies present in most MG cases. *Id.* (citing First Jerath Rep. at 2; Vinciguerra at 3). However, Petitioner affirms that Dr. Jerath's expertise and thorough evaluations are reliable basis for her diagnosis. *Id.*

Petitioner claims her pre-diagnosis evaluations and response to treatment support her diagnosis. Those records establish that she was experiencing hallmark symptoms of MG, which include dizziness, blurry vision, extremity weakness, the sensation of pins and needles in her extremities. Br. at 8–9. Later, she underwent diagnostic and EMG testing that showed decremental response during repetitive nerve stimulation—evidence of neuromuscular junction dysfunction. *Id.* at 9. And non-MG-specific treatments to manage her symptoms were ineffective. *Id.* Only after Dr. Jerath treated her with pyridostigmine and prednisone did she experience substantial improvement, recovering her strength and endurance. *Id.*

Petitioner also contends that Dr. Bromberg’s critique of her diagnosis actually supports it. Br. at 9. Dr. Bromberg stated that a clinical MG diagnosis “must be confirmed by either (1) electrophysiologic tests showing an appropriate decremental response or increased neuromuscular jitter, or (2) a clear treatment response.” *Id.* (citing Bromberg Rep. at 9). But both criteria are met. *Id.* The diagnosis was further substantiated when Dr. Jerath conducted imaging and blood tests that ruled out alternative diagnoses. *Id.* And Dr. Bromberg’s opinion that the Petitioner did not exhibit ptosis and diplopia—characteristic MG symptoms—is incorrect, since her medical files document that she experienced early diplopia in February of 2021, followed by ptosis in April 2022 - consistent with the variable progression of seronegative MG. *Id.* at 9–10.

Petitioner acknowledged that she had not tested positive for any MG-associated antibodies, but emphasized that she could still carry a proper, *seronegative* MG diagnosis. Br. at 10. Peer-reviewed literature confirms that seronegative MG is a medically recognized subset of MG that affect roughly 10–15% of MG patients. *Id.* (citing Vinciguerra). In such cases, a diagnosis hinges on clinical signs, testing, and treatment—all of which support MG as a reasonable diagnosis. *Id.* And considering that Dr. Jerath has had first-hand experience with the Petitioner and has seen and treated her, Petitioner argues that Dr. Jerath is a more qualified expert than Dr. Bromberg in this matter, who only reviewed this case retrospectively. *Id.*

Moving on to the test for causation, Petitioner maintains each prong has been met. First, she argues that she has demonstrated that the flu vaccine “can cause” seronegative MG. Br. at 10. Petitioner’s causation theory relies on immune activation and molecular mimicry, where the flu vaccine triggers an inflammatory response, and components of the flu vaccine (specifically the residual AChR proteins from its formulation), act as a molecular mimic to human AChR proteins. Br. at 12. (citing First Jerath Rep. at 1; Arumugham at 1). The mimicked proteins can activate low-affinity self-reactive (“LASR”) T cells which interact with B cells. *Id.* (citing Arumugham; A. Manfredi et al., *T Helper Cell Recognition of Muscle Acetylcholine Receptor in Myasthenia Gravis: Epitopes on the Gamma and Delta Subunits*, 92 J. Clinical Investigations 1055 (Aug. 1993), filed as Ex. 31 (ECF No. 38-2) (“Manfredi”); M. Protti et al., *Myasthenia Gravis: CD4+ T Epitopes on the Embryonic Gamma Subunit of Human Muscle Acetylcholine Receptor*, 90 J. Clinical Investigations 1558 (Oct. 1992), filed as Ex. 32 (ECF No. 38-3) (“Protti”). This leads to the production of cross-reactive antibodies that target AChR, proteins, thereby contributing to the development of MG. *Id.* (citing Arumugham; Manfredi; Protti). Articles like Olivieri and Arumugham establish that flu vaccines can trigger immune responses when antigens and host proteins share similar structures, and that the AChR protein in the flu vaccine resembles human AChR protein. Br. at 12 (citing Olivieri at 2; Arumugham at 1).

This process is relevant even for the seronegative form of MG, where the immune response may be driven more by immune cells other than antibodies. Br. at 10-13. Petitioner contends that in seronegative MG, T cells likely play a more prominent role and can initiate an autoimmune cascade by either secondarily driving antibody production through B cell interaction, or directly

mediating immune responses against human AChR. *Id.* And otherwise, existing Program decisions note that causation need not be premised on a finding of the existence of specific, disease-associated antibodies. Br. at 10 (citing *Werderitsh v. Sec'y of Health and Human Servs.*, No. 99-310V, 2006 WL 1672884, at *25 (Fed. Cl. Spec. Mstr. May 26, 2006)).

Petitioner further contends the remaining causation prongs are satisfied. Evidence that the vaccine “did cause” her MG was provided by her post-vaccination symptom onset, provider opinions, and lack of alternate cause. Br. at 14–15. She had no history of autoimmune diseases or seronegative MG before the vaccine. *See id.* at 14. However, the Petitioner started to experience tingling in her extremities within a day of vaccination, which continued and developed into more extreme and intense symptoms, leading to an MG diagnosis by April 2021. *Id.* In addition, some providers, including Dr. Jerath, believed that Petitioner’s MG was attributed to her flu vaccine. *Id.* at 15. And no other causal factor had been identified.

The timeframe in which Petitioner’s MG began was also medically acceptable, sufficient to meet the third causation prong. Petitioner acknowledges that autoimmune diseases involve a complex interplay between the innate and adaptive immune system that takes time to develop. Br. at 15–16. As a result, her onset of twenty-four hours was somewhat quick for typical development of autoimmune diseases. *Id.* But development of autoimmune diseases varies based on the individual’s immune system, genetic predisposition, biological factors, and environmental factors. *Id.* at 16. As a result, rapid autoimmune responses are medically possible under the right circumstances—as occurred here. *Id.* at 17.

In support, Petitioner notes that allergic reactions to vaccines occur within minutes to hours of administration. Br. at 15. Petitioner also states that symptom onset can also occur earlier in those with LASR T cells. T cells must be activated before aiding in the production of antibodies in a process that normally requires a few days. *Id.* However, in individuals with LASR T cells, activation may be achieved with minimal stimulation, which would allow for earlier onset of symptoms. *Id.* Similarly, an environment conducive for autoimmune activity (from the vaccine triggering the release of cytokines and antigen presentation) could lower the threshold for autoreactive T cell and B cell activation, which would allow for symptom presentation within twenty-four hours. *Id.* As corroboration for these points, Petitioner noted a case report discussing a thirty-three year-old woman who developed seronegative MG after receipt of a COVID-19 vaccine. *Id.* (citing M. Lee et al., *Early-Onset Myasthenia Gravis Following COVID-19 Vaccination*, 37 J. Kor. Med. Sci. 1, 1–2 (Mar 14, 2025), filed as Ex. 33 (ECF No. 38-4) (“Lee”). The subject in the Lee article had symptom onset only within hours after her vaccination, and was later diagnosed with a seronegative form of MG. Lee at 1–2. (Unlike the present case, however, the Lee patient displayed “ocular symptoms, *a few hours after*” the dose of vaccine deemed to instigate her disease. *Id.* at 2 (emphasis added)).

Respondent

Respondent disputes both the Petitioner's seronegative MG diagnosis and that the Petitioner has satisfied her burden under *Althen*.

Establishing a petitioner's injury can be a prerequisite to analyzing causation-in-fact. *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010). Here, Respondent deems the MG diagnosis to lack preponderant support. Opp. at 15–16. Dr. Bromberg had persuasively shown that the Petitioner's medical records are vague and unclear as to whether Petitioner in fact experienced the hallmark MG symptoms, or responded to treatment in a way that would support an MG diagnosis. Petitioner's February 8, 2021 telehealth appointment with Dr. Jerath, for example, did not include clear descriptions of ptosis, diplopia, or diffuse weakness, or findings supporting the presence of these symptoms. *Id.* at 12. Rather, its focus was the difficulty the Petitioner was having standing on her toes/heels. *Id.* (citing Bromberg Rep. at 9). Similarly, Petitioner's neurologic and limb muscle evaluations were also vague and unclear. *Id.* at 13. Evaluations conducted from March 25, 2021, through June 29, 2021 also did not reveal ptosis, diplopia, limb weakness, but rather showed limb muscles functioning within normal limits and documented only complaints of blurred vision or drooping left eye. *Id.* (citing Ex. 6 at 11–14, 19–20, 24–25, 29–30).

Petitioner's response to treatment was also less supportive of an MG diagnosis than Petitioner alleged. Opp. at 14–15. In Dr. Bromberg's view, Petitioner's responses to pyridostigmine and prednisone were only "vaguely described" in records, and failed to demonstrate whether improvement to pyridostigmine lasted "1–4 hours before the next dose," and whether the Petitioner's response to prednisone began 1–2 weeks after treatment and resulted in a "substantial and enduring improvement in strength." *Id.* at 15 (citing Bromberg Rep. at 12). At most, the records contained broad statements that Petitioner had experienced "substantial improvement in strength and endurance." *Id.* at 14 (citing Br. at 9).

Petitioner's test results do not support a diagnosis of MG either. Electrodiagnostic testing conducted on February 8, 2021, was interpreted as "borderline electrophysiological evidence of a possible neuromuscular junction disorder" but Dr. Bromberg maintains that the results showed normal change in amplitude, and thus did not constitute proof of abnormality of neuromuscular transmission. *See* Opp. at 13 (quoting Ex. 6 at 46–50). And no antibody evidence existed to support MG as a diagnosis. *Id.* at 15. Petitioner attempted to minimize this lack of proof by deeming her MG to be "seronegative," but in Dr. Bromberg's view such a diagnosis should reveal the absence of several kinds of antibodies—and Dr. Jerath only tested for the AChR antibody. *Id.*

Regarding the first causation prong, Respondent contends that Petitioner mainly relies on the temporal relationship between the vaccination and onset of symptoms, but without sufficient

independent medical/scientific evidence to support a causal link between the flu vaccine and MG. Petitioner’s causation theory relies on residual AChR proteins found in the vaccine acting as a molecular mimic to human AChR proteins, leading in turn to the activation of LASR T cells which then stimulate B cells that lead to the production of antibodies targeting human AChR proteins resulting in MG. Opp. at 16 (citing Br. at 12). But Petitioner only substantiates this with case reports and inapposite medical literature.

Wang, for example, involve one instance where a 58-year old experienced symptoms and was diagnosed with laryngeal MG after receiving the flu vaccine. Wang at 2–3. But case reports generally do not present strong evidence of causation. Opp. at 16 (quoting *Crutchfield v. Sec’y of Health & Hum. Servs.*, 2014 WL 1665227, at *19 (Fed. Cl. Spec. Mstr. Apr. 7, 2014); *Kinney v. Sec’y of Health & Hum. Servs.*, 2024 WL 2831616, at *11 n.9 (Fed. Cl. Spec. Mstr. May 8, 2024)). Wang thus only shows a temporal association between the flu vaccine and MG, and its authors recognized its limited value as proof of causation. *Id.* at 16–17; Wang at 3. Arumugham purportedly established that the AChR proteins in human and found in the flu vaccine closely resemble each other, allowing for the possibility of an autoimmune cross-reaction. Opp. at 17 (citing Arumugham at 1). But it relied on VAERS data⁴ to reach its conclusions, and it was not even published in a medical journal. Opp. at 17.

The “did cause” prong is also unsatisfied, in Respondent’s view. While Petitioner claims that “several” treating physicians noted the flu vaccine as a cause of her symptoms, Respondent points out that only two treating providers so proposed, and they were tentative in their opinions. Opp. at 17–18 (citing Ex. 2 at 45 (diagnosing the Petitioner with “[a]cute paresthesia secondary to possible additive agents of flu vaccination”) (emphasis added); Ex. 7 at 39 (Dr. Jerath stating that her “concern [was] an autoimmune reaction to the flu shot”) (emphasis added). And Respondent also maintains there is a lack of evidence supporting a logical cause and effect in the speculative opinions of Drs. Jerath and Ahmed. Opp at 18. Rather, Respondent states that only Dr. Jerath noted Petitioner’s “influenza vaccine administration was associated with the timing/onset” of her alleged MG. *Id.* (quoting Ex. 8 at 1) (emphasis added). And a temporal association alone is not sufficient to satisfy specific causation. *Id.* at 18 (citing *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992)). Otherwise, Petitioner’s pre-vaccination symptoms were comparable to what she now attributes to MG, as the record reveals, and thus could not be deemed vaccine-caused. Opp. at 18, 20 n.7 (record evidence shows that the Petitioner was experiencing pre-

⁴ 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 July 7, 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. 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”).

vaccination migraines, dizziness, eye/hand twitching, and numbness (Ex. 3 at 3–4; Ex. 7 at 5; Ex. 14 at 13; Ex. 16 at 61)).

Lastly, Respondent denies that Petitioner established that her seronegative MG began in a medically-acceptable time, measured from vaccination. *See* Opp. at 18–20. Petitioner reported onset of symptoms *thirty minutes* after vaccination. *Id.* at 19 (citing Ex. 4 at 415; Ex. 10 at 17). But Dr. Jerath never established that a thirty-minute onset would be medically appropriate for the development of an autoimmune condition like MG, opining instead about timing for allergic reactions. *Id.* at 18 (citing First Jerath Rep. at 6), 19. She also argued that the development of an autoimmune disease can occur within one to eighty days, but happens within one to two weeks on average. *Id.* at 18–19 (citing First Jerath Rep. at 6). Yet this range is not supported by medical literature. Only Kalita was offered in its support, but that is merely a case report discussing two patients who had pre-existing MG, and developed myasthenic crisis within days of contracting a wild H1N1 (swine flu) *infection*. *Id.* at 19; Kalita at 2. Kalita’s authors made no claims about the time between vaccination and the development of an allergic reaction, nor did they mention the time between vaccination and onset of an autoimmune condition. Opp. at 19 (citing Kalita at 1–3).

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*, 592 F.3d at 1321; *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).⁵ There is no Table claim for MG caused by any covered 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.

⁵ 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).

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 of 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 v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.”

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

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or even a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (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*, 121 Fed. Cl. at 245.

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.*, No. 24-1281, slip op. at 9 (Fed. Cir. July 29, 2025); *Kalajdzic v. Sec’y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments “for a less than preponderance standard” deemed “plainly inconsistent with our precedent” (citing *Moberly*,

592 F.3d at 1322)); *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec’y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *aff’d*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* “addresses the petitioner’s overall burden of proving causation-in-fact under the Vaccine Act” by a preponderance standard).

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

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec’y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant

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

B. *Legal Standards Governing Factual Determinations*

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

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

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

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

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

C. *Analysis of Expert Testimony*

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

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

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

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

Respondent frequently offers one or more experts in order to rebut a petitioner’s case. Where both sides offer expert testimony, a special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too great an analytical gap between the data and the opinion proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); see also *Isaac v. Sec’y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl.

Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

D. *Consideration of Medical Literature*

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

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 Myasthenia Gravis and its Diagnosis

MG (as the experts agreed) is an autoimmune disorder that affects the neuromuscular junction, causing normally-reliable signals between motor nerves and muscle cells to become less effective. K. Vaughan et al., *A Comparison of Epitope Repertoires Associated with Myasthenia Gravis in Humans and Nonhuman Hosts*, *Autoimmune Diseases*, 2012, filed as Ex. 26 (ECF No. 34-9) (“Vaughan”), at 1. It is characterized by fatigable weakness of the ocular, bulbar, limb, and respiratory muscles. Vaughan at 1. The most common symptoms of MG, ptosis and diplopia, affect the eye muscles. *See* Vinciguerra at 7. People with MG may also have difficulty chewing, swallowing, and speaking, and limb weakness may also occur. *See* MGFA Task Force at 17; Wang at 2.

Diagnosing MG is based on the distribution of symptoms. MGFA Task Force at 16-17. The most common initial situs for symptoms is in the ocular region. *Id.* The diagnosis of MG can be clinical based on symptoms like ocular weakness in the form of eyelid ptosis and diplopia. *See id.* Less common symptoms include limb weakness without ocular and bulbar weakness, or respiratory muscle weakness accompanied by ocular, bulbar and limb weakness. *See id.* Clinical diagnosis is appropriate based on the symptoms above, but needs to be confirmed with one of two electrophysiologic tests—either showing an appropriate decremental response pattern to repetitive motor nerve stimulation, or increased values with measurements of neuromuscular jitter (single fiber EMG). Vinciguerra at 3–4.

Notably, serologic evidence of antibodies like AChR is also important to confirm the diagnosis, and can influence choice of treatment. Those with negative pathologic antibodies test results are considered to have “sero-negative MG,” and their diagnosis is more challenging to confirm, requiring clear electrodiagnostic findings or clear treatment response. *See generally* Vinciguerra.

II. Petitioner Has not Carried Her *Althen* Burden of Proof

Because Program claimants must meet all three *Althen* prongs, a special master may limit analysis of the strength of a petitioner’s causation showing to only the prong(s) deemed unsatisfied. *Dobrydnev v. Sec’y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). In this case, the record preponderates against a favorable finding for Petitioner on the second and third *Althen* prongs.⁶

⁶ I also note, however, that Petitioner also did not preponderantly establish that the flu vaccine *can* likely cause seronegative forms of MG. The most on-point evidence for this aspect of her claim was Arumugham—an article that

Third Prong

There is a reasoned dispute between the parties as to whether Petitioner was properly diagnosed with MG. On the one hand, Petitioner’s own neurologic specialist treater, Dr. Jerath, serves in this case as an expert, and her opinion is entitled to some deference. She clearly embraces an MG diagnosis, based upon her personal knowledge of Petitioner’s condition (although she only encountered Petitioner several months after vaccination). On the other hand, Dr. Bromberg pointed out a number of discrepancies in Petitioner’s medical history that are not wholly consistent with the diagnosis. I give most weight to the absence of evidence of demonstrated ocular issues close-in-time to her first symptoms, since it has been shown that more often than not MG patients present with them. Questions about treatment efficacy, or how to read the EMG results, are harder to resolve either way.

However, even if I assume that Petitioner was properly diagnosed with a seronegative form of MG, I do not find that timeframe for its onset was shown to be medically acceptable.

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

In the Vaccine Program, onset of an alleged vaccine injury is marked by the “first symptom or manifestation of onset.” See Section 16(a)(2). As the Federal Circuit stated in *Markovich v. Sec’y of Health & Hum. Servs.*, 477 F.3d 1353, 1357 (Fed. Cir. 2007), there is a difference between a “symptom” and “manifestation of onset”—but because of the Act’s use of the disjunctive “or,” either can constitute the start of a disease process (even though a symptom could be nonspecific, or hard to link to what was later viewed as a full disease). *Markovich*, 477 F.3d at 1357–59.

By contrast, the date of diagnosis (which may in turn result from the accumulation of clinical and testing evidence over time) does not mark the onset of an alleged vaccine injury. *Carson v. Sec’y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013). Onset may occur even before the ill individual understands a presenting symptom to be concerning. See *Markovich*, 477 F.3d at 1357 (“[a] symptom may be indicative of a variety of conditions or ailments, and it

does not appear (at least on the basis of the copy filed as an exhibit in this case) to have been published in a peer-reviewed journal. In addition, Arumugham discusses at length the importance of the AchR antibodies—something Petitioner tested *negative* for. Ex. 7 at 49. It thus provides weak support for the contention that an indirect, roundabout stimulation of T-helper cells due to cross-reactions between remnant proteins in the vaccine and self proteins would result in an antibody-driven process leading to MG, in a person who has not been shown to possess these antibodies in the first place. Arumugham at 1, 5.

may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury”) (emphasis added).

Here, the record does not support the conclusion that a flu vaccine received in mid-October 2020 could provoke an immediate reaction not wholly consistent with MG, but that would later progressively “turn” into MG over the course of the subsequent four to six months. Of course, the fact that it took time before Petitioner actually saw a professional like Dr. Jerath who was capable of diagnosing MG does not mean that her onset occurred so long after vaccination. But review of Petitioner’s medical course *between* vaccination and that diagnosis is not consistent with a vaccine causing MG, and it cannot be determined from this record that Petitioner’s seronegative MG occurred in a medically-acceptable timeframe, measured from the date of vaccination.

The medical record establishes that Petitioner experienced a reaction close-in-time to vaccination, but it was non-specific for MG, and could simply reflect a transient/malaise vaccine reaction. Her initial presentation was in fact mainly deemed concerning for the possibility of GBS, although that was ruled out. Ex. 2 at 45, 61. Evaluation results conducted on the Petitioner are also equally vague. Specifically, testing from October 21, 2020, through June 29, 2021 show multiple instances of neurological evaluations and muscle functioning tests that returned results of normal functioning, although she did also consistently report weakness. *See* Ex. 4 at 420, 551; Ex. 6 at 11–14, 19–20, 24–25, 29–30.

More significantly, the evidence filed in this case establishes that MG commonly presents with ptosis or diplopia. Vinciguerra at 7; Kang at 2. In fact, seronegative MG *should* present with these kinds of ocular symptoms. Vinciguerra at 7 (“in a significant portion of patients with seronegative MG, *ocular symptoms are the principal feature*”) (emphasis added). Even Dr. Jerath noted that ocular muscle weakness symptoms, like ptosis or diplopia, are “key symptoms” of MG. Second Jerath Rep. at 2. But this is not consistent with Petitioner’s course. Although she did complain of drooping and blurred vision, but only in her left eye, and only sometime after vaccination as well. Diplopia results from a misalignment of both eyes and “in the left eye” is not sufficiently specific to be clearly interpreted as diplopia. Also, none of Petitioner’s treating providers mentioned or diagnosed her with either ptosis or diplopia upon hearing her complaints of ocular symptoms and examining her. And her eye-related complaints did not begin until later in the fall of 2020, and were combined with reports of dizziness and headaches. *See, e.g.,* Ex. 5 at 18.

This course is ultimately inconsistent with the few case reports filed in this case about MG’s onset. Putting aside the low evidentiary weight case reports generally receive in the Program,⁷ the identifiable MG would usually present with eye-related symptoms. *See generally,*

⁷ *See, e.g., Campbell*, 97 Fed. Cl. at 668 (“[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”).

Wang (table outlining four cases of MG patients where ocular symptoms occurred between three days to six weeks after vaccination); Kang (patient developed vertical binocular diplopia a week after receiving vaccine); Lee (diplopia presenting the evening of vaccination, with ptosis three days later). But the record in this case indicates a slower time horizon for when these kinds of symptoms appeared—not quickly, but over weeks to months. And assuming Petitioner’s initial vaccine reaction was part of her pathologic process leading to MG, that timing (an almost-immediate onset (within 30 minutes)) was inconsistent with most of the case reports filed in this action. Ex. 4 at 415; Ex. 10 at 17. For example, the Wang patient only developed onset of symptoms *five days* after receiving her flu vaccine. Wang at 2-3. And while Lee featured more immediate onset, it involved a different vaccine (as well as the kinds of ocular symptoms absent from the records contemporaneous with vaccination). And Dr. Jerath did not establish that a thirty-minute onset would be medically appropriate for the development of an autoimmune condition like MG, relying more on evidence pertinent to allergic reactions. First Jerath Rep. at 6.

Another problem with Petitioner’s success on the third *Althen* prong is the commonality between her pre and post-vaccination symptoms. The Petitioner’s pre-diagnosis medical record is full of comments and complaints of headaches, or muscle weakness where her legs gave out easily. *See, e.g.*, Ex. 4 at 85–87, 98; Ex. 7 at 24, 33, 38. There is some continuity between those kinds of complaints and what Petitioner reported from October 2020 to February 2021, when she first encountered Dr. Jerath. The vaccine cannot have caused a condition that predated its administration.⁸

It may be that Dr. Jerath’s seronegative MG diagnosis is correct, based on Petitioner’s presentation *when* she saw her in 2021. But these treatment events occurred more than three and one-half months after vaccination, and after a stuttering course that is in many ways inconsistent with how MG would present. I cannot on this record conclude *when* Petitioner’s MG most likely began—let alone that its relationship to receipt of the flu vaccine was medically acceptable.

Prong Two

Petitioner’s success on the “did cause” prong is frustrated for many of the same reasons that prevent me from finding in her favor on *Althen* prong three. As noted, the medical record establishes that Petitioner experienced some malaise-like symptoms (headache and vomiting) close-in-time to vaccination, but they are not characteristic of MG, and it is not evident on this record what relationship those symptoms would have with her later course. Her subsequent complaints (other than weakness/decreased strength) as often as not were not clinically confirmed. She reported some complaints of vision issues, but not of the focal/specific kind that could be deemed features of MG (especially the seronegative form). Because she did not test positive for the kind of autoantibodies associated with MG, a classic kind of autoimmune, antibody-driven

⁸ Petitioner has not alleged that the flu vaccine significantly aggravated preexisting MG, or some other neurologic illness.

mechanism cannot on this record be shown to have occurred. And Petitioner's course from the time of vaccination was intermittent, inconsistent with even the case reports she filed suggesting a close-in-time onset (with clear and more obvious symptoms of MG) should have occurred. The overall medical record is not consistent with a conclusion that the flu vaccine likely "did cause" her later-diagnosed MG.

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.⁹

IT IS SO ORDERED.

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

⁹ 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.