In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 22-258V

MYRTLE BARRETT,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: September 12, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

David Proffitt, Proffitt & Cox, LLP, Columbia, SC, for Petitioner.

Naseem Kourosh, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE

On March 7, 2022, Myrtle Barrett filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Program"),[1] ECF No. 1 ("Petition"), later amending her claim (ECF No. 23). Petitioner alleges that she suffered from myasthenia gravis ("MG") resulting from Tetanus-diphtheria-acellular pertussis ("Tdap"), and/or pneumococcal polysaccharide vaccines received on July 21, 2021. She also contended she experienced the Table claim of a shoulder injury related to vaccine administration ("SIRVA") in both shoulders resulting from the administration of both vaccines.

Respondent filed a Motion to Dismiss on December 5, 2023, arguing that Petitioner cannot show a medically acceptable temporal relationship between her vaccination(s) and the onset of her MG symptoms as required under prong three of *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). ECF No. 44 ("Mot. to Dismiss"). Respondent also claims that Petitioner

[1] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

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cannot show the onset of pain within 48 hours of a covered vaccination, as required for a SIRVA claim under the Vaccine Injury Table, 42 U.S.C. §100.3. Petitioner thereafter filed a Motion for a Ruling on the Record and a Response in Opposition to Respondent's Motion to Dismiss on March 28, 2024. ECF No. 47 ("Opp."). Petitioner seeks only to defend her claim that the Tdap vaccine (possibly in concert with the noncovered version of pneumococcal vaccine she received) caused her to develop MG, acknowledging that the alleged SIRVA claim is not compensable (and hence that aspect of the claim has been abandoned).[2]

Having reviewed the parties' submissions, I hereby determine (as discussed below) that Petitioner's symptoms did not develop within a medically acceptable timeframe for causation. For this reason, Respondent's Motion to Dismiss is granted.

I. Factual Background

Ms. Barrett's pre-vaccination medical history includes chronic epigastric pain and diarrhea, atrial and paroxysmal atrial fibrillation, seizure, restless leg syndrome, migraine, anxiety, depression, chronic anemia, hypercholesterolemia, renal insufficiency, vitamin B12 deficiency, hearing impairment, knee arthritis, left breast surgery, hysterectomy, cholecystectomy, and right and left total knee replacements. Ex. 2 at 4, 32-33, 78; Ex. 7 at 76; Ex. 19 at 10; Ex. 21 at 7-9. On July 21, 2021, Petitioner (then 85 years old) received a Tdap vaccine, administered intramuscularly in her right deltoid, and a Pneumovax 23 vaccine (not the version covered by the Program) in her left deltoid during an annual exam with Huong Phan, M.D., her primary care physician ("PCP"). Ex. 2 at 75-76, 88-89. There is no medical record evidence of any claimed immediate vaccine reaction.

Petitioner's symptoms first arose three months later, on October 28, 2021, when she checked in to urgent care, complaining of pain in both her arms and neck. Ex. 3 at 2. Petitioner also reported that over the prior week she had experienced weak spells that caused her legs to give way. *Id.* An x-ray of the cervical spine showed mild degenerative changes but was overall unremarkable. *Id.* at 5. The impression was cervical spine arthralgia and a pinched nerve, and Petitioner was advised to take Tylenol and follow up with her PCP. *Id.* at 4.

On November 1, 2021, Petitioner returned to Dr. Phan, reporting that over the previous few weeks she had been experiencing neck pain, left shoulder pain, and bilateral leg weakness. Ex. 2 at 103. A musculoskeletal exam showed limited left shoulder range of motion ("ROM") and

[2] As Petitioner admits, the version of the pneumococcal vaccine she received in her left shoulder is not covered by the Program. And a right shoulder injury due to the covered Tdap vaccine would not be compensable because medical records show that she did not experience pain and disability in her right shoulder until **October 2021** – three months post-vaccination, and therefore well outside the 48-hour period required for a SIRVA.

negative straight leg raise, but no shoulder swelling, good cervical and lumbar spine ROM, and equal strength and sensation in the upper extremities. *Id.* at 106. The physical exam was otherwise normal, and Petitioner was referred to neurology. *Id.* at 104-05.

A few weeks later, on November 19, 2021, Petitioner saw neurologist Dr. Marck Lencke, informing him that she had developed swelling and pain after receiving the Tdap vaccine. Ex. 5 at 2. She also reported that she had an episode four weeks prior in which she experienced sudden weakness in both legs that lasted for approximately ten minutes and resolved spontaneously. *Id.* She further reported a few weeks of urinary incontinence. *Id.* A detailed neurological exam showed absent Achilles reflexes but was otherwise normal. *Id.* at 4-6. A cervical spine MRI showed multilevel arthritic changes as well as multilevel moderate to severe spinal cord narrowing, but no cord compression or abnormal cord signal. *Id.* at 10.

There is a six-week records gap before Ms. Barrett again sought medical care. On January 8, 2022, she presented to Dr. Mandev Guram (internal medicine) to establish care. Ex. 4 at 2. Her physical exam was normal, and Dr. Guram ordered labs. *Id.* at 5. A few weeks later, on January 26, 2022, Petitioner returned to Dr. Guram, reporting several months of pain in multiple joints, which she described as aching and intermittent. *Id.* at 9. Based on the results of the labs, Dr. Guram diagnosed Petitioner with chronic kidney disease stage 3b. *Id.* Dr. Guram's assessment included unspecified joint and shoulder pain. *Id.* at 14.

On February 14, 2022, Petitioner complained to Dr. Guram about lower back pain that she reported had begun two weeks earlier. Ex. 4 at 16. She was referred to physical therapy ("PT"). *Id.* at 19. One week later, on February 22, 2022, Petitioner underwent a PT evaluation for lower extremity weakness and lower back pain and stiffness, that she stated began "in the last year" and "seemed to have gotten worse after reports of getting a series of vaccinations." Ex. 14 at 37.

Throughout February and March 2022, Petitioner continued to report lower back pain, leg pain, right arm pain, and pain in multiple joints. Ex. 14 at 37; Ex. 7 at 35; Ex. 4 at 31. In April 2022, Petitioner requested to be discharged from PT. Ex. 14 at 5-6. On April 7, 2022, Petitioner reported to Dr. Guram for left shoulder pain. Ex. 4 at 36. She explained that her symptoms had improved with PT, but had not completely resolved, and Dr. Guram said they could discuss steroid injections. Ex. 4 at 36, 41.

On April 29, 2022, Petitioner saw ophthalmologist Dr. Robert Edwards, complaining of double vision after she had fallen two days prior and hit the right side of her head. Ex. 15 at 6. Dr. Edwards's assessment was sixth nerve palsy, and he directed Petitioner to report to the emergency department for an MRI of her head and orbits. *Id.* at 7. The next day, on April 30, 2022, Petitioner was discharged home with a diagnosis of double vision due to refractory versus extraocular nerve weakness. Ex. 8 at 17-18.

Throughout May 2022, Petitioner continued to report double vision and generalized weakness, and was prescribed steroids. Ex. 9 at 10. On May 4, 2022, Dr. Powell conducted a physical exam of Petitioner's shoulders and diagnosed her with post-traumatic left shoulder pain with a probable rotator cuff tear. Ex. 7 at 6. On May 7, 2022, Petitioner returned to the emergency department for left-sided weakness and difficulty swallowing and speaking. Ex. 9 at 36-37. She also stated that she had been experiencing more profound weakness plus speaking and word-finding issues since that morning. *Id.* at 37. On May 20, 2022, Petitioner saw a physician assistant at Dr. Guram's office and reported difficulty swallowing, unsteady gait, and slurred speech. Ex. 4 at 43, 46-47.

On May 19, 2022, neurologist Dr. Robert Buechler ordered an MG panel. Ex. 6 at 8. The results were positive, leading to a formal MG diagnosis. Ex. 11 at 11. Dr. Buechler prescribed steroids and other medication. *Id.* Over the next few months, Petitioner's symptoms improved with the use of steroids. Ex. 12 at 18. On June 28, 2022, Petitioner reported continuing trouble with her voice, swallowing, and chewing, and Dr. Buechler increased her steroid dose. *Id.* at 47. By August 21, 2022, Petitioner had improved significantly, but her voice, swallowing, and chewing issues persisted and she often felt fatigued. *Id.* at 76. On October 14, 2022, Petitioner returned to Dr. Edwards, reporting blurred vision and worsening vision in her right eye. Ex. 15 at 9. Over the next two years, Petitioner continued to receive treatment for MG, as evidenced by medical records.

II. Expert Opinions

A. *Petitioner's Expert – Dr. David Simpson*

Dr. Simpson, a neurologist, prepared a written report on behalf of Petitioner. Simpson Report, dated Sep. 19, 2023, filed as Ex. 31 (ECF No. 39-1) ("Simpson Rep."). He proposed that it is more likely than not that the administration of the Tdap vaccine (in concert with the non-covered version of the pneumococcal vaccine) was causally related to Petitioner's MG. Simpson Rep. at 11.

Dr. Simpson is a Professor of Neurology and the Director of the Neuromuscular Division and Clinical Neurophysiology Laboratories at the Icahn School of Medicine at Mount Sinai Hospital, where he has worked as an Attending Neurologist since 1984. Simpson CV, filed on March 7, 2024, as Ex. 58 (ECF No. 45-1) ("Simpson CV"), at 2. He received his medical degree from SUNY at Buffalo School of Medicine, and underwent residency and fellowship training at Cornell University Medical Center and Massachusetts General Hospital. Simpson CV at 1. He is certified by the National Board of Medical Examiners, the American Board of Psychiatry and Neurology with subspecialties in Clinical Neurophysiology and Neuromuscular Medicine, and the American Board of Neuromuscular and Electrodiagnostic Medicine. *Id.* He has been published

extensively and has given numerous presentations and lectures on the subject of neurological disorders, including peripheral neuropathy. *Id.* at 23-64.

In his report, Dr. Simpson opined that vaccines can lead to neurological illnesses, like MG, through a variety of biological mechanisms. Simpson Rep. at 8. These mechanisms include molecular mimicry, neurotoxic effect, and loss of self-tolerance, although he favored molecular mimicry as the most relevant mechanism in this case. *Id.* at 8, 11. Dr. Simpson acknowledged that the specific trigger of MG is unknown but suggested that infections may be responsible. *Id.* Dr. Simpson also admitted that no statistical association exists between vaccinations and the onset of MG symptoms, but argued that this fact was not dispositive, since the rare effects of vaccines are not often identified in initial prospective, placebo-controlled trials. *Id.* at 9. He also noted that it was possible that the simultaneous administration of the non-covered version of the pneumococcal vaccine provided a booster effect that further enhanced the possibility of an autoimmune reaction (although his report does not explain how this would have occurred). *Id.* at 11.

Dr. Simpson then maintained that Petitioner began to experience an onset of MG symptoms shortly after she received the Tdap vaccine. Simpson Rep. at 10. He noted that Petitioner reported "weak spells in which her legs gave way" early on in her course of treatment. *Id.* She also developed ptosis[3] and diplopia[4] – symptoms consistent with the neurological manifestations of MG. *Id.* at 11. And Petitioner developed initial symptoms within weeks of receiving the vaccine, which would fall within the medically acceptable timeframe of 42 days post-vaccination. *Id.* (citing Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality* 535 (K. Stratton et al., eds. 2011), filed as Ex. 38 (ECF No. 40-7)). In Dr. Simpson's view, the sequence of events and laboratory findings supported a conclusion that the Tdap vaccine triggered Petitioner's MG. *Id.*

B. *Respondent's Expert – Dr. Eric Lancaster, Ph.D.*

Dr. Eric Lancaster, a neurologist, prepared a written report on behalf of Respondent. Lancaster Report, dated December 5, 2023, filed as Ex. A (ECF No. 43-1) ("Lancaster Rep."). He opined that there was no evidence that the vaccines Petitioner received, alone or in concert, could have caused Petitioner's MG – especially in light of the timeframe from vaccination to onset. Lancaster Rep. at 13.

As shown in his CV, Dr. Lancaster received his undergraduate degree from The John Hopkins University, and received his Ph.D. in neuroscience plus his medical degree from the University of Maryland. Lancaster CV, filed on December 5, 2023, as Ex. B (ECF No. 43-13)

[3] "Ptosis" is defined as "prolapse or drooping of the upper eyelid." *Ptosis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=42014 (last visited Sept. 11, 2024).

[4] "Diplopia" is defined as "the perception of two images as a single object; also called double vision." *Diplopia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=14354&searchterm=diplopia (last visited Sept. 11, 2024).

("Lancaster CV"), at 1. He completed his neurology residency and neuromuscular fellowship at the University of Pennsylvania. Lancaster CV at 2. Dr. Lancaster is board certified in neurology from the American Board of Psychiatry and Neurology. *Id.* He has treated thousands of neurology patients and has authored over thirty peer-reviewed articles. *Id.* at 6-8. His recent publications concern autoimmune neurologic disorders and their mechanisms. *Id.* at 8. Dr. Lancaster is presently an Assistant Professor of Neurology at the University of Pennsylvania, and his clinic focuses on autoimmune neurological diseases *Id.* at 1-2.

In his report, Dr. Lancaster emphasized the lengthy timeframe from the onset of MG back to the date of vaccinations in contending that causation could not be established. While Dr. Lancaster did not dispute the MG diagnosis, he denied that Petitioner experienced any MG-related symptoms *prior* to April 2022 – nearly nine months post-vaccination. Lancaster Rep at 9. MG, he explained, would be characterized by ptosis, diplopia, difficulty chewing and swallowing, difficulty speaking, and difficulty holding the head upright. *Id.* at 7. The medical records in this case, however, did not reveal these kinds of symptoms before Petitioner began experiencing double vision in April. *Id*. at 9. Dr. Lancaster noted that he gave more weight to the record than to Petitioner's symptoms timeline, which was created after the fact. *Id.*

Petitioner referenced other symptoms as the start of her MG, but Dr. Lancaster deemed them to be uncharacteristic of MG. For example, Dr. Lancaster acknowledged that Petitioner reported pain in her arms and neck in October 2021, but he maintained that pain is not a symptom of MG. Lancaster Rep. at 9. Dr. Lancaster also opined that the brief periods of leg weakness reported by Petitioner in November 2021 were not likely MG-related. If it were otherwise, then they should have been supported by symptoms (ptosis, diplopia, dysphagia) characteristic of MG, and the bouts of leg weakness should have been longer. *Id.* Weakness in MG, he maintained, is generally not focused on the legs, but instead would manifest with respect to the ocular, neck, bulbar, and breathing muscles. *Id.*

Dr. Lancaster also expressed doubt that reports of neck, back, and shoulder pain contained in early 2022 physical therapy notes were reflective of MG symptoms. Lancaster Rep. at 9. In fact, Petitioner's neck pain had previously been diagnosed as cervical radiculopathy in October 2021. *Id.* at 10. And an MRI in May 2022 revealed the reason for Petitioner's shoulder and arm pain – a rotator cuff tear. *Id.* In Dr. Lancaster's estimation, these two diagnoses more logically explained Petitioner's ongoing pain than MG. *Id.*

Even if earlier symptoms could be linked to MG, Dr. Lancaster still deemed the timeframe between vaccination and onset to be unreasonably long. The leg weakness documented in October 2021, for example, would place the onset of MG three months out from the vaccination date. Lancaster Rep. at 10. But in the few cases where autoimmune diseases may arguably be triggered by vaccinations, the risk window is typically 5-42 days, so this still falls far outside the acceptable

timeframe. *Id.* at 10, 12, referencing T. 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. of Epidemiology, 940–51 (1991), filed as Ex. 35 (ECF No. 40-4); Lawrence B. Schonberger et al., Gullian-Barre syndrome following vaccination in the National Influenza Immunization Program, United States, 1976-1977, 110 Am. J. of Epidemiology, 105-23 (1979), filed as Ex. 37 (ECF No. 40-6).[5]

Besides challenging onset, Dr. Lancaster contested whether vaccination could ever explain MG's cause. To that end, he noted some studies that found no reliable evidence that either of the relevant vaccines cause or aggravate MG. *Id.* at 11; T.J. Nasca et al., *Antibody response to pneumococcal polysaccharide vaccine in myasthenia gravis: effect of therapeutic plasmapheresis*, 5 J. of Clinical Apheresis, 113-39 (1990), filed as Ex. A-6 (ECF No. 43-7); G. Sansone & D. M. Bonifati, *Vaccines and myasthenia gravis: a comprehensive review and retrospective study of SARS-CoV-2 vaccination in a large cohort of myasthenic patients*, 269 J. of Neurology, 3965-81 (2022), filed as Ex. A-9 (ECF No. 43-10). And he questioned the merit of Dr. Simpson's proposed causal theories. Lancaster Rep. at 10-11. The mechanistic theory of molecular mimicry,[6] for example, was not applicable, since no showing had been made that the amino acid sequences of the components of proteins in clinical vaccines have homologic or structural similarity to skeletal muscle acetylcholine reception (AChR)[7]. *Id.* at 11. It was therefore very unlikely that any vaccine protein could instigate the production of autoantibodies that could drive the pathologic process resulting in MG. *Id.*

Dr. Lancaster also challenged Dr. Simpson's proposition of a "neurotoxic effect," whereby vaccines would directly damage the membranes of myelin or axons. Lancaster Rep. at 11. As Dr. Lancaster explained, MG's pathogenesis does not involve autoantibodies to axon and/or myelin antigens. *Id.* And Dr. Simpson's theory of vasculitis as resulting in MG was untenable because MG is a *neuromuscular* disorder. *Id.* at 12. Finally, Dr. Lancaster noted that Dr. Simpson's theory of a loss of immune self-tolerance is not supported by any data and cannot be considered a proper causal mechanism. *Id.*

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[5] Petitioners filed Safranek (Ex. 35) and Schonberger (Ex. 37) in support of Dr. Simpson's Report, and Dr. Lancaster referenced these exhibits in his report.

[6] As I have discussed in previous cases, "molecular mimicry" is a scientific concept in which a vaccine's antigens can appear similar to self-structures, either due to sequential homology (in the case of amino acid sequences that make up proteins) common to both, or outright molecular structure "fit." *Bielak v. Sec'y of Health & Hum. Servs.*, No. 18-761V, 2023 WL 35509, at *12 (Fed. Cl. Spec. Mstr. Jan. 3, 2023).

[7] Acetylcholine is a chemical that helps muscles contract and acts as a messenger between nerves and muscles. People with MG often make an abnormal protein called "AChR," which interferes with how acetylcholine works. *Acetylcholine Receptor Antibody (Blood)*, University of Rochester Medical Center Health Encyclopedia, https://www.urmc.rochester.edu/encyclopedia/content.aspx?contenttypeid=167&contentid=acetylcholine_receptor_antibody_blood#:~:text=People%20who%20have%20myasthenia%20gravis,double%20vision%20or%20drooping%20eyelids (last visited Sep. 11, 2024).

III. Procedural History

As noted above, the case was initiated in March 2022, and later that year, Petitioner added the claim of a bilateral SIRVA. After Respondent filed his Rule 4(c) Report contesting Petitioner's right to compensation (*see* ECF No. 35), the process of obtaining expert reports began, with the final report from Dr. Lancaster filed on December 5, 2023. On the same day, Respondent also filed a Motion to Dismiss. The parties subsequently briefed dismissal, and the matter is now ripe for resolution.

IV. Parties' Arguments

A. *Respondent's Motion to Dismiss*

On December 5, 2023, Respondent filed a Motion to Dismiss, arguing that Petitioner could not show a medically acceptable temporal relationship between receipt of the Tdap vaccine and the onset of her MG. Mot. to Dismiss at 1.

The third *Althen* prong, he argued, requires "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 and Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). But Dr. Lancaster's expert report persuasively established that Petitioner did not develop symptoms of MG until April 2022, which is "well outside any plausible window of causation." Mot. to Dismiss at 2-3; Lancaster Rep. at 13.

Indeed, the earliest Petitioner could have developed MG was October 21, 2021, which was "still outside any plausible window of causation." Lancaster Rep. at 13. In most successful non-Table claims, onset of symptoms for a disease process initiated by vaccination is demonstrated to have occurred no longer than six to eight weeks after vaccination. Mot. to Dismiss at 3 (citing *Reichert v. Sec'y of Health and Hum. Servs.*, 2018 WL 4496561, at *15 (Fed. Cl. Spec. Mstr. Aug. 2, 2018)). And Respondent denied awareness of any published Vaccine Program Decision that has found a timeframe longer than two months to be medically acceptable. *Id.* For these reasons, Respondent argues that Petitioner failed to prove prong three of the *Althen* test, and the claim should be dismissed. *Id.* at 4.

B. *Petitioner's Response*

Petitioner maintains she can meet all three *Althen* prongs. Regarding the first, "can cause" prong, she argues that the Tdap vaccine could cause MG through the biological mechanism of

molecular mimicry. Opp. at 12. She noted the Program has recognized the validity of the theory of molecular mimicry, although she did not cite any decisions specific to the Tdap vaccine and MG. *Id.* at 13. She also maintained that epidemiological studies that might reveal such a link are not particularly effective in identifying rare events, and thus are not required to establish any *Althen* prong. *Id.* at 14 (citing *Quackenbush-Baker v. Sec'y of Health and Hum. Servs.*, No. 14-1000V, 2018 WL 1704523, at *16 (Fed. Cl. Spec. Mstr. Mar. 14, 2018)). Dr. Simpson's opinion – that the Tdap vaccine, either alone or in combination with the non-covered pneumococcal vaccine, can cause MG – reflects the medical opinion of a qualified expert, and is sufficient to meet the preponderant standard for the first *Althen* prong. Opp. at 15.

Next, Petitioner argues that she has met the burden of *Althen* prong two by presenting a logical sequence of cause and effect showing that the Tdap vaccine, either alone or in combination with the pneumococcal vaccine, was the cause of her MG. Opp. at 15-16. In support, she contended that she was neurologically asymptomatic prior to receiving the vaccines, but slowly developed symptoms of MG in the months following receipt of the vaccines. *Id.* at 16. This sequence, she claims, is enough to meet the burden of *Althen* prong 2. *Id.* at 18.

Finally, Petitioner addresses Respondent's central argument: whether she has established a medically acceptable temporal relationship between the date she received the Tdap vaccine and her onset of MG symptoms. Opp. at 18. While Petitioner acknowledged that her symptoms are first noted in medical records on October 21, 2021, she represents that she had experienced comparable symptoms in the days and weeks immediately following the vaccines. *See* Affidavit of Myrtle Barrett, dated December 13, 2022, filed as Ex. 22 (ECF No. 26-22) ("Barrett Aff."); Opp. at 19. In Petitioner's affidavit, she testified that "I began having the various symptoms I have described in the days and weeks immediately after receiving the vaccines on July 21, 2021. Among other things, my legs became weak and gave way, and I was very tired and fatigued." Barrett Aff. at 5. Petitioner also asserts that medical records are *not* the only reliable evidence, and argues that representations in her affidavit can be employed to establish a temporal relationship. Opp. at 20. Thus, the shorter timeframe should be accepted in this case.

V. Applicable Legal Standards

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 v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed.

Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[8] There is no Table injury for MG, and as noted above Petitioner no longer advances a SIRVA claim, leaving only a causation-in-fact claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y 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 and 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 *Althen* prong 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 a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing

[8] 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. App'x. 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).

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 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

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 Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates

that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

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

B. *Legal Standards Governing Factual Determinations*

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

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

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

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

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

C. *Analysis of Expert Testimony*

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

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

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

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of

expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed 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, 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. *Resolution of Matter Without Hearing*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. 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 case 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. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

The resolution of this case primarily turns on the third *Althen* prong,[9] which requires a claimant to establish a "proximate temporal relationship" between the date of vaccination and the onset of the injury alleged. *Althen*, 418 F.3d at 1281. A proximate temporal relationship exists when Petitioner offers preponderant proof that the onset of symptoms occurred within a timeframe (measured from vaccination) in which it is medically acceptable to infer causation. *de Bazan*, 539 F.3d at 1352.

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. Simpson Rep. at 8; Lancaster Rep. at 7. It is characterized by fatigable weakness of the ocular, bulbar, limb, and respiratory muscles. Simpson Rep. at 8. The most common symptoms of MG, ptosis and diplopia, affect the eye muscles. Lancaster Rep. at 7. People with MG may also have difficulty chewing, swallowing, and speaking, and limb weakness may also occur. *Id.*

Here, the record preponderantly supports the conclusion that the onset of Petitioner's MG occurred far outside the medically accepted timeframe (assuming MG could have been triggered by vaccination) agreed upon by both parties' experts. As Dr. Lancaster persuasively established, it is unlikely Petitioner's MG actually manifested before April 2022. He reasonably distinguished her earlier symptoms as unrelated or as having different explanations. An aberrant autoimmune process is unlikely to be linked to a vaccine that was administered *nine months before* the onset of

[9] The failure to establish just one of the three prongs of the causation test is sufficient grounds for dismissal. *Dobrydnev v. Sec'y of Health & Hum. Servs.,* 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). Therefore, I need not discuss Petitioner's success or failure in establishing the remaining prongs, since I have determined the third prong is unmet.

symptoms. This timeframe is simply too long to be considered medically acceptable. *Hennessey v. Sec'y of Dep't of Health & Hum. Servs.*, 91 Fed. Cl. 126, 142 (2010) (rejecting theory in which vaccination event long preceded onset, since "it would be virtually impossible to determine that the vaccine, and not some other environmental condition, was the original triggering event").

My conclusion is the same even if the earliest possible onset (as established in the record) – three months post-vaccination – were deemed the first manifestation of Petitioner's MG. Ex. 3 at 2. While neither expert in this case proposed a timeframe for vaccine-caused MG, both Drs. Simpson and Lancaster agreed that a general timeframe for an immune-mediated injury from vaccination would be no more than 42 days, or six weeks. Simpson Rep. at 11; Lancaster Rep. at 10. An onset in the second half of October 2021 – *twelve* weeks post-vaccination – would constitute a timeframe double the accepted length.

The record shows that Petitioner received the vaccines on July 21, 2021, and did not report any side effects or symptoms to a health care provider until three months later, on October 28, 2021. *Id.* The medical records from October 28, 2021, further indicate that Petitioner told her physician that her legs gave way approximately one week earlier, on October 21, 2021. *Id.* The records from that day do not include any other statements by Petitioner about pain or weakness in the preceding weeks or months. Days later, on November 1, 2021, Petitioner returned to her physician and stated that she had been experiencing leg weakness "for the last few weeks," but did not elaborate further. Ex. 2 at 103. A few weeks later, on November 19, 2021, Petitioner visited the doctor again. Ex. 5 at 2. The medical records from this appointment reflect Petitioner's claim from her first appointment – that she experienced sudden weakness in her legs four weeks prior. *Id.* Accordingly, the records place the onset of symptoms right around October 21, 2021, just barely three months after Petitioner received the vaccines.

Although the records place the onset of symptoms outside of the medically acceptable timeframe, and make no mention of an earlier onset, Petitioner alleges that her symptoms actually developed well *within* the 42-day window – no later than a few days of receiving the vaccine. Barrett Aff. at 5. But these witness contentions lack record corroboration – there is no record evidence of such claims from later instances of Petitioner's efforts to obtain medical assistance for her symptoms. And I find the medical records in this case to be far more persuasive than Petitioner's statements. When reviewing evidence in a case, a special master "must consider all relevant and reliable evidence." *See* Vaccine Rule 8. But a special master has discretion to weigh the evidence presented and may give greater weight to medical records. *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952, *958 (Fed. Cir. 2011). As this court explained in *Cucuras v. Sec'y of Health & Human Servs.*:

> "The Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight. *United States v. United States Gypsum Co.*, 333 U.S. 364, 396, 68 S.Ct. 525, 92 L.Ed. 746 (1948) .... Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied

to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." 993 F.2d 1525, 1528 (Fed.Cir.1993).

In this case, Petitioner's statements about an earlier onset made over a year after her first doctor's appointment following the vaccines, conflict with the medical records. The medical records mark the onset of Petitioner's symptoms as October 21, 2021, at the absolute earliest. After Petitioner received the vaccines on July 21, 2021, she did not see a health care provider in any capacity until three months later. And then (October 28th) she complained of leg weakness that had begun *one week* earlier, around October 21, 2021. Ex. 3 at 2. Had Petitioner begun to experience leg weakness immediately following receipt of the vaccines, she likely would have disclosed this to her physician at the first appointment, or at the very least, at any appointment thereafter. But Petitioner did not make this claim until she filed her affidavit, 14 months later (and it is also not a given that any earlier symptoms were even related to *any* of her subsequent complaints – let alone MG – for the reasons offered by Dr. Lancaster).

The record does not preponderantly support the conclusion that the onset of Petitioner's MG symptoms occurred in a medically acceptable timeframe, measured from the date of vaccination. For this reason, the claim cannot succeed.

CONCLUSION

Claimants must carry their burden of proof. Because Petitioner cannot show by preponderant evidence that onset of her MG occurred in a medically acceptable timeframe, I deny entitlement.

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.[10]

IT IS SO ORDERED.

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

[10] 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.