

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

MALINDA GIBBONS,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 18-531V

Special Master Christian J. Moran

Filed: December 10, 2025

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner;
Debra A. Filteau-Begley, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

Seeking compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 through 34 (2018), Malinda Gibbons alleges that a tetanus-diphtheria-acellular pertussis (“Tdap”) vaccine caused her to suffer a neurologic problem known as Guillain-Barré syndrome (“GBS”), more specifically the Miller-Fisher syndrome. Ms. Gibbons supports her claim with opinions from a neurologist, Lawrence Steinman, and a gynecologist, Karen Friday. She advocated through briefs.

The Secretary opposes an award of compensation. The Secretary relies upon opinions from a neurologist, Dara Jamieson, and a reproductive endocrinologist, David Frankfurter. He also advocated through briefs.

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

Ms. Gibbons has not established she is entitled to compensation because she has not established that her Miller-Fisher syndrome lasted more than six months. Thus, she does not fulfill the Vaccine Act's requirement that any vaccine-induced injury be severe. Because severity is a dispositive issue, the question of causation is not reached.

I. Summary of Evidence concerning Ms. Gibbons's Medical History

A. Before Vaccination

Ms. Gibbons was born in 1969. Exhibit 2 (aff., signed May 14, 2018). Before the vaccination, she worked as a part-time copywriter. Exhibit 3 (damages aff., signed July 13, 2018) at 1; see also Exhibit 69 (affidavit, filed Sep. 23, 2024) ¶¶ 14-18.

In addition to working as a copywriter, Ms. Gibbons had earned a Master of Science in oriental medicine with a focus on orthopedics, pain, and women's health. Exhibit 56 (aff., signed Nov. 10, 2022) ¶ 6. She earned this degree in 2002 and in the same year Ms. Gibbons became licensed as an acupuncturist in California. Exhibit 69 (affidavit) ¶¶ 11-12. In 2015, the year before the vaccination, she worked approximately five hours per week as an acupuncturist. Id. at ¶ 19. But, in 2016, before she received the allegedly causal vaccination, she did not work as an acupuncturist. Id. at ¶ 20.

In January 2013, Ms. Gibbons sought treatment for a bulge in her vagina, pelvic pressure, urinary frequency and urgency, and incontinence. Exhibit 1 at 13-14. She told her gynecologist that at times she felt an internal obstruction. After an examination, the gynecologist assessed her as having a mild cystourethrocele. Id. at 15. A "cystourethrocele" is the protrusion of the bladder and urethra into the vagina. Dorland's Illus. Med. Dict. 459 (33rd ed.). The Secretary's expert, Dr. Frankfurter, stated that this finding is a sign that Ms. Gibbons was developing a mature cystic teratoma. Exhibit C at 14-15. A "cystic teratoma" is a type of tumor often found in the ovaries. See Dorland's at 457 (defining "cystic") and 1854 (defining "teratoma").

In January 2014, Ms. Gibbons emailed her primary care provider, Jay Ferns, telling him that for several days, she had "numbness and tingling in [her] neck and chin." Exhibit 1 at 21. During a January 30, 2014 appointment, Ms. Gibbons stated that these symptoms were aggravated by stress and alleviated by a hot bath. Id. at 26-27.

She saw another doctor about her three-month history of tingling along her neck and into her face on March 21, 2014. Exhibit 1 at 60. Although a cervical x-ray detected mild degenerative disease, this was not considered to be the cause of the problem. Id. at 61-5.²

² Ms. Gibbons omits the events from 2014 from her brief. See Pet'r's Br., filed Feb. 2, 2023, at 2. However, as discussed below, the reports about tingling are relevant to assessing reports of tingling in January 2017.

As noted earlier, Ms. Gibbons was earning income as a copywriter. She estimated that in April 2016, she was spending about five to six hours per day working on a MacBook. Exhibit 69 (affidavit) ¶ 43.

B. Vaccination, Urinary Problems, and Neurologic Problems: April to August 2016

Ms. Gibbons returned to the office of her primary care provider on April 19, 2016, when she was 47 years old. She reported that she had “chronic and progressively worsening urinary urgency and frequency.” Exhibit 1 at 132-33. The doctor prescribed a medication for an overactive bladder, Sanctura. Id.; see also Dorland’s at 1639 (defining Sanctura), 1942 (defining tiroprium chloride). During this appointment, she received the allegedly causative dose of the Tdap vaccination. Exhibit 1 at 137.

In the next few weeks, Ms. Gibbons continued to complain about and seek medical attention for her bladder problems. E.g. Exhibit 1 at 150 (email on May 7, 2016), 159-160 (treatment with an internist on May 9, 2016), 172-86 (emergency room treatment on May 9, 2016).

On May 15, 2016, which is 26 days after the vaccination, Ms. Gibbons telephoned her primary care provider to report that she had “tingling all over body . . . Yesterday developed gum tingling, now legs, feet, scalp tingling. Unsteady feeling.” Exhibit 1 at 208-09. These symptoms are accepted as the initial manifestations of her neurologic problem. See Pet’r’s Br. at 35; Resp’t’s Br. at 35.

Although Ms. Gibbons was experiencing tingling all over her body, her appointment on May 16, 2016 was with a urologist. Exhibit 1 at 214. The urologist stated that she had urinary retention of unclear etiology. Id. at 217.

The next day, Ms. Gibbons sought care in an emergency room due to numbness throughout her body and vertigo. Exhibit 7 at 17. An examination showed reduced sensation in her upper extremities. Id. at 18. The examination also showed that her tympanic membranes were bulging. Thus, she was diagnosed with a bilateral ear infection, prescribed antibiotics, and released. Id. at 20.

On May 18, 2016, Ms. Gibbons reported a two-day history of vertigo and difficulty walking. Exhibit 1 at 237. Eye movements triggered her vertigo. Id. at 245. Tests revealed an infection in her urinary tract. She was prescribed lorazepam and amoxicillin. Id. at 253, 257.

Two more days later, the urinary tract infection persisted. Id. at 271. She also reported to medical personnel in an emergency room that she had vertigo, nausea, vomiting, and whole-body numbness. She was admitted for further testing. Her motor and strength exams were normal. Id. at 290-91. However, her deep tendon reflexes were diminished at all sites. Id. at 291. She could not track any movement with her eyes because her eyes were fixed.

A neurologist, Howard Noack, evaluated Ms. Gibbons on May 22, 2016. Ms. Gibbons could not move her right eye and had moderate movement in her left eye. Her strength,

sensation, and deep tendon reflexes were normal. Exhibit 1 at 306-07. Dr. Noack did not “know what to make of diffuse tingling and numbness . . . [t]hus have asked ophthalmology to take a look.” Id. at 307. Dr. Noack considered “Miller-Fisher but she has normal deep tendon reflexes.” Id. The ophthalmologist stated that Ms. Gibbons did not have any meaningful eye movement. Id. at 307 (May 22, 2016).

In the hospital, Ms. Gibbons’s again experienced urinary retention and a catheter was placed. Exhibit 1 at 284, 312, 315-16. The May 25, 2016 discharge report included urinary retention as a problem. Id. at 284. The Secretary comments that the “paresthesias (tingling/numbness) was not described as an active problem at discharge.” Resp’t’s Br. at 21-22.

In her September 23, 2024 affidavit, Ms. Gibbons averred that during the May 2016 hospitalization, she had tingling in her “face, legs, and toes, and cramping in her mid-back.” Exhibit 69 ¶ 44. Although she was directed to cite any medical record supporting her assertion, Ms. Gibbons stated that she did not know if these assertions were in her medical records. See id.

As an out-patient, Ms. Gibbons saw a neuro-ophthalmologist, Kenneth Kubis, on June 7, 2016. Exhibit 1 at 472. She reported continued dizziness and difficulty focusing near and far. On examination, Dr. Kubis observed eye weakness and mild ptosis. Id. at 481. (“Ptosis” is a medical term for drooping eyelids. Dorland’s at 1527). Dr. Kubis suspected that Ms. Gibbons might have the Miller Fisher variant and he ordered a test for the GQ1b antibody. Exhibit 1 at 481-82.

Ms. Gibbons saw a neurologist, Vidya Hawkins, on June 15, 2016. Exhibit 1 at 505. She was experiencing double vision. She also had some difficulty with walking. Dr. Hawkins stated that Ms. Gibbons could have “atypical MFS.” Id. at 509. Dr. Hawkins recommended a three-day trial of IVIG.

The laboratory reported that Ms. Gibbons was positive for GQ1b antibodies. Exhibit 1 at 501 (reported date of June 17, 2016).³ The result of this testing is a basis for the diagnosis of MFV. See Exhibit 10 (Dr. Steinman’s report) at 10; Exhibit A (Dr. Jamieson’s report) at 17.

³ On June 20, 2016, Dr. Hawkins directed his staff to inform the patient “Labs normal.” Exhibit 1 at 527. But, on June 24, 2016, Dr. Kubis attempted to tell Ms. Gibbons about the positive test. Id. at 551.

*Miller-Fisher Syndrome*⁴

MFV is “generally considered to be a benign, self-limited illness, and prognosis is generally quite favorable, with most patients experiencing complete resolution of symptoms and signs by 6 months.” Exhibit A, Tab 9 (Sejvar) at 602.⁵

On June 22, 2016, Ms. Gibbons saw a new doctor for increased blood pressure. Exhibit 1 at 531. The notes associated with this visit state that the “working diagnosis is Miller Fisher variant.” *Id.* at 533.

A three-day course of IVIG started on June 27, 2016. *See* Exhibit 1 at 579. When Ms. Gibbons followed up with Dr. Hawkins, Ms. Gibbons said that the IVIG treatments had helped. Exhibit 1 at 619-20 (Aug. 2, 2016). Ms. Gibbons reported that she felt 95% back to normal with improvements in her double vision and balance. *Id.* at 620. She stated that her problems worsened in the heat.

Dr. Hawkins diagnosed Ms. Gibbons as suffering from GBS-MFV. However, Dr. Hawkins did not order any further neurologic treatment. Dr. Hawkins recommended that Ms. Gibbons see a urologist for her urinary symptoms. Exhibit 1 at 621.

Ms. Gibbons’s statement about this medical record. When asked in this litigation to explain the problems for which she saw Dr. Hawkins, Ms. Gibbons said that she was having double vision and difficulty balancing. Exhibit 69 (affidavit) ¶ 45. She stated that her eyes fatigued easily, and she was experiencing general fatigue. She also stated that she was not having leg cramps and/or toe cramps. *Id.*

Another follow up visit occurred on August 9, 2016. This one was with the neuro-ophthalmologist, Dr. Kubis. Exhibit 1 at 640. She stated that her double vision and ptosis had resolved in July. She reported that she felt “much better and near normal unless I get overheated and then I have to sit down.” *Id.* Dr. Kubis examined her and found that her eye weakness and ptosis are “now resolved.” *Id.* at 647. He recommended neurology follow ups as needed.

Ms. Gibbons’s statement about this medical record. Ms. Gibbons stated that around this time, she was experiencing episodes of double vision that lasted longer than one minute, once or twice per week. Exhibit 69 ¶ 46. Although she was asked to identify medical records in which a

⁴ Miller-Fisher Syndrome is also referred to as Miller-Fisher Variant or Fisher syndrome and is sometimes abbreviated as MFS (or GBS-MFS) or MFV (or GBS-MFV). Those abbreviations are referring to the same subtype of GBS.

⁵ James J. Sejvar et al., Guillain-Barré syndrome and Fisher syndrome: Case definitions and guidelines for collection, analysis, and presentation of immunization safety data, 29 Vaccine 599, 602 (2011); filed as Exhibit A, Tab 9.

medical professional documented a complaint about double vision after August 2016, she did not. See id.

Expert Commentary about August medical records. Both endocrinologists retained in the litigation opined that in August 2016, Ms. Gibbons was in perimenopause. Exhibit A at 12-13; Exhibit 52 at 5. This means that Ms. Gibbons was no longer producing sex steroids as much as she had previously. See Exhibit A, Tab 8 (Rodriguez) at 3.⁶

According to Dr. Jamieson, these appointments demonstrate that Ms. Gibbons's MFS did not last longer than six months. Exhibit A at 11-12. The Secretary has adopted this position. Resp't's Br. at 19-35. Ms. Gibbons argues otherwise. Pet'r's Br. at 12-20.

C. Other Records in 2016

Ms. Gibbons saw a urologist, Michelle Koski, on August 29, 2016. She described her history of urinary retention and frequency, including occasional accidents. Exhibit 1 at 655. An exam showed evidence of urethral prolapse. Id. at 657. A urethral prolapse, also known as urethrocele, is "prolapse of the urethral mucosa" and is "a diverticulum of the urethral walls encroaching upon the vaginal canal." Dorland's at 1977. Dr. Koski prescribed estrogen.

In Dr. Koski's medical record, Dr. Koski states that Ms. Gibbons denied fatigue. Exhibit 1 at 656. Ms. Gibbons's response to questions about this notation is ambiguous. On the one hand, Ms. Gibbons stated that the medical record was accurate to her knowledge. However, Ms. Gibbons also did not recall being asked about fatigue and stated that she would not tell a urogynecologist about fatigue. Exhibit 69 (affidavit) ¶ 47.

Ms. Gibbons emailed her neuro-ophthalmologist, Dr. Kubis, stating that she was having blurry vision in her right eye. She asked if blurry vision could be related to GBS-MFV. He stated that it "shouldn't be," and recommended that she see an optometrist. Exhibit 1 at 669.

Ms. Gibbons's statement about this medical record. Ms. Gibbons stated that she has a regular eye doctor at Redhawk Vision. Exhibit 69 ¶ 48. However, Ms. Gibbons did not submit any records from Redhawk Vision. Thus, there is no documentary evidence about persistent problems with blurry vision.

D. January 16-17, 2017

Ms. Gibbons emailed her neurologist, Dr. Hawkins on January 16, 2017. Exhibit 1 at 765. She stated she was having increased urinary retention, tingling in her gums and jaw, and she was concerned she may be having a relapse of GBS. A nurse associated with Dr. Hawkins spoke with Ms. Gibbons the next day. Ms. Gibbons clarified that her tingling sensation lasted only half of a day and resolved, she had no vision problems, but she did report a recent increase

⁶ Maria Rodriguez & Donna Shoupe, Surgical Menopause, 44 Endocrinol Metab Clin N Am 531, 534 (2015); filed as Exhibit A, Tab 8.

in stress. Id. at 765-66. Dr. Hawkins recommended no further workup. Id. at 764. As discussed below, this exchange of emails in January 2017 is one basis for Ms. Gibbons's argument that her MFS lasted more than six months. See Pet'r's Br. at 14-15.

E. Detection of Pelvic Mass and Removal of Ovaries

A January 22, 2017 CT scan revealed that a large mass was displacing Ms. Gibbons's uterus and bladder. Exhibit 1 at 777-79. An operation was planned.⁷ As part of the preoperative evaluation, Ms. Gibbons reported "continued mild fatigue with no current paresthesias or neurologic sequelae." Id. at 819-20. Ms. Gibbons underwent an operation on February 16, 2017. The mass was identified as a "large left ovarian cyst . . . that completely filled the pelvis." Exhibit 1 at 941; see also Exhibit 5 at 7. The surgeons removed both of Ms. Gibbons's ovaries and her left fallopian tube. An operation to remove one or both ovaries is called an "oophorectomy." Dorland's at 1305.

The next day, Ms. Gibbons emailed her surgeon to ask about estrogen patches and progesterone. The surgeon stated that she could start those medications right away. Later, adjustments could be made to make "sure you do not have strong hot flashes." Exhibit 1 at 843.

The Secretary summarized Ms. Gibbons's initial pharmacy record with hormonal medications:

Date Filled	Ex.	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment until next fill ⁴
2/28/2017	55 at 2	Estrace Vag .1 MG/G cream 100 day supply	June 8, 2017	Not filled again	Not filled again
2/28/2017	55 at 2	Progesterone 200 MG 5 day supply –	March 5, 2017	March 6, 2017	None
2/28/2017	55 at 2	Climara . 8 patches/ 56 day	April 25, 2017	July 3, 2017	69 days
3/6/2017	55 at 2	Progesterone 200 MG 55 day supply –	April 30, 2017	May 21, 2018	386 days

Resp't's Br. at 9. Ms. Gibbons did not challenge this summary. See Pet'r's Reply.

Ms. Gibbons saw her gynecologist, Dr. Meredith McMullen, on March 13, 2017. Exhibit 1 at 880-83. Ms. Gibbons reported that she was taking Climara as a form of HRT. Because this medical record did not list progesterone, the Secretary infers that Ms. Gibbons was not taking

⁷ Dr. Frankfurter commented that from his review of the records, Ms. Gibbons's doctors did not advise her before the operation that she would probably require hormone replacement therapy. Exhibit F at 2.

progesterone. Resp't's Br. at 9. Ms. Gibbons did not report any symptoms of menopause and Dr. McMullen recommended that Ms. Gibbons continue her HRT.

Ms. Gibbons's statement about this medical record. Ms. Gibbons recognized that after the operation, she could have been experiencing fatigue. She was limited in her activities. Exhibit 69 ¶ 50.

Ms. Gibbons informed Dr. McMullen that she was menstruating on March 22, 2017 and asked whether this was normal. Exhibit 1 at 897. Dr. McMullen stated that when starting HRT, bleeding can occur. After the hormone levels stabilize, the bleeding will stop.

According to the Secretary's calculations reflected in the chart above, Ms. Gibbons's prescription for Climara ran out by April 25, 2017 and the supply of progesterone ran out by April 30, 2017. See Resp't's Br. at 10. Ms. Gibbons did not fill her Climara again until July 3, 2017, 69 days after her prescription would have lasted had she been taking it as prescribed. Ms. Gibbons did not refill her progesterone until May 21, 2018, 386 days after her prescription would have lasted had she also taken it as prescribed.

On May 4, 2017, Ms. Gibbons emailed Dr. Hawkins and reported heat intolerance, stating that she "walked around at a street festival last week where it was 75 degrees and almost passed out," and she was "sure is related to my nerves" and her GBS-MFV. Exhibit 1 at 901-02. Dr. Hawkins did not comment on whether this symptom was related to GBS-MFV, but he explained that Ms. Gibbons should avoid environments with excess heat. Id. The Secretary contends that "there is no evidence petitioner explained that she had recently undergone removal of her ovaries and was recently prescribed HRT." Resp't's Br. at 10.

Ms. Gibbons's statement about this medical record. Ms. Gibbons agreed that she did not tell Dr. Hawkins about her hormone replacement therapy. However, in Ms. Gibbons's view, she expected that Dr. Hawkins would know about the hormone replace therapy because it was documented in her medical records. Exhibit 69 (affidavit) ¶ 51.

Ms. Gibbons also elaborated upon the notation of having a problem in the heat. She stated that heat intolerance has a "gradual onset." She feels shortness of breath, nausea, and a sense that she needs to sit down before she falls down. In contrast, a hot flash brings about sudden heat and sweating without lasting fatigue. Id. at ¶ 51.b.

On this date, Ms. Gibbons experienced dizziness in the context of almost passing out. She was also fatigued. Exhibit 69 ¶ 51.

In June 2017, Ms. Gibbons traveled from her home in California to North Carolina to visit her parents. Exhibit 69 (affidavit) ¶ 30.

The Secretary presented more information about Ms. Gibbons's use of HRT:

Date	Ex.	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
July 3, 2017	55 at 2	Climara 8 patches/ 56 day	August 28, 2017	November 9, 2017	73 days

Resp't's Br. at 10.

On September 7, 2017, Ms. Gibbons sought care from a mental health provider for anxiety and possible depression. Exhibit 8 at 4. She described low energy, sleep problems, and a history of depression. Id. She described trouble staying asleep, “hormone ?” Id. When reporting her current medications, she only noted Ativan, and when asked if she took any over the counter medications, her response was “you name it . . .” Id. at 7.

On September 12, 2017, Ms. Gibbons saw Dr. Hawkins and reported trouble with sleep, daytime fatigue, anxiety, intermittent tingling in her perioral region, and an increased need for “screening breaks since GBS.” Exhibit 6 at 20-21. Dr. Hawkins completed an exam and explained that there were “no objective neurological deficits,” prescribed a trial of nortriptyline for paresthesia (likely referring to her intermittent perioral tingling), and he explained that a “[c]oexisting mood disorder likely influences her symptoms.” Id. at 21. Nortriptyline is an anti-depressive medication that is also used to relieve chronic, severe pain. Dorland's at 1273.

Ms. Gibbons's statement about this medical record. Ms. Gibbons stated that she had begun experiencing tingling in her perioral region in May 2016. Exhibit 69 (affidavit) ¶ 52.c. When she talked to Dr. Hawkins in September 2017, Ms. Gibbons was experiencing the tingling several times per day with episodes ranging from a few minutes to a few hours. Id. at ¶ 52.a-b. The tingling in her perioral region was prompting Ms. Gibbons to take breaks from using screens because she was worried that she was having a relapse of GBS. Id. at ¶ 52.j.

For the report of “daytime fatigue,” Ms. Gibbons stated that she had “whole body fatigue after basic daily activities, such as going to the grocery store.” Id. at ¶ 52.e. This fatigue started in May 2016. Ms. Gibbons denied having leg cramps and/or toe cramps. Id. at ¶ 52.i. She also did not recall having dizziness. Id. at ¶ 52.l.

In a brief submitted after Ms. Gibbons filed her affidavit, she argues that Dr. Hawkins's September 12, 2017 medical record shows that she the residual effects of her MFV lasted more than six months. More specifically, she argues that the notations about anxiety and depression meet her burden. Pet'r's Suppl. Br. The Secretary contends that this evidence is not sufficient. Resp't's Suppl. Br.

During a return visit to her therapist on October 4, 2017, Ms. Gibbons again reported concerns with fatigue and sleep issues. Exhibit 8 at 10. She reported a recent prescription for nortriptyline, but she did not fill that prescription. Id. Her only reported medications were melatonin and Ativan. Id. Ms. Gibbons averred that she did not list her HRT because these medications were irrelevant to an appointment for mental health concerns. See Exhibit 56 at 2; see also Pet'r's Br. at 11.

Ms. Gibbons's statement about this medical record. Ms. Gibbons stated that the fatigue was preventing her from doing "many activities with [her] daughter and [her] family." Exhibit 69 (affidavit) ¶ 53.a. She was taking breaks during the day.

Ms. Gibbons also stated that for hormone replace therapy, she was using "Climara estrogen patches, Pometrium progesterone, and Estrace vaginal cream." Id. at ¶ 53.b.

On October 16, 2017, Ms. Gibbons was seen for a weight management program, and she reported that she exercised three days a week at a moderate or strenuous level. Exhibit 6 at 41. Although Ms. Gibbons had recorded information about her exercises in a notebook, she no longer possesses it. Exhibit 69 (affidavit) ¶ 54.d.

Her next HRT medication refills occurred as follows:

Date	Ex.	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
November 9, 2017	55 at 2	Climara 8 patches/ 56 day	January 4, 2018	March 2, 2018	57 days
March 2, 2018	55 at 2	Climara 8 patches/ 56 day	April 27, 2018	May 21, 2018	24 days

Resp't's Br. at 11.

F. Records from 2018

On February 24, 2018, Ms. Gibbons called Dr. McMullen to discuss hormone concerns. Exhibit 9 at 110. She had been lifting weights for four months, and her body had not changed. Id.

On May 21, 2018, Ms. Gibbons saw a provider associated with her PCP for unrelated concerns. Exhibit 6 at 100. However, medications were discussed, and Ms. Gibbons stated that she uses Climara once a week, but that she ran out and is getting more. Id. at 101. She only uses Estrace as needed, and the record states that she was not taking progesterone. Id. at 102. She explained that she was currently using a cream (although she did not explain what cream she was using), and she was considering restarting progesterone. Id. When asked about this cream, Ms. Gibbons stated that she was using progesterone cream as that form was better for her than progesterone pills. Exhibit 69 (affidavit) ¶ 55.a.

HRT prescriptions were filled as follows:

Date	Ex.	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
May 21, 2018	55 at 2	Progesterone 200 MG 60 day supply –	July 20, 2018	July 19, 2018	None
May 21, 2018	55 at 2	Climara 8 patches/ 56 day	July 16, 2018	July 11, 2018	None
July 11, 2018	55 at 2-3	Climara 1 patch – 7 days	July 23, 2018	October 30, 2018	99 days

Resp't's Br. at 12.

On July 19, 2018, Ms. Gibbons visited her gynecologist, Dr. McMullen. Exhibit 6 at 114-17. Dr. McMullen documented that the patient was using estradiol patches and oral micronized progesterone. Id. at 116. Ms. Gibbons complained of low libido and requested testosterone. Id. at 115. There were no other gynecological complaints. Id. There was no mention of hot flashes. Medications were documented with estradiol patch 0.05 mg/24h, applied once weekly, micronized progesterone 200 mg/d and estradiol vaginal cream. Id. at 116. On exam, her vagina was documented as normal appearing, suggesting an estrogen effect in the vagina. Id. Dr. McMullen documented that they reviewed hormone replacement therapy (HRT) in detail. Id. at 117. Ms. Gibbons wanted to switch to oral meds. Id. Her other HRT medications, including estrogen patch, oral micronized progesterone and vaginal estrogen cream were continued in that clinic documentation. Id.

Date	Ex. 55	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
July 19, 2018	3	Progesterone 60 day supply	September 17, 2018	October 30, 2017	42 days
July, 19, 2018	3	Estrogen 60 day supply	September 17, 2018	Not refilled	Not refilled
October 30, 2018	3	Progesterone 60 day supply	December 29, 2018	January 17, 2019	19 days
October 30, 2018	3	Climara 84 day supply	January 22, 2019	January 17, 2019	No Gap

Resp't's Br. at 12.

In January 2019, the following HRT medications were filled:

Date	Ex. 55	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
January 17, 2019	3	Progesterone 60 day supply	March 18, 2019	Not refilled	Not refilled
January 17, 2019	3	Climara 12 patches , 84 day supply	April 11, 2019	April 28, 2019	17 days

Resp't's Br. at 13.

On March 25, 2019, Ms. Gibbons saw Cynthia Sorrell, M.D., for complaints of bilateral cramping in her legs and toes that began a few days earlier and reoccur upon exertion. Exhibit 47 at 20. She was working out on an elliptical for 20 minutes a day, and during the last few days she experienced cramping in the backs of her legs and toes. Id. She explained that she experienced muscle cramping and an electrolyte disturbance when she was diagnosed with GBS. Id. at 20. Her medications were discussed, and Ms. Gibbons explained that she stopped taking oral prometrium due to her belief that it caused irregular bleeding, but she was using a Climara patch. Exhibit 47 at 20. The assessment was abnormal vaginal bleeding, and bilateral leg cramping. Id. at 21. Labs were ordered to check Ms. Gibbons's electrolytes and she was urged to talk with her gynecologist about changes to her HRT. Id.

Ms. Gibbons's statement about this medical record. Ms. Gibbons stated that these leg and toe cramps "started intermittently in 2017." Exhibit 69 (affidavit) ¶ 56.b. She rated them as 7 or 8 in severity with 10 being a maximum. She also stated that one month after this report, she "probably" still had leg and toe cramps. However, she does not remember any specific incidents. Id. at ¶ 56.e.

In this litigation, Ms. Gibbons also connects this March 25, 2019 leg cramping to her earlier neurologic disorder. Exhibit 48 (aff., signed Jan. 26, 2021) ¶ 6. The parties dispute whether this leg cramping was a sequelae to the MFS. Compare Pet'r's Br. at 13-14 with Resp't's Br. at 32-34.

Also on March 25, 2019, she emailed Dr. Hawkins and reported issues with a headache, cramping, and nausea, and feeling dehydrated. Exhibit 47 at 31. She also stated that when she had GBS-MFV, she "had trouble with [her] sodium potassium balance" and that "this feels like the same thing." Id. at 31. Dr. Hawkins stated that she can try taking over-the-counter magnesium, and if that does not work, she could take muscle relaxers. Id.

Ms. Gibbons's statement about this medical record. Ms. Gibbons stated she does not recall whether she was experiencing tingling in her perioral region, fatigue, or dizziness. Exhibit 69 (affidavit) ¶ 58.

On March 26, 2019, Ms. Gibbons emailed Dr. Sorrell and expressed concern that her labs showed low electrolytes, and Ms. Gibbons was told that while she had a borderline low chlorine, she should not be concerned unless she is experiencing active diarrhea, and her results were otherwise normal. Exhibit 47 at 54. Her PCP reviewed the same labs and agreed that they were normal and suggested that Ms. Gibbons take a potassium tablet for one week to help with her cramping. Id. at 58.

On March 28, 2019, Ms. Gibbons saw Dr. Hawkins for leg cramping that was waking her at night. Exhibit 47 at 66. He also noted that she does not drink much water and that her electrolyte panel was normal. Id. Dr. Hawkins stated that a history of GBS may pre-dispose a person to cramping, and he recommended increased hydration and magnesium supplements. Id. at 67.

The Secretary recounts the next steps for HRT:

Date	Ex. 55	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
April 28, 2019	3	Climara 12 patches , 84 day supply	July 29, 2019	August 29, 2019	39 days

Resp’t’s Br. at 14.

On April 30, 2019, Ms. Gibbons saw Dr. McMullen, who noted that Ms. Gibbons was previously prescribed both progesterone and Climara, and that “she does not consistently use the progesterone,” and “[s]ometimes she does not use the estrogen consistently either,” and she “occasionally uses over-the-counter progesterone lotion.” Exhibit 47 at 77. Dr. McMullen noted that Ms. Gibbons was not taking any medications at the time of this appointment. Id. at 81. Dr. McMullen explained that Ms. Gibbons should take HRT as prescribed, including simultaneous use of progesterone and Climara. Id. at 78. She changed Ms. Gibbons’s progesterone to Prometrium 100mg, and recommend she also continue the Climara patch. Id. She cautioned Ms. Gibbons that if she did not take her medication as directed, she could experience spotting. Id.

In September 2019, Ms. Gibbons returned to working as an acupuncturist on a part-time basis. Exhibit 69 (affidavit) ¶ 23. She asserted that various health problems did not prevent her from working more. Id. at ¶ 23.f.

G. Records from 2020

The Secretary recounts Ms. Gibbons’s HRT prescriptions:

Date	Ex. 55	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
August 29, 2019	3	Climara 12 patches , 84 day supply	November 21, 2019	January 6, 2020	46 days
January 6, 2020	3	Climara 12 patches , 84 day supply	April 22, 2020	June 2, 2020	41days
June 2, 2020	3	Climara 12 patches , 84 day supply	August 25, 2020	August 31, 2020	6 days

Resp’t’s Br. at 15.

On August 7, 2020, over a year after she last saw Dr. McMullen, Ms. Gibbons emailed Dr. Hawkins and stated that she was having more severe foot and leg cramps, and she was still taking magnesium and drinking mineral water. Exhibit 57 at 28. She asked what other prescription drugs were recommended and she asked for a mental health counselor in Escondido.

Id. Baclofen was recommended. Id. Baclofen is a medication to relax muscles. Dorland's at 188.

Ms. Gibbons noted that this medical record is a second time that a medical record documents a complaint about leg cramps with the first instance being a March 25, 2019 instance. Exhibit 69 (affidavit) ¶ 56.f.

The Secretary presents information about Ms. Gibbons's HRT:

Date	Ex. 55	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
August 31, 2020	3	Climara 12 patches, 84 day supply	November 13, 2020	February 1, 2021	80 days

Resp't's Br. at 15.

Ms. Gibbons saw or spoke to her PCP twice more in 2020 and reported no relevant issues. Exhibit 57 at 38, 44.

The Secretary presents one more chart related to Ms. Gibbons's HRT:

Date	Ex. 55	Prescription – length of supply	If taken as prescribed, would last until	When filled again	Gap in treatment
February 1, 2021	3	Climara 12 patches, 84 day supply	April 2021	No further refills noted ⁶	No further refills

Resp't's Br. at 16.

In March 2021, Ms. Gibbons emailed Dr. Hawkins about the COVID vaccines and saw an allergist about the same concerns. Ms. Gibbons did not report any GBS-MFV complaints. In August 2021, Ms. Gibbons asked her PCP for a letter supporting her need to cancel a gym membership. Exhibit 57 at 137.

In January 2022, Ms. Gibbons sought care for an unrelated issue, and in July 2022, Dr. McMullen's records note that Ms. Gibbons's attorneys requested to set up a call to discuss a vaccine injury claim. Exhibit 57 at 209-10.

These are the most recent medical records addressed by the parties.

II. Procedural History

Represented by Attorney Richard Gage, Ms. Gibbons alleged that the Tdap vaccine caused her to suffer the Miller Fisher variant of Guillain-Barré syndrome. Pet., filed Apr. 11, 2018. She further alleged that her condition lasted more than six months. Id. ¶ 7. Over the next year or so, Ms. Gibbons submitted evidence, such as medical records and an affidavit. The Secretary advised the record appeared complete. Resp't's Status Rep., filed May 28, 2019.

The Secretary reviewed the evidence and recommended against an award of compensation. Resp't's Rep., filed pursuant to Vaccine Rule 4 on July 12, 2019. The Secretary interposed several objections. First, the Secretary questioned whether the Miller Fisher variant was an appropriate diagnosis. Second, the Secretary disputed whether Ms. Gibbons's condition lasted longer than six months. Third, the Secretary maintained that Ms. Gibbons failed to present evidence that the Tdap vaccine caused her (assumed) Miller Fisher variant. Id. at 9-10.

Because the parties anticipated obtaining reports from experts, a set of instructions was proposed. After the parties did not interpose any objections, the instructions became final. Orders, issued Oct. 29, 2019 and Nov. 22, 2019.

Ms. Gibbons supported her claim with a report from Dr. Steinman. Exhibit 10. Dr. Steinman asserted that the Miller Fisher variant is an appropriate diagnosis. As to how the Tdap vaccine can cause the MFV, Dr. Steinman proposed molecular mimicry. Dr. Steinman also maintained that Ms. Gibbons's disease lasted more than six months. With respect to severity, Dr. Steinman's report consists of one paragraph, largely quoting a medical record from January 2017 about tingling in her jaw. Id. at 36, citing Exhibit 1 at 764-65.

The Secretary responded with reports from experts in two fields. First, Dr. Jamieson agreed that the MFV was an appropriate diagnosis. Exhibit A at 12. However, in other respects, Dr. Jamieson disagreed with Dr. Steinman's opinion. She maintained that Ms. Gibbons's "symptoms and signs of MFS resolved completely towards the end of August 2016, approximately 3 months after their onset." Exhibit A at 17. In this context, she disputed how Dr. Steinman interpreted the jaw tingling from January 2017. Id. at 11-12. Dr. Jamieson also contested the assertion that the Tdap vaccine can cause the MFV. Id. at 17-18.

The Secretary's second expert is Dr. Frankfurter. The crux of his opinion is to provide an alternative explanation for some of Ms. Gibbons's complaints. Dr. Frankfurter wrote:

Based upon my review of the materials provided, it is my opinion that petitioner had a long standing history of urge urinary incontinence due to extrinsic compression of bladder outflow due to an ovarian mass. Subsequent findings of bilateral ovarian cysts and consequent bilateral salpingo-oophorectomy [sic]⁸ lead to a

⁸ Dr. Frankfurter probably intend to write: "salpingo-oophorectomy." The prefix "salingo" refers to a tube, including a uterine tube. Dorland's at 1638.

surgical menopause. The spectrum of symptoms reported by petitioner, heat intolerance, fatigue, and memory issues, and the time course of their manifestation indicate that they most likely arise from her menopausal experience.

Exhibit C at 13.

In the ensuing status conference, Mr. Gage stated that he had not decided whether to retain a reproductive endocrinologist. Instead, Mr. Gage and Ms. Gibbons might propose an informal way to resolve the case. See Order, issued Sep. 29, 2020.

A settlement proposal was not made promptly. Instead, Ms. Gibbons averred that she suffers from leg cramps. Exhibit 48 (affidavit, signed Jan. 26, 2021). With that affidavit, she added a second report from Dr. Steinman, who opined that Ms. Gibbons's Miller Fisher symptoms lasted more than six months because she had fatigue, leg cramps, and jaw tingling. Exhibit 49.

In the next status conference, the parties disputed the value of this recently filed evidence. Mr. Gage asserted that settlement should be more viable now that Dr. Steinman addressed severity. To him, an endocrinologist would be relevant to only damages. However, the Secretary, speaking through Attorney Debra Filteau-Begley, disagreed. In the Secretary's view, Dr. Frankfurter, the endocrinologist, addressed both the fatigue and leg cramps as manifestations of menopause. The parties requested a tentative finding.

A Tentative Finding about six-month severity determined that "Dr. Steinman's opinion is neither persuasive nor credible." Tentative Finding, issued Mar. 22, 2021, at 2. In short, Dr. Steinman overlooked important details and failed to engage with the opinions from Dr. Jamieson and Dr. Frankfurter. The Tentative Finding did not resolve the case but did advise that continuing the case beyond this point might lack reasonable basis. Id. at 3-4.

Despite the warning, Ms. Gibbons decided to press onward. Pet'r's Status Rep., filed Apr. 21, 2021. Ms. Gibbons could retain an endocrinologist and was instructed to have the endocrinologist address whether Ms. Gibbons took estrogen as her doctors prescribed. Order, issued May 5, 2021.

The first report from Dr. Friday was filed on October 16, 2021. Exhibit 52. Dr. Friday concluded that: "There is no evidence Ms. Gibbons was non-compliant with hormone replacement therapy." Id. at 8. Dr. Friday also stated that "her symptoms of fatigue cannot be solely attributed to estrogen deficiency following bilateral oophorectomy." Id. (Again, a "bilateral oophorectomy" means both ovaries have been removed. Dorland's at 1305.)

The Secretary responded with reports from both his experts. Dr. Jamieson stated that neither fatigue, nor leg cramps, nor transient symptoms from January 2017 are manifestations of Miller Fisher syndrome. Exhibit E at 6-7. Dr. Frankfurter generally opined that Ms. Gibbons's symptoms after her bilateral oophorectomy were more likely than not related to her menopause. Exhibit F at 2-4. He also discussed Ms. Gibbons's (lack of) hormone replace therapy. Id. at 4-5.

In Dr. Friday's next report, she continued to dispute the significance of Ms. Gibbons's menopause with Dr. Frankfurter. Exhibit 54. Dr. Friday recommended seeking more information from the doctors who were treating Ms. Gibbons.

Thus, in the next status conference, the parties explored whether and how they might obtain information from a treating doctor. Order, issued Aug. 10, 2022. But, Ms. Gibbons relayed that her treating doctor was not interested in testifying. Pet'r's Status Rep., filed Sep. 9, 2022. The parties, thus, determined that the expert report phase had concluded. The parties were directed to file briefs, addressing severity as well as the Althen prongs. Order, issued Nov. 4, 2022.

Ms. Gibbons submitted updated medical records. Exhibit 57. She also presented another affidavit. Exhibit 56 (signed Nov. 10, 2022).

As permitted in the November 4, 2022 order, Ms. Gibbons submitted another report from Dr. Steinman about severity. Exhibit 63. Ms. Gibbons also argued that she was entitled to compensation. The portion regarding severity runs approximately eight double-spaced pages. Pet's Br., filed Feb. 2, 2023, at 12-20. Ms. Gibbons primarily argues that the evidence supporting her burden to meet the severity requirement include tingling, fatigue, eye strain, muscle cramps in her legs, and the worsening of her symptoms in external heat. Id. at 14. These are discussed in greater detail below.

The Secretary submitted his set of pre-adjudication materials on May 11, 2023. This set included a brief and an updated curriculum vitae for Dr. Jamieson. The Secretary's argument against severity spans about 16 double-spaced pages. Resp't's Br., filed May 11, 2023, at 19-35. Ms. Gibbons defended her position. Pet'r's Reply, filed June 12, 2023 (essentially four pages of which nearly all were devoted to severity).

In her primary brief, Ms. Gibbons seemed to be arguing that (a) she was experiencing various residual symptoms during a relevant time but (b) she declined to tell medical professionals about the symptoms. See Pet'r's Br. at 15. Thus, the undersigned directed her to answer a lengthy series of questions about her health and the medical records. Order, issued June 6, 2024. It appeared that asking questions in writing might be advantageous because she could consult material such as paper documents and electronic documents.

Ms. Gibbons submitted her statement as Exhibit 69 on September 23, 2024. She did a good, but not perfect, job at answering questions. She disclosed that she had visited acupuncturists.

Although another legal brief had not been requested, Ms. Gibbons again argued that her case meets the severity requirement. Pet'r's Suppl. Br., filed Oct. 18, 2024. Over the course of approximately two pages, she primarily discussed fatigue and anxiety. She did not discuss the information communicated through her February 23, 2024 affidavit, which is filed as Exhibit 69.

The Secretary requested that Ms. Gibbons present documents around her employment, such as W-2's. Resp't's Status Rep., filed Oct. 23, 2024. In an October 30, 2024 status

conference, the Secretary explained that compared to the MFS, the surgery for her ovarian tumor might have more greatly contributed to a loss of earnings.

Ms. Gibbons attempted to gather records from acupuncturists. Some entities reported that they had no records. Exhibits 70-72. Other records were submitted as Exhibits 73-75. Updated medical records were filed as Exhibit 76 and tax returns from 2015 to 2020 were filed as Exhibit 77.

Ms. Gibbons communicated a settlement demand. Pet'r's Status Rep., filed Feb. 21, 2025. The Secretary declined to participate in alternative dispute resolution. Resp't's Status Rep., filed June 24, 2025. As settlement was not likely, the case returned to the litigation path.

The Secretary responded to Ms. Gibbons's October 18, 2024 memorandum on severity with his own brief devoted to this topic. The Secretary again maintained that the evidence did not support a finding that Ms. Gibbons satisfied the six-month severity requirement. Resp't's Suppl. Br., filed Aug. 8, 2025.

Ms. Gibbons defended her position that symptoms associated with her Miller-Fisher syndrome lasted more than six months. Pet'r's Suppl. Reply, filed Sep. 19, 2025. With that submission, the case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

In determining whether the evidence weighs in a petitioner's finding, special masters are required to consider the record as a whole. 42 U.S.C. § 300aa-13(a)(1). When special masters consider all the evidence, they have discretion in how to weigh the evidence. Whitecotton v. Sec'y of Health & Hum. Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1996).

IV. Element of Petitioner's Claim: Severity

To receive compensation in the Vaccine Program, a petitioner must demonstrate with preponderant evidence five elements found in paragraphs (A) through (E) of 42 U.S.C. § 300aa-11(c)(1). Most frequently, the disputed element is the causation element, which is found in paragraph (C). In this case, too, the parties dispute causation. However, the more critical element is the severity element, which is found in paragraph (D).

A petitioner may meet this element by establishing that her injury lasted more than six months.⁹ The failure to establish six months of injury results in a denial of compensation. See Stavridis v. Sec'y of Health & Hum. Servs., No. 07-261V, 2009 WL 3837479, at *4 (Fed. Cl. Spec. Mstr. Oct. 29, 2009); Song v. Sec'y of Health & Hum. Servs., No. 92-279V, 1993 WL 534746 (Fed. Cl. Spec. Mstr. Dec. 15, 1993), mot. for rev. denied, 31 Fed. Cl. 61 (1994), aff'd, 41 F.3d 1520 (Fed. Cir. 1994) (table).

In looking to determine whether a problem lasted more than six months, special masters have considered whether there is a gap between when the allegedly vaccine-induced illness concluded and when the alleged symptom of that disease was first manifest. See Moyler v. Sec'y of Health & Hum. Servs., No. 21-1720, 2025 WL 3167857, at *6-7 (Fed. Cl. Sep. 3, 2025) (ruling that the special master was not arbitrary in finding that petitioner's brachial neuritis did not last six months due to a gap in treatment), appeal docketed, No. 2026-1115 (Fed. Cir. Oct. 30, 2025); Wyatt v. Sec'y of Health & Hum. Servs., 144 Fed. Cl. 531, 539-40 (2019) (ruling that the special master reasonably found that petitioner's lack of complaint for many years meant that petitioner's pain was not the residual effect of petitioner's alleged vaccine-related injury).

V. Analysis

Ms. Gibbons advances several problems that she alleges that the Miller-Fisher syndrome caused her to experience more than six months after onset. These include the following: tingling, fatigue, leg cramps, eye strain, heat sensitivity, and anxiety/depression. The Secretary disputes each allegation. An analysis of each point follows.

A. Tingling

When first called upon to present an opinion that Ms. Gibbons meets the severity requirement, Dr. Steinman relied exclusively upon the January 2017 email exchange between Ms. Gibbons and the office of her neurologist. Exhibit 10 at 36 (citing Exhibit 1 at 764-65). Dr.

⁹ The Vaccine Act also allows a petitioner to receive compensation if either the vaccinee died or the vaccinee underwent a surgical procedure. However, Ms. Gibbons did not die and has not undergone a surgery for her reaction to the vaccine.

Jamieson responded to Dr. Steinman's contention, arguing against the persistence of MFS symptoms. Exhibit A at 11-12.

Consistent with Dr. Steinman's opinion, Ms. Gibbons argues that tingling that she experienced in January 2017 and later in September 2017 was because her cranial nerves had not yet completely healed. Pet'r's Br. at 15. The Secretary challenged this position. Resp't's Br. at 31-32.

Dr. Steinman's opinion appears to be based upon a selective and incomplete review of the medical records. First, as Dr. Jamieson points out, in 2017, when Ms. Gibbons reported tingling in her jaw, she also reported stress. Exhibit A at 12; see also Exhibit 1 at 766. Ms. Gibson also reported tingling in the context of stress in 2014. Exhibit 1 at 26-27. Dr. Steinman fails to account for this earlier episode.

Second, Dr. Steinman also overlooks the remainder of the trouble reported in January 2017. Ms. Gibson told the neurologist's nurse that the "tingling sensation only lasted half day." Exhibit 1 at 764. According to Dr. Jamieson, the "report of hours of transient sensory complaints absolutely does not indicate a duration of MFS symptoms beyond 3 months." Exhibit A at 12.

Although Dr. Steinman opined that the "most likely cause of the 2017 symptom is that the cranial nerve that was attacked during the acute phase of [Ms. Gibson's] GBS had not yet fully healed," Exhibit 49 at 2, this opinion lacks persuasiveness. Dr. Steinman has not persuasively explained why there appears to be only two episodes of tingling after August 2016, separated by approximately eight months. See id. If the nerve were not healed, then it seems reasonable to expect that the damaged nerve would cause problems frequently and more consistently. Moreover, Dr. Steinman's opinion that Ms. Gibbons's nerves had not completely healed is inconsistent with her report to Dr. Hawkins on June 16, 2016 that she was not having any numbness and tingling. Exhibit 1 at 507.

For these reasons, the report of tingling does not satisfy Ms. Gibbons's burden to show her Miller Fisher syndrome lasted more than six months.

B. Fatigue

Ms. Gibbons points to fatigue as a manifestation of her GBS. Pet'r's Br. at 13-14. She cites three articles about fatigue and GBS. These articles constitute a basis for finding that GBS can have fatigue as a sequela.

She also maintains that she suffered from fatigue. Of the five sources Ms. Gibbons listed to support her assertion that she had fatigue, three of them are her affidavits. See Pet'r's Br. at 14, citing Exhibit 3 (damages affidavit, signed July 13, 2018); Exhibit 48 (affidavit, dated January 26, 2021); Exhibit 56 (affidavit, dated November 10, 2022). A preponderance of evidence supports a finding that Ms. Gibbons, periodically, suffered from fatigue. In today's world, it would be relatively difficult to find adults who are not fatigued from time-to-time. Virtually everyone's life is busy. See Exhibit 52 (report of Dr. Friday) at 8 ("fatigue can be

attributed to a number of conditions, including lingering effects of MFGBS”); see also Meylor v. Sec’y of Health & Hum. Servs., No. 10-770V, 2016 WL 3165774, at *12 (Fed. Cl. Spec. Mstr. May 16, 2016) (citing testimony of petitioner’s expert that symptoms typical for menopause include fatigue).

Even with a finding that (a) GBS can cause fatigue, and (b) Ms. Gibbons experienced some fatigue, it is not automatically the case that GBS caused Ms. Gibbons’s fatigue. To make this finding automatically would conflict with the well-established principle that a temporal sequence in which one event preceded another event does not mean that earlier event caused the latter event. See, e.g., Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d 1328, 1347-48 (Fed. Cir. 2010).

In this regard, a critical piece of evidence is Ms. Gibbons’s report to Dr. Koski on August 29, 2016 that she was not having fatigue. Exhibit 1 at 656. Ms. Gibbons stated that she was not having fatigue just a few weeks after her neuro-ophthalmologist determined that her eye weakness and ptosis were resolved. Exhibit 1 at 647 (Aug. 9, 2016). If the GBS caused Ms. Gibbons to experience fatigue, then the fatigue would appear in medical records created close in time to when Ms. Gibbons was being seen by doctors for the GBS.

Other than the three affidavits, Ms. Gibbons brought forward two medical records in which fatigue was mentioned. Pet’r’s Br. at 14. Both medical records were created months after Dr. Koski’s record. The earlier of these two records was created on February 9, 2017, when Ms. Gibbons was facing a surgery to remove at least one ovary due to a mass in her abdomen. Exhibit 1 at 818-19 (noting mild fatigue). The other medical record that Ms. Gibbons cited was Dr. Hawkins’s September 12, 2017 record. But, in addition to reporting daytime fatigue, Ms. Gibbons reported trouble with sleep as well as anxiety. Exhibit 6 at 20-21.¹⁰

On balance, the weight of the evidence does not support finding that fatigue was a residual to Ms. Gibbons’s GBS because she has not provided preponderant evidence to meet her burden, such as contemporaneously created medical records that relate her fatigue to her GBS. Her primary evidence consists of her affidavits describing her fatigue and relating it to her GBS. Thus, this symptom does not help her fulfill the severity requirement.

C. Leg Cramps

Ms. Gibbons proposes that she suffered leg cramps as a sequela to GBS. Pet’r’s Br. at 13. Through Dr. Steinman, she presented an article finding that roughly half the patients with GBS suffer residual leg cramps. Exhibit 51 (Bernsen).¹¹ She also asserts that she complained about legs cramps in 2019 and 2020. She emphasizes a report to Dr. Hawkins on March 28,

¹⁰ Ms. Gibbons argues that the anxiety was due to GBS. This point is addressed below.

¹¹ R.A.J.A.M. Bernsen et al., Long-term sensory deficit after Guillain-Barré syndrome, 248 J Neurol 483 (2001); filed as Exhibit 51.

2019. Pet'r's Br. at 11-13. In this report, Dr. Hawkins wrote that Ms. Gibbons's prior "Guillain-Barré history may predispose her to be more likely to getting cramps." Exhibit 47 at 67.

The Secretary disagrees. According to an article Dr. Jamieson cited, leg cramps are common in the general population, not just people with GBS. Exhibit E, Tab 2 (Hallegraeff).¹² Moreover, the study on which Dr. Steinman relied found that people with leg cramps also had sensory deficits detectable on examination. Exhibit 51 (Bernsen) at 484.

The Secretary pointed out that Ms. Gibbons differs from people discussed in the Bernsen article. While those people had GBS and leg cramps, they also had sensory deficits. But, Ms. Gibbons was evaluated for sensory deficits and found not to have any. Exhibit 1 at 306-07 (May 22, 2016); at 507-08 (June 15, 2016); at 620-21 (Aug. 2, 2016); Exhibit 6 at 20-21 (Sep. 12, 2017). Ms. Gibbons did not persuasively counter this argument.

Another problem with Ms. Gibbons's argument is the latency. The earliest time that leg cramps appear in medical records is in 2019. See Pet'r's Br. at 13. Ms. Gibbons experienced the worst of the GBS in the summer of 2016. Thus, approximately three years passed between the onset of the GBS and the reports of leg cramping. Neither Dr. Steinman nor Ms. Gibbons has persuasively explained how this sequence suggests that the GBS caused the leg cramping.

The lack of explanation also diminishes, to a degree, the report from Dr. Hawkins. To repeat, Dr. Hawkins stated that a history of GBS "may predispose" Ms. Gibbons to getting cramps. Exhibit 47 at 67. As a statement from a doctor treating Ms. Gibbons, Dr. Hawkins's statement merits careful consideration but is not dispositive. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006); Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n.67 (2009). On its face, the phrasing of Dr. Hawkins's statement introduces questions about its persuasiveness. See Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 883 (Fed. Cir. 2013) (testimony from a treating doctor that causation was "not impossible" fails to provide support for causation); Nieves v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 422, 429 (2023) (ruling that special master was not arbitrary and capricious in not crediting statement from treater that vaccine-causation was "possible"); Henkel v. Sec'y of Health & Hum. Servs., 165 Fed. Cl. 153, 159 (2023) (ruling that special master reasonably gave little weight to a treating doctor's statement that the vaccinee's condition "may or may not have been related to a flu vaccine"), aff'd, 2024 WL 3873569 (Fed. Cir. Aug. 20, 2024); Orloski v. Sec'y of Health & Hum. Servs., 147 Fed. Cl. 713, 726 (2020) (ruling that special master was not arbitrary in refraining from crediting report from treating doctor when, among other points, the treater did not address timing), aff'd, 839 F. App'x 538 (Fed. Cir. 2021); Doe v. Sec'y of Health & Hum. Servs., 19 Cl. Ct. 439, 452 (1990) ("a vague statement that something may be possible cannot serve as the linchpin for meeting a burden of proof by the preponderance of the evidence"); Stricker v. Sec'y of Health & Hum. Servs., No. 18-56V, 2024 WL 263189, at *24 (Fed. Cl. Spec. Mstr. Jan. 2, 2024) (finding that a treating doctor's statement that vaccine-

¹² Joannes Hallegraeff et al., Criteria in diagnosing nocturnal leg cramps: a systematic review, 18 BMC Family Practice 1 (2017); filed as Exhibit E, Tab 2.

causation is “very possible” is not a statement supporting causation), mot. for rev. denied, 170 Fed. Cl. 701, 722 (2024) (reasoning that the special master’s finding that a treating doctor’s statement that uses “very possible” to suggest vaccine causation does not by itself meet the preponderant standard was not arbitrary).

This set of (non-binding) precedents reflect a common theme---a doctor’s statement that something “may” happen reflects indeterminacy. In other words, an expression that something “may” happen is similar to saying that something “may not” happen. Although in the Vaccine Program, petitioners are not required to establish their cases with scientific certainty, petitioners do bear a burden of proof to show that whatever they are proposing is more likely than not. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Here, the ambiguousness in Dr. Hawkins’s statement, the long latency between when Ms. Gibbons experienced GBS and when she reported leg cramps, the lack of explanation from Dr. Steinman for why the latency was several years, and the frequency in which leg cramps afflict people without GBS combine to make the leg cramps not likely to be a sequela to GBS.

D. Eye Strain

Ms. Gibbons includes “eye strain” among her residual symptoms of GBS-MFV. Pet’r’s Br. at 19. She points to a report of eye strain to Dr. Hawkins on September 12, 2017. Id. at 10, citing Exhibit 6 at 20-21. Her affidavits also mention eye strain. Exhibits 48 and 56, cited in Pet’r’s Br. at 12. She contends that menopause does not cause eye strain.

A problem with Ms. Gibbons’s arguments is that a gap interferes with her proposed chronology. It is certainly correct that Ms. Gibbons experienced problems with her vision when she was hospitalized for MFS. See, e.g., Exhibit 1 at 306 (May 22, 2016), id. at 307 (consult with ophthalmologist on May 23, 2016). The question is how long did she experience these problems because during the hospitalization, her vision issues improved. Exhibit 1 at 507 (June 15, 2016).

On August 2, 2016, she stated there was “Improvement in double vision, balance post IVIG.” Exhibit 1 at 620. This report is consistent with an August 9, 2016 report to Dr. Kubis that her “double vision slowly resolved near latter portion of July 2016.” Exhibit 1 at 640.¹³

A few months later, Ms. Gibbons was concerned about blurry vision in her right eye. She wrote to Dr. Kubis wondering if it were related to her MFS-GBS. Dr. Kubis replied: it “Shouldn’t be” and advised her to see an optometrist as soon as possible. Id. at 669 (Oct. 24, 2016). Ms. Gibbons did not promptly seek treatment with an optometrist. See Exhibit 69 ¶ 48. Moreover, no records from Redhawk Vision were submitted.

In connection with Ms. Gibbons’s report of tingling in her jaw, Nurse Carmen Gutierrez memorialized information from Ms. Gibbons that she had “No vision problem.” Exhibit 1 at 764

¹³ The information that Dr. Kubis gathered is especially important because Dr. Kubis specializes in neuro-ophthalmology. Exhibit 1 at 307.

(Jan. 17, 2017). This affirmative statement that Ms. Gibbons was not having vision problems differentiates this case from situations in which relevant records are silent. See Kirby v. Sec’y of Health & Hum. Servs., 997 F.3d 1378, 1383 (Fed. Cir. 2021).

Thus, there is a period in which Ms. Gibbons did not report any problems with eye strain. In August 2016, she reported improvement in double vision. In October 2016, a neuro-ophthalmologist informed her that any blurry vision was unlikely to be due to her MFS-GBS. In January 2017, Ms. Gibbons reported no vision problems. This period in which Ms. Gibbons did not report any eye strain separates her later reports of eye strain. See Song v. Sec’y of Health & Hum. Servs., 31 Fed. Cl. 61, 68 (1994) (ruling that an intervening normal neurologic evaluation was a basis for the special master to find that subsequent speech delay was not related to the problem a vaccination allegedly caused, a seizure), aff’d, 41 F.3d 1520 (Fed. Cir. 1994). With a statement from Dr. Kubis that blurry vision arising in October 2016 was not likely to be due to MFS-GBS, why should the development of eye strain about 11 months after the blurry vision be related to the MFS?

The doctor to whom Ms. Gibbons reported her eye strain, Dr. Hawkins, did not connect the MFS to the eye strain. Instead, Dr. Hawkins found “no objective neurologic deficits.” Exhibit 6 at 21. He suspected various symptoms were due to Ms. Gibbons’s “coexisting mood disorder.” Id.

Accordingly, the evidence does not support a finding that Ms. Gibbons’s eye strain was a sequela to her MFS.

E. Heat Sensitivity

Ms. Gibbons argued that the Miller-Fisher variant caused her to be sensitive to temperature (heat) and this sensitivity has lasted more than six months. Pet’r’s Br. at 12, 14-19. Ms. Gibbons relies, in part, on the opinions from Dr. Steinman and Dr. Friday. Exhibit 52 at 8-9, Exhibit 49 at 1-2. In contrast, relying upon the opinions from Dr. Frankfurter, the Secretary contends that episodes of hot flashes “are a known symptom associated with estrogen withdrawal, consistent with peri-menopause.” Resp’t’s Br. at 26.

The parties agree that Ms. Gibbons first reported a symptom consistent with heat intolerance in August 2016. See Pet’r’s Br. at 16; Resp’t’s Br. at 29. More specifically, on August 2, 2016, Ms. Gibbons told her neurologist, Dr. Hawkins, that she “[f]eels her symptoms worsen in heat.” Exhibit 1 at 620. On August 9, 2016, she saw Dr. Kubis and recounted that felt “much better and near normal unless I get overheated and then I have to sit down.” Id. at 640.

August 2016 is significant for two reasons. First, August 2016 is less than six months after the onset of the Miller-Fisher variant. Thus, even if these reports of heat sensitivity were due to the Miller-Fisher variant, they would not, by themselves, establish that Ms. Gibbons meets the six-month requirement. Second, in August 2016, Ms. Gibbons was likely in perimenopause. Two doctors retained for their expertise on this topic agree about Ms. Gibbons’s being in perimenopause. Dr. Friday wrote: Ms. Gibbons “was likely perimenopausal, even before her bilateral oophorectomy, based [on] her age of 47 years as well as documentation of hot flashes in

the [neurology] note by Dr. Koski." Exhibit 52 at 8. Dr. Frankfurter, in turn, wrote: "I agree with Dr[.] Friday that Ms. Gibbons was likely experiencing hot flashes associated with menopause in August 2016." Exhibit F at 1-2. Thus, reliable evidence supports a finding that Ms. Gibbons's perimenopause (and not her Miller-Fisher variant) caused her heat intolerance and hot flashes in August 2016. See also Exhibit C at 17-18 (Dr. Frankfurter explaining that "'hot flashes' or 'flushes' are viewed as a classic menopausal finding").

Ms. Gibbons transitioned from perimenopause to a sudden menopause when her ovaries were removed in February 2017. Exhibit 1 at 856. The lack of ovaries means that Ms. Gibbons was likely to experience symptoms of menopause. Exhibit C at 18; see also Exhibit C, Tab 2 (Bachmann) at S313.¹⁴ In this regard, Dr. Frankfurter appears to criticize the doctors caring for Ms. Gibbons because they did not document that they advised Ms. Gibbons before her bilateral oophorectomy that she could require hormone replacement therapy. Exhibit F at 2.

The next question is what was the effect, if any, of hormone replacement therapy? Based upon Ms. Gibbons's prescription records, the Secretary painstakingly established with preponderant evidence that "petitioner's records show that she rarely took HRT as prescribed, she almost never took prescribed progesterone and there were frequently large gaps in time when she was not taking Climara." Resp't's Br. at 30. In this regard, Dr. Friday's assertion that "There is no documented evidence that Ms. Gibbons was non-compliant with hormone replacement therapy," Exhibit 54 at 4, is not based upon a thorough review of the pharmacy records, which Dr. Friday stated she had reviewed. Dr. Friday's failure to investigate Ms. Gibbons's (lack of) hormone replacement therapy reduces Dr. Friday's credibility as an expert witness.

According to information the Secretary presented, and which Ms. Gibbons did not rebut, assuming that Ms. Gibbons took her medications as prescribed, Ms. Gibbons ran out of Climara patches and progesterone at the end of April 2017. Resp't's Br. at 9. On May 4, 2017, Ms. Gibbons informed Dr. Hawkins that she was "still having issues with intolerance to heat which I am sure is related to my nerves and the MFGBS. I walked around at a street festival last week where it was 75 degrees and almost passed out." Exhibit 1 at 902.

This May 4, 2017 medical record from Dr. Hawkins is a focus of the parties' arguments regarding severity as this event occurred more than six months after the onset of the Miller-Fisher variant. See Pet'r's Br. at 14, 16-17. It also appears to be the last time that Ms. Gibbons complained about a heat problem.

Several reasons prevent a finding that this May 4, 2017 episode was a sequela to the June 2016 episode of Miller-Fisher syndrome. First, as noted with respect to leg cramps and eye strain, there is a latency between the two events. (The problems with heat in August 2016 do not really help Ms. Gibbons because Dr. Friday has recognized that the August 2016 problems were

¹⁴ Gloria A. Bachmann, Vasomotor flushes in menopausal women, 180 Am J Obstet Gynecol S312, S313 (1999); filed as Exhibit C, Tab 2.

due to perimenopause.) There is not persuasive evidence to explain why, if the Miller Fisher syndrome were causing problems with heat, the problems would not become apparent until more than 10 months later.

Second, Dr. Steinman's opinion that heat intolerance is due to Miller Fisher syndrome is not persuasive. To start, Dr. Steinman attempted to link heat intolerance to a peripheral neuropathy in his fourth report on the topic. See Exhibit 63 at 3. Although it is certainly the case that, theoretically, continued review and analysis could lead to insights not initially appreciated, Dr. Steinman's proposal of heat intolerance seems to be a belated afterthought. In any event, Dr. Steinman reasoned that people with peripheral neuropathies can have dysautonomia and dysautonomia can include problems with heat. Id. at 4; see also Pet'r's Br. at 13 (discussing dysautonomia for two sentences). However, Ms. Gibbons has not presented any persuasive evidence that she suffers from dysautonomia. Exhibit 69 ¶ 63 (failing to identify any doctors who stated that she has dysautonomia).

Third, and the most important reason, is that evidence weighs in favor of finding that Ms. Gibbons's problem with heat is more likely than not due to her abrupt menopause. Menopause can cause women to have problems with heat. Exhibit 63 (Dr. Steinman's report) at 3-4; see also Meylor, 2016 WL 3165774, at *10 (citing testimony of petitioner's expert that "hot flashes and night sweats [are] the hallmarks of the menopausal transition") (internal quotation marks omitted). As already noted, Dr. Friday has acknowledged that the August 2016 episodes of heat intolerance were due to perimenopause. Thus, Dr. Friday attempts to differentiate what Ms. Gibbons reported in May 2017 from what she reported in August 2016. See Exhibit 52 at 7, 9 (point 4); Exhibit 54 at 2. In doing so, Dr. Friday concedes that with respect to the May 2017 episode reported to Dr. Hawkins, "I can't eliminate the possibility of menopause related symptoms." Exhibit 54 at 2, Dr. Friday continues: "but this brief comment certainly does not confirm a menopause causation." Id.

Dr. Friday mentions that Dr. Hawkins did not connect the near fainting at the street festival to menopause. Exhibit 54 at 2. Dr. Friday's observation is accurate. See Exhibit 1 at 902. But, the inference that seems to be requested is not preponderantly established. One problem is that Dr. Hawkins also did not state that Ms. Gibbons's heat intolerance was due to GBS. Dr. Hawkins's lack of attribution could be problematic because Dr. Hawkins had treated Ms. Gibbons for her Miller-Fisher syndrome. See, e.g., Exhibit 1 at 509. The other side of this coin is that Dr. Hawkins appears not to have been aware that Ms. Gibbons had her ovaries removed about three months earlier. Exhibit 69 (affidavit) ¶ 51; see also Resp't's Br. at 30. This lack of awareness could explain why Dr. Hawkins did not raise any hormonal explanations for her problems.

In any event, because Dr. Hawkins is basically silent about any causes for Ms. Gibbons's heat problem, Ms. Gibbons must rely upon the opinions from her experts. (Dr. Steinman's opinion has been addressed above.) Dr. Friday accepts that "menopausal associated symptoms of heat intolerance are possible." Exhibit 54 at 2. However, Dr. Friday appears to require a relatively high level of proof as she wrote menopausal associated symptoms of heat intolerance "are certainly not the only explanation" and Dr. Kubis's assessment "certainly does not confirm

a menopause causation.” At a level of proof in which certainty is not required, Dr. Frankfurter’s opinion that the May 2017 episode is from menopause is credited. See Exhibit F at 1.

The acceptance of the opinion from the Secretary’s retained expert leads to the fourth and final reason for not finding that the May 2017 episode was from the Miller-Fisher syndrome. Ms. Gibbons argues that her statement to Dr. Hawkins (the “intolerance to heat which I am sure is related to my nerves and the MFGBS”) should be credited. Pet’r’s Br. at 14, citing Exhibit 56. Admittedly, Ms. Gibbons stands in a different position from most petitioners in the Vaccine Program in the sense that she worked on projects involving women’s health. See Exhibit 56 ¶ 5; Exhibit 69 ¶ 10; see also *Dobrydney v. Sec’y of Health & Hum. Servs.*, 94 Fed. Cl. 134, 147 (2010), reversed on other grounds, 566 Fed. App’x 976 (Fed. Cir. 2014).

The accuracy of Ms. Gibbons’s causal conclusion can be disputed without necessarily challenging the observation. See *James-Cornelius v. Sec’y of Health & Hum. Servs.*, 984 F.3d 1374, 1380 (Fed. Cir. 2021). Drawing a causal connection (Ms. Gibbons’s Miller Fisher syndrome caused her heat intolerance) would seem to require a medical degree. See 42 U.S.C. § 300aa–13(a). Ms. Gibbons does not possess this qualification. Although Ms. Gibbons may have sincerely believed that her heat intolerance was neurologic, the neurologist who was treating her, Dr. Hawkins, did not endorse that belief. Further, the neurologist whom Ms. Gibbons retained in the litigation, Dr. Steinman, seemed to come up with the idea that the heat intolerance was due to the Miller-Fisher variant as an afterthought.

For these reasons, Ms. Gibbons has not persuasively shown that the May 2017 episode of heat intolerance was a sequela to her Miller-Fisher syndrome. Thus, heat intolerance does not assist her in satisfying the severity requirement.

F. Anxiety / Depression

After Ms. Gibbons answered a lengthy series of questions (Exhibit 69, affidavit, filed Sep. 23, 2024) she was permitted to file a supplemental brief. She proposed that she suffered from anxiety and depression. Pet’r’s Suppl. Br.

The basis for Ms. Gibbons’s argument is as follows: on August 2, 2016, Ms. Gibbons self-referred herself to see her neurologist, Dr. Hawkins, for “mild depressive symptoms.” Exhibit 1 at 620-21. Dr. Hawkins directed Ms. Gibbons to follow up in three months. However, it appears that Ms. Gibbons did not return around November 2016.

Rather, Ms. Gibbons returned to Dr. Hawkins on September 12, 2017. Exhibit 6 at 20. Her current problems included “anxiety related symptoms.” *Id.* at 21.¹⁵ Dr. Hawkins recorded

¹⁵ Ms. Gibbons appears to misinterpret Dr. Hawkins’s September 12, 2017 medical record. Although this medical record does list “Psych self referral for mild depressive symptoms,” this information appears under a heading “LV [last visit] 8/2016.” *Id.* at 20. As explained in the text, the medical record from August 2, 2016 does reflect a presentation for mild depressive symptoms.

that Ms. Gibbons has “been seen by psychologist recently which was helpful.” Id. Dr. Hawkins’s assessment included: “Coexisting mood disorder likely influences her symptoms, seeing psychologist.” Id.

The account that Ms. Gibbons had seen a psychologist was accurate. The records show that on September 7, 2017, Ms. Gibbons had her first appointment with a psychologist named Victoria Steese. Exhibit 8 at 9 (doctor’s signature). Ms. Gibbons informed Dr. Steese that she had Guillain-Barré / Miller Fisher variant in May 2016 and her ovaries removed in March 2017. Id. at 7. The history of present illness relates, in part, that Ms. Gibbons reports “high anxiety depressive [symptoms] low energy sleep prob. [Client] reports a [history] of depression & recent [diagnosis] of major illness & unknown prognosis causing anx, depressive [symptoms] to return.” Id. at 4. Dr. Steese reached an initial diagnosis of moderate depression and unspecified anxiety. Id. at 9. Dr. Steese planned to treat Ms. Gibbons by, among other things, teaching coping skills.

Ms. Gibbons had a second (and apparently final) appointment with Dr. Steese on October 4, 2017. Dr. Steese memorialized that her client said she was “feeling better.” Exhibit 8 at 10. Although Dr. Steese recommended that Ms. Gibbons return in 1-2 weeks, no other medical records appear within Exhibit 8.

Various problems prevent the September-October 2017 reports of anxiety and depression from being persuasively connected to the June 2016 episode of Miller-Fisher syndrome. A preliminary issue is that whether purely psychologic harms satisfy the six-month severity issue appears unsettled. See Valdez v. Sec’y of Health & Hum. Servs., No. 18-1550V, 2024 WL 3738449, at *31 (Fed. Cl. Spec. Mstr. July 8, 2024).

The second issue is that between the Miller-Fisher episode and the report of depression and anxiety, Ms. Gibbons underwent a bilateral oophorectomy. Ms. Gibbons told Dr. Steese about both the Miller Fisher variant and the removal of her ovaries in March 2017. The presence of these two conditions makes the reference to a “recent [diagnosis] of a major illness” ambiguous. Strictly in terms of timing, the operation for her ovarian cyst was more recent than the Guillain-Barré syndrome.

The removal of Ms. Gibbons’s ovaries, in turn, leads to a third problem with Ms. Gibbons’s argument that her reports of anxiety and depression in September and October 2017 were due to the June 2016 episode of Miller-Fisher syndrome. This third problem is that the Secretary is proposing an alternative explanation for the anxiety and depression, Ms. Gibbons’s failure to take hormone replacement therapy as prescribed. Resp’t’s Suppl. Resp., filed Aug. 8, 2025, at 7, citing Exhibit F (Dr. Frankfurter’s report) at 5. The argument that anxiety and depression come from menopause is far from frivolous. See Meylor, 2016 WL 3165774, at *10 (citing testimony of petitioner’s experts that anxiety and depression can be symptoms of premature ovarian insufficiency). For these reasons, Ms. Gibbons has not met her burden in establishing that she has met the six-month severity requirement.

G. Summary

As presented above, Ms. Gibbons presents a series of problems that she attempts to relate to her Miller-Fisher syndrome. The series is drawn from her briefs, which unfortunately did not always separate one type of problem from the next. The undersigned has attempted to decipher Ms. Gibbons's arguments as best as possible.

Overall, the relatively lengthy list of potential long-lasting sequela weakens Ms. Gibbons's arguments. The expansive list leaves an impression that Ms. Gibbons is grasping for a straw to anchor her argument that she fulfills the statutory requirement for a severe illness. If it were readily apparent, on a more likely than not basis, that one of the potential problems were a sequela to the Miller-Fisher syndrome, then it seems that the other potential problems would not have been advanced.

Regardless of how Ms. Gibbons argued her case, the undersigned has reviewed the entire records, particularly her medical records, her affidavits, and the reports from her experts. When considered as a whole, this evidence does not amount to a persuasive showing that her Miller-Fisher syndrome lasted more than six months.

As stated much earlier, Congress imposed a requirement that petitioners in the Vaccine Program establish five elements. Often the element disputed in causation-in-fact cases is causation (42 U.S.C. § 300aa-11(c)(1)(C)) and causation is an issue here. But, in other cases, severity (42 U.S.C. § 300aa-11(c)(1)(D)) is disputed. When petitioners do not meet the severity requirement, special masters find that petitioners are not entitled to compensation. See Williams v. Sec'y of Health & Hum. Servs., 178 Fed. Cl. 551 (2025) (denying motion for review of special master's decision finding that petitioner did not establish severity and addressing public policy concerns); Weiss v. Sec'y of Health & Hum. Servs., 177 Fed. Cl. 238 (2025) (denying motion for review of special master's decision finding that petitioner's Guillain-Barré syndrome did not last six months); Shanes v. Sec'y of Health & Hum. Servs., No. 20-1411V, 2024 WL 4234975 (Fed. Cl. Sep. 4, 2024) (denying motion for review of special master's decision that petitioner's Miller-Fisher syndrome did not last six months).

VI. A Hearing Is Not Required

The foregoing analysis is based upon a review of the entire record. Nevertheless, at various points, Ms. Gibbons suggests that a hearing would be appropriate. E.g. Pet'r's Br. at 1, 14; Pet'r's Reply at 4 n.1.

When both parties have had a fair opportunity to present their evidence and their arguments, special masters may resolve the case based upon the papers. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020).

Here, as recounted in the procedural history, Ms. Gibbons has enjoyed multiple opportunities to demonstrate that she met the severity requirement. The Secretary alerted Ms. Gibbons that severity was disputed more than five years ago. Resp't's Rep., filed July 12, 2019, at 9-10. Dr. Steinman's first attempt to show a sequela to the Miller-Fisher syndrome was to

identify Ms. Gibbons's report of tingling in her jaw. Exhibit 10 at 36. This opinion was easily rebutted by Dr. Jamieson. Exhibit A at 11-12.

After this round of expert reports, Ms. Gibbons added an affidavit saying that she experienced leg cramps. Exhibit 48. That affidavit was a foundation for Dr. Steinman's second report, which was devoted to severity. Exhibit 49.

The March 22, 2021 Tentative Finding stated that Ms. Gibbons was unlikely to prevail upon her arguments that she satisfied the six-month requirement. But, this Tentative Finding did not stop Ms. Gibbons from presenting more evidence and more arguments.

In the briefing stage, Ms. Gibbons presented another affidavit, which presented more information from Ms. Gibbons about severity. Exhibit 56. She also attempted to reinforce her arguments by presenting another report from Dr. Steinman. This report from Dr. Steinman largely repeats his previously expressed opinions regarding severity but adds the idea that Ms. Gibbons's peripheral neuropathy might have caused heat sensitivity. Exhibit 63. Finally, Ms. Gibbons advocated through both a primary brief and a reply brief. These memoranda have been reviewed multiple times.

Because, in part, Ms. Gibbons requested a hearing, the undersigned proposed a series of questions for her to answer. Order, issued June 6, 2024. The posing of written questions with the expectation of receiving written answers was used to allow Ms. Gibbons a chance to review her medical records. The posing of written questions gave Ms. Gibbons an opportunity to consult her medical records and to think carefully about how she answered the questions. Thus, arguably, the response to written questions produced answers that are more accurate than if Ms. Gibbons testified orally and answered questions spontaneously without going through her medical records. Ms. Gibbons presented her answers in the affidavit. Exhibit 69. Thus, her request to testify has been granted, although she testified in writing, not orally.

Next, Ms. Gibbons was permitted to raise a new argument regarding her anxiety and depression in a supplemental brief. This practice is usually not allowed. See SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1320 (Fed. Cir. 2006) (stating that arguments not raised in primary briefs are ordinarily waived). She was allowed the final word on this topic. Pet'r's Suppl. Reply, filed Sep. 19, 2025.

Given this extensive development, which occurred over multiple years, it is difficult to imagine what additional evidence Ms. Gibbons could present orally at a hearing. She has been permitted to submit whatever evidence she wished, including affidavits to present her account. The determination that this evidence does not demonstrate that her Miller-Fisher syndrome lasted six months reflects the quality of the evidence, not a procedural obstacle.

VII. Conclusion

Ms. Gibbons received a dose of the Tdap vaccination and developed Miller-Fisher syndrome within about one month. Ms. Gibbons could understandably interpret this sequence as one meaning that the Tdap vaccination caused her to suffer Miller-Fisher syndrome.

The Miller-Fisher syndrome required Ms. Gibbons to be hospitalized for approximately five days. With the benefit of some intense treatments, Ms. Gibbons essentially recovered from the Miller-Fisher syndrome within about three months. This recovery is fortunate for Ms. Gibbons's well-being.

Unfortunately, for purposes of the litigation, Ms. Gibbons's relatively quick recovery precludes her from meeting one of the requirements for compensation, which is the adverse reaction be severe enough to last six months. Without a preponderant showing on this element, Ms. Gibbons cannot receive compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master