

In the United States Court of Federal Claims

No. 20-285

(Filed Under Seal: October 24, 2024)

(Reissued: November 8, 2024)¹

KIMBERLY F. FLOWERS, *
*
Petitioner, *
*
v. *
*
SECRETARY OF HEALTH AND HUMAN *
SERVICES, *
*
Respondent. *

Jeremy S. McKenzie, McKenzie & Hart, LLC, Savannah, GA, counsel for Petitioner.

Alec Saxe, U.S. Department of Justice, Civil Division, Washington, DC, counsel for Respondent.

OPINION AND ORDER

DIETZ, Judge.

Petitioner Kimberly F. Flowers (“Flowers”) seeks review of Chief Special Master (“CSM”) Brian Corcoran’s decision denying her compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 *et seq.* (“the Act”). Flowers alleges that she suffered from Guillain-Barré Syndrome (“GBS”) following an influenza (“flu”) vaccine. She filed a petition for compensation. The CSM dismissed her petition, concluding that the onset of her GBS occurred too soon following her vaccination to qualify either as a Vaccine Injury Table (“Table”) claim or a non-Table claim. Because Flowers has not demonstrated that the CSM’s decision was arbitrary or capricious, the Court **DENIES** her motion for review and **SUSTAINS** the CSM’s decision.

¹ Pursuant to Vaccine Rule 18(b) of the Rules of the United States Court of Federal Claims, the Court issued this Opinion and Order under seal on October 24, 2024, and provided the parties fourteen days to propose redactions. *See* [ECF 47]. The parties did not propose any redactions. Accordingly, the Court reissues this Opinion and Order without redactions.

I. BACKGROUND²

Flowers identifies as a fifty-year-old female. [ECF 1-3] at 9. Prior to receiving the flu vaccine at issue, she suffered from numerous health issues, including “obesity, irritable bowel syndrome, hypertension, type 2 diabetes, bipolar disorder, and immune thrombocytopenic purpura—an autoimmune blood platelet deficiency disease for which she received specific treatment.” *Flowers*, 2024 WL 2828211, at *1. Further, “[i]n January 2016, she was diagnosed with a lung neuroendocrine tumor,” which later “proved to be nonaggressive.” *Id.* One month before her vaccination, Flowers received “neurologic treatment for chronic daily headaches” that she had experienced since 2014. *Id.* “She also then reported left anterolateral thigh numbness and tingling.” *Id.* Flowers’ neurologist, Dr. Yi Tsai, concluded that her headaches were “likely caused by cervical spondylosis” and “proposed that the thigh numbness was attributable to a condition involving sensory nerve compression.” *Id.*

On October 26, 2018, Flowers visited the Kaiser Permanente TownPark Advanced Care Center (“TP-ACC”) to check on a blister. [ECF 1-3] at 5. Flowers received the flu vaccine while at the TP-ACC that day. *Id.* at 10, 14. “There is no immediate contemporary record evidence of any vaccine reaction.” *Flowers*, 2024 WL 2828211, at *2.

Eleven days later, on November 6, 2018, Flowers returned to the TP-ACC complaining of “chest pain, shortness of breath, fever, ‘tingling all over body,’ [and] cough for the past 3 days.” [ECF 1-4] at 13. Flowers stated that she “had the flu shot last Friday and [symptoms] began shortly afterward.” *Id.* After examining Flowers, her treaters assessed that she suffered an “adverse [e]ffect of flu [v]accine.” *Id.* at 12. She was prescribed medications for her symptoms, discharged, and told to “[f]ollow-up with [her] Primary Care Physician.” *Id.*

On November 8, 2018, Flowers again returned to the TP-ACC complaining that, “since [her] flu vaccine . . . [she] has been ill with cough, fatigue, severe joint pain, and [nausea and vomiting]” and that her “[p]ain is severe now and [she] barely can walk.” [ECF 1-5] at 5. Following an exam, her treaters found her positive for “fatigue,” “myalgias,” and “global weakness,” and stated that “[s]he is able to ambulate w[ith] assistance.” *Id.* at 8-9. They discharged her with a diagnosis of musculoskeletal pain and pruritus. *Id.* at 15.

The next day, November 9, 2018, Flowers went by ambulance to the emergency room (“ER”) at Emory St. Joseph’s Hospital (“Emory/St. Joseph’s”). *Flowers*, 2024 WL 2828211, at *2. According to the ambulance patient care report, Flowers complained of “weakness/general pain, and general numbness.” [ECF 1-17] at 6. Flowers stated that “she received the flu vaccine on 10/27 and had been [complaining of] generalized body pain, generalized numbness, and generalized weakness.”³ *Id.* She also stated that “she had been unable to walk for the last 2 days due to progressing weakness.” *Id.*

² The background is derived from the CSM’s decision, see *Flowers v. Sec’y of Health & Hum. Servs.*, 2024 WL 2828211 (Fed. Cl. May 8, 2024), and the record evidence. Citations to the record evidence are based on the filing numbers and page numbers generated by the CM/ECF system.

³ Several medical records incorrectly state that Flowers received the flu vaccine on October 27, 2018. However, it is undisputed that Flowers received the flu vaccine on October 26, 2018. When quoting the medical records in this opinion, the Court recites the vaccination date contained in the medical records, even if it is the incorrect date.

The ER physician's record lists Flowers' chief complaint as "[w]eakness." [ECF 9-7] at 51. It explains that Flowers "had a flu shot on 10/27 and she reports she has been having trouble since that time." *Id.* It indicates that Flowers "had some numbing and tingling around her teeth initially, but that has progressed to her whole body and affects mostly her lower extremities." *Id.* The record notes Flowers' history of diabetes and bipolar disorder. *Id.* It further explains that Flowers was brought to the ER for evaluation and treatment because "there was concern of [GBS] or some other side effect" due to "her continued symptomology." *Id.* After examination, the ER physician assessed her as "hyperreflexic in the lower extremities, in the knees and ankle" with "[s]ymmetric reflexes in the upper extremities" and "[d]eferred 2 point discrimination in the lower extremities from the foot to the thigh and decreased motor strength." *Id.* at 52. She was admitted to the hospital on November 9, 2018. *Id.* at 53. The ER physician's diagnostic impression noted, among other conditions such as diabetes, a "[p]ossible side effect adverse reaction to influenza vaccination" and expressed a "need to rule out [GBS] or other neurologic disorder." *Id.* The ER admission report stated: "pt from home reporting since had flu shot has been having general weakness to her extremities [especially] to [both] legs, [nausea and vomiting], and pain." *Id.* at 54. It also notes Flowers' history of diabetes. *Id.*

Flowers' "History and Physical" report dated November 9, 2018, lists her chief complaint as "[g]eneralized pins and needles and weakness affecting mostly lower extremities x3 days."⁴ [ECF 9-7] at 91. It states that Flowers, "with [a] history of bipolar disorder, diabetes mellitus, went to [TP-]ACC a couple of times in the last two days and had some workup done over there . . . but [s]he was not found to have anything abnormal on the workup and was discharged." *Id.* It further explains that Flowers "claims that she has been getting weak gradually especially over the last three days" and that "[s]he was able to walk around three days ago, but gradually she has been losing her strength to the point that today, her husband had to carry her to the bathroom." *Id.* It states that Flowers "claims that she feels pins and needles and increased pain all over her body mostly over the lower extremities below the hips and is currently not able to stand." *Id.* It notes that Flowers "had her flu vaccine on 10/27/2018, and that was followed with a course of upper respiratory symptoms especially cold symptoms that resolved gradually on its own." *Id.* at 92. The concluding impression states: "Gradual weakness of her lower extremities in last three days. This appears to be some kind of demyelinating/inflammatory process. Because of history of recent influenza vaccine, there is a possibility that it could be [GBS] although this needs to be worked up." *Id.* at 94. In addition to correcting an insulin dosage for her diabetes, the treatment plan included a neurology consultation.⁵ *Id.*

⁴ The Emory/St. Joseph's discharge documentation dated November 14, 2018, shows that Flowers was "[a]dmitted to ESJH on 11/9/2018 for [complaints of] paresthesia and [lower extremity] weakness x 3 days." [ECF 9-7] at 88. It states that "[p]rior to admission [Flowers] lost balance and fell on her husband . . . [and that] [s]he was evaluated by Neurology and started on [Intravenous Immunoglobulin ("IVIG")] for possible GBS." *Id.* IVIG "is a blood product used to treat patients with antibody deficiencies, including neurological disorders." *Flowers*, 2024 WL 2828211, at *14 n.3 (citing *Clinical Use of Intravenous Immunoglobulin*, NCBI (2005) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480> (last visited on October 21, 2024)).

⁵ A subsequent medical record from her stay at Emory/St. Joseph's dated November 10, 2018, shows that Flowers "present[ed] due to acute onset of bilateral paresthesias/weakness in ascending manner after flu vaccination on 10/27, as well as associated diarrhea for 5-6 days afterwards" with a "likely etiology of weakness/paresthesias related to GBS." [ECF 9-7] at 174. A record from November 13, 2018, reflects that Flowers "presented with progressive neurologic decline over 2 weeks post flu shot" with admission [work up] for GBS." *Id.* at 133.

Flowers underwent a neurology consultation with Dr. Ramesh Kumar on November 9, 2018. [ECF 9-7] at 104. The consultation record states that Flowers “received ‘Flu’ vaccine end of Oct[ober] 2018 [and that] since then she has been having facial numbness, bilateral foot sensory symptoms with worsening symptoms in last few days.” *Id.* It further explains that Flowers “has been weak with both [lower extremities], unable to walk as per [her] husband . . . and has generalized pain all over the body.” *Id.* After examination, Dr. Kumar assessed Flowers with “[p]ain/sensory symptoms/leg weakness/gait disorder [status post] Flu vaccine in [October 2018] of unclear etiology,” adding that her symptoms were “[n]ot typical for GBS or [Miller Fisher Syndrome] variant.” *Id.* at 106. He noted that the reflex symptoms were “likely from chronic [diabetes mellitus peripheral neuropathy].” *Id.* As a precautionary measure, Dr. Kumar ordered IVIG treatment. *Id.*

Flowers commenced the IVIG treatment on November 10, 2018, and it was stopped on November 12, 2018, after failing to improve her bilateral lower extremity weakness. [ECF 9-7] at 88. During treatment, Flowers experienced a seizure due to a “suspected airway edema.” *Id.* She was intubated and her MRI “was consistent with FLAIR abnormalities in parietoccipital region concerning for PRES syndrome.”⁶ *Id.* On November 13, 2018, Flowers was transferred to the Intensive Care Unit at Emory University Hospital Midtown (“Emory/Midtown”) for monitoring and management. *Id.* at 89. She remained at Emory/Midtown until December 6, 2018, when she was discharged to the Shepherd Center, an in-patient rehabilitation center. [ECF 25-5] at 32, 40. Her discharge summary lists her discharge diagnosis as GBS and her chronic diagnoses as diabetes and bipolar disorder. *Id.* at 32. It states that Flowers was seen on October 27, 2018, “for cold [symptoms] and given flu shot” and that “[u]pon returning home, she began to experience gradual weakening and pins and needles sensation to lower extremities, and inability to stand.” *Id.* at 32. Her “History and Physical” report also states that she received the flu shot and that “[u]pon returning home, she began to experience gradual weakening to [her bilateral lower extremities] that worsened to the point that her husband had to carry her to the restroom.” *Id.* at 52. Flowers was treated at the Shepherd Center from December 6, 2018, until February 16, 2019. [ECF 9-11] at 287. Upon discharge, Flowers “ha[d] made improvements in activity tolerance, endurance, self-care and functional mobility” and was able to perform all activities of daily living with supervision. *Id.* at 290. She could ambulate with assistance, primarily using a motorized wheelchair. *Id.* Her discharge diagnosis listed many conditions, including GBS and diabetes mellitus. *Id.* at 287.

In May 2019, Flowers saw neurologist Dr. Cui Yang for a follow-up neurology consultation. [ECF 9-2] at 79-80. The record from her visit noted that she “came in for recent[ly] diagnosed [GBS].” *Id.* at 80. In the history section, it explained that Flowers “got her flu shot on 10/27/2018, [and] since the second day, she developed gradual weakness, pins and needles sensation in all ext[remities]. At the point, she was not able to stand.” *Id.* It further explained that, since her discharge from the Shepherd Center, Flowers has been in a wheelchair and

⁶ “PRES” is an acronym for “posterior reversible encephalopathy syndrome.” *Flowers*, 2024 WL 2828211, at *3. It is “a syndrome resulting from leukoencephalopathy with edema in posterior parts of the occipital and parietal lobes, characterized by headaches, confusion, seizures, and visual disturbances; the brain lesions are most often related to hypertension, and sometimes to use of certain immunosuppressive drugs or to some other cause.” *Id.* at *14, n.5. (citing *Reversible Posterior Leukoencephalopathy Syndrome*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=111286> (last visited May 8, 2024)).

receiving physical therapy and that she “still has had severe needle like pain.” *Id.* at 81. However, on the date of her consultation, Dr. Yang recorded that Flowers showed greater strength in all extremities and normal reflexes. *Id.* at 84-85. In her assessment, Dr. Yang stated that Flowers “could have Flu shot related GBS, but normally it happen[s] days or weeks after getting a vaccination [and] her symptoms started one day after her flu shot.” *Id.* at 88. Dr. Yang posited that this “doesn’t fit the typical GBS” because, “[f]or GBS, [the] patient would have the absence of [Deep Tendon Reflexes (‘DTR[s]’)], which she might have [had] when she was in hospital . . . however, her DRTs were normal today.” *Id.* She further explained that “[n]ormally[,] if [a] patient has GBS, the absence of DTRs will last months to years or never recover[.]” *Id.* Following her assessment, Dr. Yang recommended an NCS/EMG study to look for “any evidence of GBS (demyelinating features), [l]arge fiber [d]iabetic neuropathy or cervical/lumbar radiculopathy.”⁷ *Id.* at 88.

The results from Flowers’ NCS/EMG study, which was performed in mid-June of 2019, were abnormal. [ECF 9-2] at 124. Dr. Yang found “[the] findings [to be] nonspecific for etiology but . . . consistent with an axon loss polyneuropathy predominately affecting the distal motor fibers of the lower extremity, as may be seen in diabetes mellitus.” *Id.* at 124-25. She noted that “[t]his study doesn’t show any typical demyelinating features.” *Id.* at 125. Dr. Yang therefore proposed the following treatment plan: “diabetes control/rule out other treatable causes/symptomatic treatment” with pain management, physical therapy, and a neurology clinic follow-up. *Id.*

Flowers’ treatment records from 2020 largely reflect concerns about diabetes-related symptoms. *See* [ECF 17-2] at 57 (visit to primary care physician in February 2020 complaining of elevated sugars); *id.* at 117-18 (telemedicine appointment in April 2020 for diabetes care management); *id.* at 153-54 (visit to primary care physician in July 2020 for diabetes mellitus). However, in August 2020, Flowers returned to the neurologist for a “follow up of [her history] of GBS and neuropathy related to [diabetes mellitus].” *Id.* at 202. Flowers reported “numbness in all four extremities,” ongoing neuropathic pain, and difficulty ambulating. *Id.* at 202-03. Her difficulties were confirmed on exam. *Id.* at 209. The examination also revealed slightly decreased strength in lower extremities, along with normal reflexes and normal response to sensory touch. *Id.* at 208-09.

On March 13, 2020, Flowers filed the instant petition, seeking compensation under the Act “for injuries, including [GBS], resulting from adverse effects of a quadrivalent influenza vaccination received on October 26, 2018.” Pet. [ECF 1] at 1.⁸ On May 7, 2020, the CSM assigned the case to the Special Processing Unit (“SPU”), [ECF 11], because he thought that Flowers might easily be able to establish a Table claim. *Flowers*, 2024 WL 2828211, at *1.⁹

⁷ “NCS/EMG” is an acronym for Nerve Conduction Study/Electromyography. *Electromyography (EMG) and Nerve Conduction Study*, WEBMD (Mar. 14, 2024), <https://www.webmd.com/brain/emg-and-nerve-conduction-study> (last visited October 21, 2024).

⁸ All page numbers in the petition for compensation and the parties’ briefings refer to the page numbers generated by the CM/ECF system.

⁹ On November 2, 2020, while the case was assigned to the SPU, the government filed its report under Vaccine Rule 4(c), arguing that Flowers was not entitled to compensation under the Act because she failed to demonstrate that she

However, on September 6, 2023, after it became apparent that there were several disputed fact issues, the CSM reassigned the case to his regular docket. *Id.*; *see also* Order [ECF 35].

On September 18, 2023, the CSM ordered Flowers to show cause why her case should not be dismissed on the grounds “that the evidence preponderates in favor of an onset occurring earlier than three days post-vaccination.” Order [ECF 37] at 1. The CSM also advised Flowers to consider whether, alternatively, she could “establish that a non-Table claim of GBS after the flu vaccine could be viable even if onset were within two days or so of vaccination.” *Id.* at 2. Based on Flowers’ response to the show cause order and the government’s response to Flowers’ filing,¹⁰ the CSM found that “[t]he record preponderates in favor of the conclusion that [Flowers’] GBS onset occurred too soon post-vaccination to meet the Table timeframe—and given that record, such a short onset would also not be medically-acceptable even under a non-Table causation-in-fact analysis.” *Flowers*, 2024 WL 2828211, at *1. Therefore, on May 8, 2024, the CSM denied Flowers’ petition for entitlement. Entitlement Decision [ECF 41]. Flowers sought review of the CSM’s decision on June 5, 2024. Pet.’s Mot. [ECF 43]. The government responded on July 5, 2024. Gov.’s Resp. [ECF 45]. The Court held oral argument on October 11, 2024. [ECF 46].

II. STANDARD OF REVIEW

This Court has jurisdiction under the Act to review a special master’s decision. 42 U.S.C. § 300aa-12(e)(2). In reviewing a special master’s decision, this Court may:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision, (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court’s direction.

42 U.S.C. §§ 300aa-12(e)(2)(A)-(C).

This Court reviews a special master’s findings of fact under the “arbitrary and capricious” standard, legal questions under the “not in accordance with law” standard, and discretionary rulings under the “abuse of discretion” standard. *Turner v. Sec’y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001). With respect to the arbitrary and capricious

either suffered a Table injury or that the vaccination caused her GBS. Gov.’s Rule 4(c) Report [ECF 20] at 10-12. Thereafter, the SPU ordered the parties to brief the question of when Flowers’ neurologic symptoms began. Order [ECF 23] at 1. After the parties submitted their briefs, *see* Pet.’s Br. [ECF 26]; Gov.’s Br. [ECF 28], the SPU informed them that even if Flowers established that the onset of her GBS occurred within three to 42 days following vaccination, the issue of whether her GBS was caused by other factors remained. Order [ECF 29] at 1. Therefore, the SPU ordered the parties to indicate whether they could informally resolve the petition. *Id.* On July 7, 2022, the parties filed a joint status report indicating that the government wished to continue to defend its position. Joint Status Report [ECF 34] at 1.

¹⁰ *See* Pet.’s Br. [ECF 39]; Gov.’s Br. [ECF 40].

standard, “no uniform definition . . . has emerged,” but it is “a highly deferential standard of review” such that “[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.” *Hines v. Sec’y of Health & Hum. Servs.*, 940 F.2d 1518, 1527-28 (Fed. Cir. 1991); *accord Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (a decision is arbitrary and capricious only if it is “so implausible that it could not be ascribed to a difference of view”). The arbitrary and capricious standard of review is difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact. *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). “[I]t is not . . . the role of this court to reweigh the factual evidence, [] to assess whether the special master correctly evaluated the evidence[, or to] . . . examine the probative value of the evidence or the credibility of the witnesses.” *Lampe*, 219 F.3d at 1360 (quoting *Munn v. Sec’y of Health & Hum. Servs.*, 970 F.2d 863, 871 (Fed. Cir. 1992)). “These are all matters within the purview of the fact finder.” *Id.*

The “not in accordance with law” standard, on the other hand, is applied without deference to legal determinations, such as “[w]hether the special master applied the appropriate standard of causation” *Deribeaux v. Sec’y of Health & Hum. Servs.*, 717 F.3d 1363, 1366 (Fed. Cir. 2013). Lastly, the abuse of discretion standard applies to the special master’s evidentiary rulings, such as determinations regarding the qualification of experts and the admissibility of their testimony. *Piscopo v. Sec’y of Health & Hum. Servs.*, 66 Fed. Cl. 49, 53 (2005) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). “The [abuse of discretion standard] will rarely come into play except where the special master excludes evidence.” *Munn*, 970 F.2d at 870 n.10; *accord Caves v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 131 (2011), *aff’d*, 463 F. App’x 932 (Fed. Cir. 2012).

The Federal Circuit has made clear that special masters, as the finders of fact, have the responsibility to weigh the persuasiveness and reliability of evidence presented to them, and if appropriate, the credibility of testimony. *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010); *see Terran v. Sec’y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (“[T]he rules of evidence require that the trial judge determine whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline.”) (internal quotation marks omitted). The special master has broad discretion in determining the credibility of witnesses and weighing the evidence, and these credibility determinations are “virtually unreviewable” by the reviewing court. *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In other words, the reviewing court does not reweigh the evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses because all of these matters are within the purview of the factfinder. *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010) (citing *Munn*, 970 F.2d at 871); *accord Loyd, Next Friend of C.L. v. Sec’y of Health & Hum. Servs.*, 2023 WL 1878572, at *2 (Fed. Cir. Feb. 10, 2023).

III. LEGAL STANDARDS

The Act was established to compensate individuals for a vaccine-related injury or death after a showing that the vaccine caused that injury or death. 42 U.S.C. § 300aa-11(a)(5)(B)(10).

Under the Act, a petitioner may establish causation in two ways. *Munn*, 970 F.2d at 865. First, a petitioner may demonstrate causation through a statutorily prescribed presumption by showing that the alleged injury meets the criteria listed on the Table. 42 U.S.C. § 300aa-14. According to the Table, a petitioner is considered to have suffered from GBS due to a seasonal influenza vaccine if onset occurs “not less than 3 days and not more than 42 days” after vaccination. 42 C.F.R. § 100.3(a). “[I]f a petitioner can establish that she received a listed vaccine and experienced such symptoms or injuries within the specified timeframes, she has met her prima facie burden to prove that the vaccine caused her injuries.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008). A petitioner must satisfy the requirements by a preponderance of evidence. 42 U.S.C. § 300aa-13(a)(1). However, neither the special master nor the Court may find that a petitioner satisfies the requirements based solely on the petitioner’s claims, unsubstantiated by medical records or medical opinion. *Id.*

Alternatively, if a petitioner suffered an injury listed on the Table but not within the specified time period, or if a petitioner suffered an “off-Table injury,” he must prove “causation-in-fact” by a preponderance of the evidence.¹¹ *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii); *see also Broekelschen*, 618 F.3d at 1341-42. “Causation-in-fact in the Vaccine Act context is the same as ‘legal cause’ in the general torts context.” *de Bazan*, 539 F.3d at 1351. Thus, “the vaccine is a cause-in[-]fact when it is ‘a substantial factor in bringing about the harm.’” *Id.* (quoting Restatement (Second) of Torts § 431(a)). In *Althen*, the Federal Circuit articulated a three-part test for showing causation-in-fact:

[A petitioner must] show by preponderant evidence that the vaccination brought about [petitioner’s] injury by providing: (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 a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278. Before applying the *Althen* test, however, the court must determine whether a petitioner has shown by preponderant evidence a “medically recognized injury” that is “more than just a symptom or manifestation of an unknown injury.” *Lombardi v. Sec’y of Health & Hum. Servs.*, 656 F.3d 1343, 1352-53 (Fed. Cir. 2011) (citing *Broekelschen*, 618 F.3d at 1349) (explaining that “if the existence and nature of the injury itself is in dispute,” then “identification of a petitioner’s injury is a prerequisite to an *Althen* analysis of causation”).

“Once the petitioner has established a prima facie case for entitlement to compensation and thus met her burden to prove causation-in-fact, the burden shifts to the government to prove ‘[by] a preponderance of the evidence that the [petitioner’s injury] is due to factors unrelated to the administration of the vaccine described in the petition.’” *de Bazan*, 539 F.3d at 1352 (quoting 42 U.S.C. § 300aa-13(a)(1)(B)). Under the Act, “factors unrelated to the administration of the vaccine” may include “infection, toxins, trauma (including birth trauma and related anoxia), or

¹¹ “This court has interpreted the ‘preponderance of the evidence’ standard referred to in the Vaccine Act as one of proof by a simple preponderance, of ‘more probable than not’ causation.” *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005) (citing *Hellebrand v. Sec’y of Health & Hum. Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)).

metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." 42 U.S.C.A. § 300aa-13(a)(2). Significantly, a petitioner need only demonstrate that the vaccine was a substantial factor in bringing about the alleged harm. *de Bazan*, 539 F.3d at 1354. However, the government must demonstrate that an unrelated factor "was the sole substantial factor in bringing about the injury." *Id.* In addition, the government's proof of alternative actual causation-in-fact must satisfy the same standard as the petitioner's proof of actual causation-in-fact in non-Table cases. *Deribeaux*, 717 F.3d at 1368 (citing *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). If the Court finds that the government failed to prove alternative actual causation-in-fact, the petitioner is entitled to compensation. *de Bazan*, 539 F.3d at 1352. If the Court finds the parties' evidence to be in equipoise, the petitioner is entitled to compensation. *Heinzelman v. Sec'y of Health & Hum. Servs.*, 2008 WL 5479123, at *19 (Fed. Cl. Dec. 11, 2008) (citing *Knudsen*, 35 F.3d at 550).

IV. ANALYSIS

In this case, the CSM denied Flowers' petition, finding that her "GBS onset occurred too soon post-vaccination to meet the Table timeframe—and given that record, such a short onset would also not be medically-acceptable even under a non-Table, causation-in-fact analysis." *Flowers*, 2024 WL 2828211, at *1. Flowers objects to both conclusions, arguing that the CSM's determinations arbitrarily ignore contradictory medical records, evidence, and expert testimony. [ECF 43] at 6, 14. For the reasons stated below, the Court finds that the CSM considered the relevant evidence, drew plausible inferences, and articulated a rational basis for his conclusions, and that, therefore, Flowers has not shown that the CSM's decision was arbitrary or capricious.

A. The CSM's Determination That Flowers' GBS Was Not a Table Injury

First, Flowers objects to the CSM's determination that the onset of her GBS symptoms did not occur within the timeframe set by the Table. [ECF 43] at 6. Flowers argues that the CSM "ignored the [TP-ACC] record of November 6, 2018[,] in which [Flowers] reported the onset of GBS-related symptoms 'for the past 3 days,'" and that this record is "the most contemporaneous medical record that provides a definite time period in which [Flowers'] GBS-related symptoms began." *Id.* at 8. In her view, the November 6, 2018, record definitively establishes that her GBS qualifies as a Table injury. *Id.* Flowers also contends that the CSM placed undue reliance on statements in her later medical records and that he should not credit caselaw interpreting temporal indicators such as "since," "shortly after," or "following," as meaning "within 48 hours of vaccination." *Id.* at 8-9 (internal quotation marks omitted). Flowers states that "other decisions of this court do not place such vague temporal references as to the timing of onset on such high a pedestal, particularly in the face of other conflicting evidence." *Id.* at 9. Also, Flowers argues that, in addition to the November 6, 2018, record, her own declaration and those of her family members establish that the onset of her GBS symptoms occurred more than one week after she received the vaccination "and override any vague, nonspecific onset statements." *Id.* at 10. Flowers further argues that her unrefuted expert witness, Dr. David Simpson, corroborates her contention that onset did not occur "until more than three days after her vaccination." *Id.* at 12.

The Court finds that the CSM's determination that Flowers' GBS was not a Table injury was rationally based on the record evidence. Beginning in the "Fact History" section of his opinion,¹² the CSM notes that on multiple occasions, Flowers reported experiencing symptoms close in time to the vaccination. The CSM states that "on November 6, 2018, Ms. Flowers returned to the TP-ACC with several complaints, including cough, shortness of breath, and paresthesias she characterized as 'tingling all over her body.'" *Flowers*, 2024 WL 2828211, at *2. According to the CSM, "[s]he specifically reported . . . that these symptoms had begun 'shortly after' receiving the flu vaccine . . ." *Id.* In support of these statements, the CSM cites to the notes taken by a physician and a nurse at TP-ACC. *Id.*; [ECF 1-4] at 12-13 (11/6/2018 notes by Dr. Shakira N. Thomas stating: "She thinks her symptoms may be due to recent flu shot. . . . Poss symptoms are due to the recent flu shot"; 11/6/2018 notes by RN Erin M. Burkhalter stating: "States had flu shot last Friday and sx's began *shortly afterward*." (emphasis added). The CSM also states that Flowers made similar statements regarding the onset of her symptoms when she returned to the TP-ACC on November 8, 2018. *Flowers*, 2024 WL 2828211, at *2. In this instance, the CSM cites to notes from Flowers' visit to the TP-ACC on that date. *Id.* (citing [ECF 1-5] at 5) ("States *since had flu vaccine on 27th* has been ill with cough, fatigue, severe joint pain, and N/V") (emphasis added).¹³

Next, the CSM avers that Flowers made similar statements regarding symptom onset when she was transported to the ER on November 9, 2018, and during the early period of her hospitalization, even though the symptoms became acute shortly before her ER visit. *Flowers*, 2024 WL 2828211, at *2. In support of these findings, the CSM again cites to notes made by her treating physicians and nurses. *Id.*; [ECF 9-7] at 51, 54, 91, 133, 174 (notes by Dr. Alan Aidan Farabaugh stating: "[Flowers] had a flu shot on 10/27 and she reports she has been having trouble *since that time*"; notes by Nurse Charles Lwanga stating: "pt from home reporting *since had flu shot* has been having general weakness to her extremities esp to b/legs. NV, and pain. hx DM"; notes by Dr. Satya Deo Singh stating: "Patient claims that she has been getting weak *gradually especially over the last three days*"; notes by Doctor Helen M. Ward stating: "[Flowers] presented with *progressive neurologic decline over 2 weeks post flu shot* and acute URI/diarrhea symptoms"; notes by Dr. Shawnay N. Mazell stating: "[Flowers] presents due to acute onset of bilateral paresthesias/weakness *in ascending manner after flu vaccination on 10/27, . . .*") (emphasis added).

The CSM also cites to the notes made by neurologist, Dr. Kumar, regarding his November 9, 2018, consultation with Flowers, noting that Flowers "again provid[ed] a comparable history (including onset of symptoms right after vaccination) to what she had offered other treaters." *Flowers*, 2024 WL 2828211, at *3 (citing [ECF 9-7] at 104) (11/9/2018 notes by Dr. Kumar). In his notes, Dr. Kumar stated: "Member received 'Flu' vaccine end of oct 2018. *since then* she has been having facial numbness, bilateral foot sensory symptoms *with worsening symptoms in last few days*." [ECF 9-7] at 104 (emphasis added). Further, the CSM states:

¹² In assessing whether the CSM's determination regarding the onset of Flowers' GBS symptoms was arbitrary or capricious, the Court reviews both the "Fact History" and "Analysis" sections of his opinion.

¹³ It is unclear from the record who authored these notes.

Petitioner's initial neurologic work-up [after her November 13, 2018, transfer to Emory/Midtown] memorializes her report that *the same day as vaccination*, she had experienced "gradual weakening to [bilateral lower extremities] that worsened to the point that her husband had to carry her to the restroom," later progressing [to] the point where she sought emergency care earlier that month.

Flowers, 2024 WL 2828211, at *3 (alteration added) (emphasis in original). In support of these findings, the CSM cites to the notes taken by two of Flowers' treaters. *Id.* (first citing [ECF 25-5] at 52; then citing [ECF 9-2] at 81) (11/14/2018 notes by Ronald K. Fuller¹⁴ and 5/3/2019 notes by Dr. Yang, respectively). In his notes regarding Flowers' November 13, 2018, visit to Emory/Midtown, Mr. Fuller stated:

50 year old female with PMH BiPolar Disorder, DM who presented to Kaiser ACC on 10/27 for c/o cold sx and was discharged home on hydrocodone cough syrup and was also administered the flu shot. *Upon returning home*, she began to experience gradual weakening to BLE that worsened to the point that her husband had to carry her to the restroom. She c/o pins and needles sensation to lower extremities and was unable to stand up. Her husband called 911 because of the worsening of her sx and she was transported to SJH ED. After evaluation by the ED MD, neurology was called and pt was admitted on 11/9 for further evaluation.

[ECF 25-5] at 52 (emphasis added). In her notes regarding Flowers' May 3, 2019, visit to Kaiser Permanente/Townpark Medical Center ("KP/TMC"), Dr. Yang stated: "50 year old female with PMH BiPolar Disorder, DM was seen at Kaiser clinic on 10/27 for cold sx and given flu shot. *Upon returning home*, she began to experience gradual weakening and pins and needles sensation to lower extremities, and inability to stand." [ECF 9-2] at 81 (emphasis added).

Regarding Flowers' May 2019 visit with Dr. Yang at KP/TMC, the CSM remarks: "The history of present illness section from the record of this visit identified the second day from vaccination as when [Flowers] first began to experience weakness and paresthesias in her extremities." *Flowers*, 2024 WL 2828211, at *4 (internal quotation marks omitted) (citing [ECF 9-2] at 80) (5/3/2019 notes by Dr. Yang regarding Flowers' 5/3/2019 visit to KP/TMC stating: "She got her flu shot on 10/27/2[0]18, *since the second day*, she developed gradual weakness, pins and needles sensation in all exts.") (emphasis added). The CSM then states: "In her assessment, Dr. Yang allowed for the *possibility* of GBS attributable to the flu vaccine, but also noted that 'normally [GBS] happened days or weeks after getting a vaccination, but her symptoms started one day after her flu shot,' which 'doesn't fit the typical GBS.'" *Flowers*, 2024 WL 2828211, at *4 (emphasis in original) (quoting [ECF 9-2] at 88) (5/3/2019 notes by Dr. Yang).

In the "Analysis" section of his opinion, the CSM explains why "[t]he medical records preponderantly establish that [Flowers'] onset most likely occurred *less than* three days after

¹⁴ Mr. Fuller's title is not clear from the record.

vaccination—thus sooner than the 3-42 day timeframe provided for by the Vaccine Injury Table.” *Flowers*, 2024 WL 2828211, at *11 (emphasis in original). Here, the CSM again cites to Dr. Kumar’s notes following his neurology consultation with Flowers and her husband on November 9, 2018. *Id.* (citing [ECF 9-7] at 104). In addition, the CSM cites to two medical records from Emory/Midtown. *Flowers*, 2024 WL 2828211, at *11. The first document, the notes from a December 6, 2018, assessment by Brian J. Sestrich,¹⁵ states: “50 year old female with PMH BiPolar Disorder, DM was seen at Kaiser clinic on 10/27 for cold sx and given flu shot. *Upon returning home*, she began to experience gradual weakening and pins and needles sensation to lower extremities, and inability to stand.” [ECF 25-5] at 32 (emphasis added). The second document, which the CSM previously referenced in his “Fact” section, is Mr. Fuller’s notes from Flowers’ November 13, 2018, visit to Emory/Midtown. *See id.* at 52. Further, the CSM cites to two medical records from Kaiser Permanente. *Flowers*, 2024 WL 2828211, at *11. The first document, the notes from a February 26, 2019, assessment by Dr. Kristen M. Foster, states: “Kimberly F Flowers is a pleasant patient who presents with complaint of last fall went to TP and had flu shot. *Notes developed GB soon after*. Was at St. Joseph to Memory Midtown. No fc. Slowly regaining strength.” [ECF 9-2] at 12 (emphasis added). The second document, which the CSM also previously referenced in his “Fact” section, is Dr. Yang’s notes from her May 3, 2019, assessment of Flowers. *See* [ECF 9-2] at 88. Based on the medical records, the CSM determined that Flowers “*consistently* claimed to have begun experiencing neurologic symptoms within a day or two of vaccination—even as soon as the very same day.” *Flowers*, 2024 WL 2828211, at *11 (emphasis in original).

In addition to citing to multiple sources within Flowers’ medical records in support of his conclusion that her GBS symptoms began less than three days after vaccination, the CSM explains why he was not persuaded by the arguments of her expert medical witness, Dr. Simpson. *Flowers*, 2024 WL 2828211, at *11. First, although the CSM concedes that certain references in the contemporaneous record regarding the onset of Flowers’ GBS are “nonspecific and vague,” he maintains that his determination regarding onset is supported by “*all of the evidence*.” *Id.* (emphasis in original). According to the CSM, terms such as “since” and “shortly after” have been interpreted by other special masters as meaning “*very close in time—immediately, or at most within a day or two*.” *Id.* (emphasis in original). Additionally, the CSM contends that, in the context of assessing a petitioner’s claim that a vaccine caused a shoulder injury, similar language has been interpreted as meaning within the first 48 hours following vaccination. *Id.* Therefore, he reasons that, because the Vaccine Program does not outright dismiss or reject such vague language in the context of onset timing, it—coupled with other evidence—not only deserves consideration, but in this case supports a finding that onset of Flowers’ GBS occurred “less than three days of vaccination, and perhaps as early as the same day.” *Id.*

Next, the CSM criticizes Dr. Simpson for failing to distinguish between when Flower’s GBS could be diagnosed and when onset occurred. *Flowers*, 2024 WL 2828211, at *12. Citing the Act, the CSM contends that “onset occurs at first manifestation of a symptom, *regardless* of whether the disease it fortells could be diagnosed at that time—and thus whether the onset symptoms would be clearly understood to reflect the start of the illness.” *Id.* (emphasis in original). The CSM also avers that “there is a distinction between the start of an acute and

¹⁵ Mr. Sestrich’s title is not clear from the record.

monophasic illness like GBS, and when it reaches nadir (as the Table reflects).” *Id.* In other words, the CSM contends that, while GBS may first appear in an individual at an earlier date, the key for purposes of the Act is to determine when onset or the first manifestation of symptoms occurs. *Id.* The CSM therefore finds that “[h]ere, the evidence preponderantly establishes that not only was [Flowers] experiencing sufficiently-alarming neurologic symptoms to seek treatment for them eleven days post-vaccination, but that *at that time and consistently thereafter* she reported they had begun no later than a day after vaccination.” *Id.* (emphasis in original).¹⁶

Finally, the CSM concedes that Dr. Yang’s May 2019 records may be internally inconsistent as to the date of onset, or identify the wrong vaccination date. *Flowers*, 2024 WL 2828211, at *12. Nevertheless, the CSM states that “there [are] ample records much closer in time to vaccination suggestive of an early onset, [including] some that even pinpoint it as the same day.” *Id.* *Flowers*, 2024 WL 2828211, at *12. Thus, despite the issues raised by Flowers relating to the inconsistent medical records, the CSM concludes: “It remains the case that overall, preponderant evidence is not favorable to [Flowers’] onset contention.” *Id.*

In her motion for review, Flowers challenges the CSM’s onset timing conclusion on multiple grounds, but none have merit. First, Flowers challenges the CSM’s interpretation of the terms “since,” “shortly after,” or “following” within her medical records. It is not, however, this Court’s role to reassess or reweigh the evidence. *See Cedillo v. Sec’y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (“We do not sit to reweigh the evidence. [If] the Special Master’s conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.”) (internal quotation marks omitted) (alteration in original). As detailed above, the CSM’s finding that Flowers’ GBS symptoms first appeared within three days of vaccination was rationally based on statements in her medical records.¹⁷ Significantly, the CSM credits Flowers’ own account of when her

¹⁶ The CSM cites to Flowers’ Discharge Summary dated November 14, 2018, to support this statement. *See Flowers*, 2024 WL 2828211, at *12 (citing [ECF 9-7] at 88). The Discharge Summary states that Flowers was “[a]dmitted to ESJH on 11/9/2018 for c/o par[esthesias and LE weakness x 3 days. Prior to admission she lost balance and fell on her husband.” [ECF 9-7] at 88. While this document provides support for the portion of the CSM’s statement that Flowers experienced sufficiently-alarming neurologic symptoms to seek treatment eleven days post-vaccination, it does not provide support for the portion stating that “*at that time and consistently thereafter* she reported they had begun no later than a day after vaccination.” *See Flowers*, 2024 WL 2828211, at *12 (emphasis in original). The Court views this omission as harmless error because, throughout the CSM’s decision, he cites to the record evidence to support his finding that Flowers had reported that her symptoms began less than three days after vaccination.

¹⁷ “Medical records, in general, warrant consideration as trustworthy evidence.” *Cucuras v. Sec’y of Dep’t of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). That is because “[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions[at a time when, with] proper treatment hanging in the balance, accuracy has an extra premium.” *Id.* Further, [t]hese records are also generally contemporaneous to the medical events.” *Id.*; *accord Paluck v. Sec’y of Health & Hum. Servs.*, 786 F.3d 1373, 1383 (Fed. Cir. 2015) (noting the importance of contemporaneous medical records in vaccine cases); *see also Canuto v. Sec’y of Health & Hum. Servs.*, 660 F. App’x 955, 958 (Fed. Cir. 2016) (noting that “[b]ecause of their impartial nature, medical records strongly ‘warrant consideration as trustworthy evidence’”); *Simanski v. Dep’t of Health & Hum. Servs.*, 601 F. App’x 982, 987-88 (Fed. Cir. 2015) (“And to the extent that the finding relied on medical records from treating physicians, we note that we have held such records can be ‘quite probative’ or ‘favored’ when considering issues relating to claims under the Vaccine Act.”); *Zatuchni v. Sec’y of Health & Hum. Servs.*, 69 Fed. Cl. 612, 624 (2006) (stating that the petitioner’s documentary evidence was “especially thorough and compelling,

symptoms began—as memorialized in the notes made by the doctors, nurses, and other providers who treated her starting on November 6, 2018, when she visited the TP-ACC to complain of her post-vaccination symptoms and ending on May 3, 2019, when she followed up with Dr. Yang for a neurology consultation. That other special masters have interpreted these terms differently in other cases does not establish that the CSM’s interpretation in this instance was irrational—a fact Flowers appears to concede when she states that “[d]ecisions in this Court have previously held that nonspecific reports regarding the timing of onset *do not always* require a determination that onset occurred within 2 days of a vaccination.” [ECF 43] at 9 (emphasis added). In each case, it is up to the special master to determine when onset occurred based on the preponderance of the evidence. Thus, the presence of nonspecific terms in Flowers’ medical records does not mandate that the CSM or this Court reach any particular conclusion regarding onset. In this case, the CSM’s conclusion regarding onset timing hinged on his overall assessment of and assignment of weight to the record evidence, not on the application of a rule governing nonspecific or vague onset references in the medical records.

Next, Flowers challenges the CSM’s crediting certain medical records over Flowers’ own testimony and that of her immediate family members. This argument, too, is without merit. Here, Flowers argues that her testimony and that of “her husband and daughter are ‘consistent, clear, cogent, and compelling’ as to the fact that [her] GBS symptoms did not arise until well after three days following her flu vaccination,” and that “[s]uch testimony should be particularly controlling since it is wholly consistent with the November 6, 2018 medical record reporting that Petitioner’s GBS symptoms developed at least a week after her flu vaccine.” [ECF 43] at 12. Flowers states: “Such testimony is not refuted by facially inaccurate, vague and/or self-contradictory statements regarding onset made by her healthcare providers in her subsequent medical records, but is instead corroborated by the November 6, 2018[,] medical record.” *Id.* Once more, Flowers asks the Court to reweigh the evidence that was before the CSM, which is not something this Court can or will do. Also, simply because the CSM relied upon contemporaneous medical records that were arguably vague as to when Flowers first began to experience GBS symptoms does not mean that these records were inaccurate or self-contradictory. In sum, the CSM’s conclusions are not rendered irrational because he placed more evidentiary weight on certain medical records than on Flowers’ own testimony or that of her family.¹⁸ *See Giles v. Sec’y of the Dep’t of Health & Hum. Servs.*, 37 Fed. Cl. 525, 541 (1997) (noting that “the special master was fully within his discretion to believe the contemporaneous medical records over recollection testimony offered by the petitioners”), *aff’d sub nom. Giles v. Sec’y of Health & Hum. Servs.*, 168 F.3d 1316 (Fed. Cir. 1998).

consisting of the medical records of the many physicians who examined [her], or who reviewed the history of [her] symptoms and provided their medical opinion”).

¹⁸ In his decision, the CSM referenced the affidavits of Flowers and her family members only one time—in a footnote when summarizing Flowers’ arguments. Nevertheless, the CSM is not required to discuss every piece of evidence or testimony in the record, so long as the decision makes clear that he fully considered Flowers’ arguments. *See Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 728 (2009). The Court “generally presume[s] that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.” *Moriarty v. Sec’y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016). Here, it is clear from the decision that the CSM fully considered Flowers’ position regarding the onset of her GBS symptoms, and, while the CSM only referenced the affidavits one time in a footnote, the Court presumes that the CSM considered the affidavits in reaching his conclusions.

Lastly, Flowers contends that the CSM failed to consider and give “controlling weight” to Dr. Simpson’s testimony regarding onset. [ECF 43] at 13. Regarding onset, Flowers further argues that the CSM’s reliance on Dr. Yang’s notes from her May 3, 2019, visit was arbitrary because the records were created more than six months after Flowers received her vaccine and because Dr. Yang mistakenly stated that Flowers “received her shot on October 28, 2018 (versus October 2[6], 2018).” *Id.* However, according to the CSM, he discounted Dr. Simpson’s testimony regarding the onset of Flowers’ symptoms in part because he was not persuaded by his arguments and in part because he found that the Korean study Dr. Simpson relied upon lacked scientific or medical support. Just because Dr. Simpson’s testimony was not directly refuted by a government expert witness does not mean that the CSM must accept it. Furthermore, as explained above, the CSM conceded that Dr. Yang’s May 2019 records identify the wrong vaccination date. *Flowers*, 2024 WL 2828211, at *12. Despite this deficiency, he concluded that there are “ample records much closer in time to vaccination” that demonstrate that Flowers experienced an early onset of the GBS symptoms—a conclusion that is supported by the record evidence.¹⁹ *Id.* In sum, the CSM provided a rational explanation for his rejection of Dr. Simpson’s testimony, as well as his interpretation of and reliance on the medical records. While Flowers may not agree with the CSM’s assignment of weight to the record evidence, such disagreement does not demonstrate that the CSM acted arbitrarily or capriciously. *See Stricker v. Sec’y of Health & Hum. Servs.*, 170 Fed. Cl. 701, 716 (2024) (noting that “mere disagreement is not an adequate basis for rejecting a special master’s reasoned conclusion”).

B. The CSM’s Determination That Flowers’ GBS Was Not a Non-Table Injury

Flowers also objects to the CSM’s determination that her GBS did not qualify as a non-Table injury. [ECF 43] at 14. According to Flowers, because the government does not contest the fact that the flu vaccine can cause GBS, the first *Althen* prong (providing a medical theory causally connecting the vaccination and the injury) has been satisfied.²⁰ *Id.* at 16. Flowers also contends that the second *Althen* prong (providing a logical sequence of cause and effect showing that the vaccination was the reason for the injury) has been satisfied because her expert, Dr. Simpson, testified that her GBS was likely caused by her flu vaccine. *Id.* at 18. Lastly, Flowers argues that the third *Althen* prong (providing a showing of a proximate temporal relationship between vaccination and injury) has been satisfied because she has established a proximate temporal relationship between her vaccination and GBS. *Id.* at 19. Regarding the third prong, Flowers contends that there exists preponderant proof that the onset of her symptoms occurred within the medically accepted timeframe such that causation-in-fact may be inferred. *Id.* In support of her argument, Flowers points to the 2017 Korean National Immunization Program study that Dr. Simpson relied upon, as well as “other cases decided by this Court in which GBS developed less than three days after vaccination.” *Id.*

The Court finds that the CSM’s determination that Flowers’ GBS was not a non-Table injury was not arbitrary or capricious. The CSM concluded that Flowers failed to satisfy the third

¹⁹ The CSM correctly noted in his decision that Flowers was vaccinated on October 26, 2018.

²⁰ The CSM does not discuss the first *Althen* prong in his decision.

Althen prong “because a one to two-day onset (or even sooner) has not been shown to be medically acceptable.” *Flowers*, 2024 WL 2828211, at *12.²¹ The CSM begins his analysis by stating that the Table’s timeframe “*best captures* the most likely period in which vaccine-caused GBS would begin, based on the most persuasive and reliable science currently available.” *Id.* (emphasis in original). In his view, special masters should not extend this timeframe simply because an expert opines otherwise, noting that “to do so would eliminate the distinction between Table and non-Table claims entirely.” *Id.* Rather, the CSM contends that when petitioners seek to establish that a shorter timeframe is medically acceptable, they must explain why “*the specific facts of their case* suggest a faster onset would occur.” *Id.* (emphasis in original). According to the CSM, “this occurs only where other factors establish that some synergistic combination of causes involving the vaccine and the claimant’s own preexisting health likely caused a faster immune stimulation process.” *Id.* In this case, the CSM concludes that “the kind of special factors evidenced from the medical record that would render a short onset more acceptable are absent.” *Id.* Additionally, the CSM notes that Dr. Simpson does not identify any special factors unique to Flowers that would support a finding that she suffered an earlier than usual onset of GBS and that the Korean study he cited “only reveals that a different country’s vaccine compensation program *paid* damages in a few cases involving short onset, with no discussion of whether such an onset actually had scientific or medical support.” *Id.* at *13 (emphasis in original).²²

Flowers’ challenge to the CSM’s review of her GBS as a non-Table injury fares no better than her challenge to his review of her GBS as a Table injury. Regarding the CSM’s analysis under the third *Althen* prong, Flowers argues that “there is no credible evidence that [her] GBS-related symptoms occurred less than three days after her flu vaccine,” and that even if her symptoms did begin two days after vaccination, the Korean study cited by Dr. Simpson found that 54.2% of the individuals studied experienced symptoms within two days of receiving the vaccination. [ECF 43] at 19. In support of her position, Flowers cites three “other cases decided by this Court in which GBS developed less than three days after vaccination.” *Id.* (citing *Block v. Sec’y of Health & Hum. Servs.*, 2021 WL 2182730 (Fed. Cl. Apr. 26, 2021); *Garcia v. Sec’y of Health & Hum. Servs.*, 2008 WL 5068934 (Fed. Cl. Nov. 12, 2008), *adh’d to on recons.*, 2010 WL 2507793 (Fed. Cl. May 19, 2010); *Lehrman v. Sec’y of Health & Hum. Servs.*, 2018 WL 1788477 (Fed. Cl. Mar. 19, 2018)). First, none of the cases cited by Flowers are persuasive, as

²¹ Although unnecessary to his conclusion that Flowers fails to establish that her GBS was an off-Table injury, the CSM also concludes that Flowers fails to satisfy the second *Althen* prong. *Flowers*, 2024 WL 2828211, at *13. To satisfy the second prong, Flowers was required to establish a logical sequence of cause and effect from vaccine to injury that is supported by the record evidence. *Lozano v. Sec’y of Health & Hum. Servs.*, 958 F.3d 1363, 1371 (Fed. Cir. 2020). In the CSM’s view, although certain individuals who treated Flowers noted that she was vaccinated before her symptoms appeared, they did not opine on a causal relationship. *Id.* He also notes that the record does not contain any testing or clinical observations that would support a finding of causation. *Id.* Furthermore, the CSM states that “[u]ltimately, [Flowers’] treaters did not coalesce around vaccination as the reason for her GBS.” *Id.* These findings are supported by the record evidence. *See* [ECF 9-7] at 106 (Dr. Kumar noting that Flowers’ symptoms are not typical for GBS variant); [ECF 9-2] at 88 (Dr. Yang noting the same); [ECF 9-2] at 124 (test results showing findings as typically seen with diabetes mellitus).

²² The CSM further notes that he came to the same conclusion in a previous vaccine petition where Dr. Simpson was similarly offered as an expert witness and cited the Korean study in support of his theory of causation. *Flowers*, 2024 WL 2828211, at *13.

they are not binding on this Court and are based on distinguishable facts.²³ While these cases demonstrate that it is possible for a petitioner to demonstrate that a shorter onset timeframe is medically acceptable—a point that the CSM acknowledges in his decision—they do not mandate a particular outcome based on the facts and record evidence in the instant case. Further, under the third prong, Flowers is “required to establish the timeframe for which it is medically acceptable to infer causation.” *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011). Here, as noted by the CSM, Flowers has not explained how or provided any evidence demonstrating that in this case, in an exception to the generally accepted timeframe for the onset of symptoms, the flu vaccine caused her to experience GBS symptoms less than three days after vaccination. The Court will not assess whether the CSM correctly evaluated Dr. Simpson’s opinion or the Korean study in this regard. *See Munn*, 970 F.2d at 871. Based on this record, the CSM rationally concluded that Flowers did not satisfy the third *Althen* prong because she failed to establish the medical acceptability of her early onset. *See Martinez v. Sec’y of Health & Hum. Servs.*, 165 Fed. Cl. 76, 88 (2023) (noting that “cases in which onset occurs too early fail *Althen* prong three because, as with late onset cases, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked”) (internal quotation marks omitted).

V. CONCLUSION

Flowers has not demonstrated that the CSM’s decision was arbitrary or capricious. Therefore, Flowers’ motion for review of the CSM’s decision [ECF 43] is **DENIED**, and the CSM’s entitlement decision of May 8, 2024, is **SUSTAINED**. The Clerk of the Court is **DIRECTED** to enter judgment accordingly.

IT IS SO ORDERED.

s/ Thompson M. Dietz
THOMPSON M. DIETZ, Judge

²³ For example, in *Garcia*, the vaccine at issue was not the flu vaccine, but rather a vaccination for tetanus. *Garcia*, 2008 WL 5068934, at *1. There, the special master found that the petitioner’s “diarrheal illness pre-primed [p]etitioner’s immune response, such that when Petitioner received the tetanus vaccine, his immune system was highly reactive” and that “the tetanus vaccine, once administered, [] triggered an over-reactive autoimmune response that led Petitioner’s immune system to attack his own nervous system, resulting in symptomatology best described as the syndrome known as Guillain–Barré Syndrome.” *Id.* at 10. In *Lehrman*, although the Special Master concluded “that the petitioner had an abrupt onset of atypical GBS within 24 hours of his flu vaccine,” *Lehrman*, 2018 WL 1788477, at *14, he did so based on an extensive evidentiary record, which included the petitioner’s own testimony, petitioner’s medical records, the reports of petitioner’s two expert neurologists, and the reports of respondent’s expert neurologist, and medical literature, *id.* at *1. Furthermore, the petitioner in *Lehrman* “suffered from a [upper respiratory infection] shortly before receiving his flu vaccination” which “caused an aberrant response or acted in a synergistic manner.” *Id.* at 19. Lastly, in *Block*, the CSM did not—as Flowers suggests—hold that the petitioner’s GBS developed within three days of her vaccination. Rather, the CSM held that, based on Dr. Simpson’s expert testimony plus his reliance on the Park study, that the petitioner had “offered *barely* enough evidence on the third *Althen* prong . . . to allow the claim to go forward for now.” *Block*, 2021 WL 2182730, at *9 (emphasis in original). The CSM added: “Respondent will be given the opportunity now to file an expert report or other evidence rebutting the contention that a one-day onset is medically acceptable—and if he does so, the balance will likely tip against Petitioner.” *Id.* In fact, both parties submitted additional materials after this decision issued and the CSM ultimately found that the petitioner was unable to establish causation-in-fact under *Althen* and dismissed her non-Table claim. *Block v. Sec’y of Health & Hum. Servs.*, 2021 WL 5709764, at *6 (Fed. Cl. Oct. 29, 2021).