

BACKGROUND

The Special Master's decision in this case contains a comprehensive and thorough discussion of all of the evidence of record. What follows is a summary of those aspects of the record most pertinent to the issues raised in Ms. Chinae's petition for review.

I. The Evidence Regarding Ms. Chinae's Health Between Her Flu Vaccination and the Diagnosis of GBS Three Months Later

On October 31, 2012, Ms. Chinae (then fifty-six years old) underwent a routine physical with her primary care physician, Dr. Sergio Neira. Pet'r's Ex. 1, at 1, 43, Docket No. 7 (Dr. Neira's Health Screening Report). Dr. Neira's notes reflect that Ms. Chinae was experiencing allergy-related wheezing, and he recorded her then-current conditions of conductive hearing loss, fatigue, and post-herpetic neuralgia. Id. at 11–12. Ms. Chinae received a flu vaccination in her left deltoid during the same visit. Id. at 1, 43.

At the time of the vaccination, Ms. Chinae served as Director of Activities for Alma Joy Villa, a residential facility for the elderly that she opened in 2009. Hr'g Tr. at 7, 17, Docket No. 83. Ms. Chinae has described herself as a "healthy and vibrant individual with abundant energy" before the vaccination, and characterized her life as a busy and active one. Pet'r's Decl. at 2, Docket No. 2; Hr'g Tr. 6–7; see also Hr'g Tr. 127–29 (testimony of Mr. Chinae, Ms. Chinae's husband, describing her usual high energy level); Hr'g Tr. 186–87 (testimony of a friend describing Ms. Chinae as "a dynamo").

Ms. Chinae testified that a week or two after she received her flu vaccination she began experiencing a lack of energy. Hr'g Tr. at 19, 52, 80. She recalled missing a meeting in mid-November because she overslept. Id. at 23. She testified that on Thanksgiving, she "didn't have much energy" and was unable to participate in her usual holiday activities. Id. at 26. A friend testified that during a Thanksgiving celebration they both attended, Ms. Chinae was quiet, tired, and walking slowly. Id. at 170–71, 175; see also id. at 192–93 (another friend describing Ms. Chinae as "exhausted" and "quiet" during Thanksgiving holiday). Ms. Chinae recalled that in addition to a lack of energy during this time period, she was experiencing a heightened sensitivity to touch, the sensation of an "overgrown" tongue, and a metallic taste in her mouth, as well as intermittent tingling in her hands and toes, among other symptoms. Id. at 23–31.

The record also contains testimony concerning Ms. Chinae's state of health in December 2012. According to her declaration, Ms. Chinae was unable to participate in annual church celebrations that month because she "was not feeling well." Pet'r's Decl. at 3. She also recalled experiencing extreme fatigue that limited her involvement at a family Christmas gathering. Id.; see also Hr'g Tr. 111–13 (testimony of friend regarding Ms. Chinae's lack of energy during two social engagements in December). One family friend testified that at a dinner at Outback Steakhouse in December 2012, Ms. Chinae "started gasping for breath and choking" on a piece of meat. Hr'g Tr. at 46–47, 196–97.

Ms. Chinae submitted five declarations from family members and friends, attesting to the fact that she had decreased energy during the early weeks of November, and that the fatigue continued into December. See generally Pet'r's Ex. 61–65, Docket No. 62. The declarants also

referenced other symptoms they observed Ms. China suffering from during this time period, including voice problems, arm pain, low stamina, shortness of breath, and loss of appetite. Pet'r's Ex. 61, at 4 (Hovarth Declaration); Pet'r's Ex. 62, at 4 (Neilson Declaration); Pet'r's Ex. 63, at 4 (Garay Declaration); Pet'r's Ex. 64, at 4 (Calderon Declaration); Pet'r's Ex. 65 at 6–7 (Carrillo Declaration).

Notwithstanding these symptoms, the record reflects that Ms. China did not seek any medical treatment during November and December other than with her gynecologist, Dr. Adrienne Lara. On December 10, 2012, Ms. China visited Dr. Lara for her annual exam. Pet'r's Ex. 4, at 3, Docket No. 7 (Dr. Lara's Physical Examination Report). Dr. Lara's notes of that visit do not contain any mention of non-gynecological complaints such as weakness, fatigue, or tingling of the limbs. Id. at 4. To the contrary, her exam notes indicate that Ms. China "continues to be successful and it is going to be a good year" and that "[t]here was nothing else on her mind." Id. Ms. China had a follow-up appointment with Dr. Lara on December 21. Id. at 1–2. Dr. Lara did not document any non-gynecological complaints during this visit either. Id.

Ms. China testified at the hearing that, despite the absence of any mention of non-gynecological symptoms in Dr. Lara's notes, she discussed her lack of energy and other symptoms with Dr. Lara during the December 2012 appointments. Hr'g Tr. at 34; see also Pet'r's Decl. at 3 (stating that at the December appointments Ms. China told Dr. Lara about her loss of energy, as well as other symptoms, including hoarse voice and difficulty swallowing). Ms. China also submitted typewritten notes into the record that she alleged she had written before her appointments with Dr. Lara. Pet'r's Ex. 82 and 83, Docket No. 81 (Ms. China's notes); Hr'g Tr. at 34–35. The notes, dated December 10, 2012, reflect that Ms. China wished to secure "guidance and support" regarding a number of medical problems, including exhaustion, severe arm pain, lack of appetite, and a feeling of "coldness." See Pet'r's Ex. 82–83.

In addition, Ms. China submitted a November 2014 letter signed by Dr. Lara. See Pet'r's Ex. 4. In the letter, Dr. Lara stated that during the December 2012 appointments Ms. China had reported "significant loss of energy on a daily basis" as well as, among other things, hoarseness, throat swelling and difficulty swallowing, numbness of the extremities and sensitivity to cold, and weakness in her wrists and arms. Id. at 24. Dr. Lara also stated in her letter that Ms. China was "depressed and tearful" during the appointment. Id.¹

In mid-January, Ms. China began to experience watery eyes and respiratory symptoms that she initially believed were caused by an allergic reaction to a cat. Id.; Pet'r's Ex. 7, at 4–5, Docket No. 8 (Community Memorial Health System History and Physical Report). On January 27, 2013, Ms. China was unable to make remarks at a book-signing event because her voice "was totally [gone]"—i.e., it was "very raspy and very deep." Hr'g Tr. at 51. By January 28, Ms. China began to experience "profound weakness" as well as other symptoms, including headaches, dizziness, balance issues, congestion, and problems with her voice. Pet'r's Ex. 7, at 4;

¹ In an August 2016 deposition, Dr. Lara attempted to explain the discrepancy between her contemporaneous notes and the representations made in her November 2014 letter. She testified that the reason she had not included the additional symptoms in her records of the December 2012 visits was because the exams were focused on gynecological issues. See Docket No. 58 at 9–10, 21–22 (Deposition of Dr. Adrienne Lara).

Pet'r's. Ex. 1, at 40. On January 29, Ms. China recalled "seeing double" when she ran into a neighbor's garage with her car. Pet'r's Decl. at 3.

On January 30, 2013, Ms. China's husband called Dr. Neira for guidance in light of Ms. China's worsening condition. *Id.* He reported that his wife's symptoms included a fever of ninety-nine degrees, weakness, a headache, dizziness, two days of congestion that had worsened the previous night, and an inability to get out of bed. *Id.* In response, Dr. Neira's office prescribed Tamiflu. Pet'r's Ex. 1, at 39.

II. The GBS Diagnosis and Treatment

On January 31, 2013, Ms. China went to the emergency room at Community Memorial Health System. Special Master's Decision ("SM Dec.") at 3, 9, Docket No. 89; Pet'r's Ex. 7, at 4. At that time, she could not walk, stand, or keep her head up, and she had difficulty swallowing. Pet'r's Ex. 7, at 4; Pet'r's Decl. at 4. She complained of "generalized weakness" and reported the upper respiratory symptoms that had begun in mid-January. Pet'r's Ex. 7, at 4. A physical examination showed slurred speech, slow movements in all four limbs, absent deep tendon reflexes, decreased muscle strength, and paresthesia of the hands and feet. *Id.* at 5.

Mr. China provided information for the emergency room intake notes. *See* Hr'g Tr. at 56–58. The notes characterize Ms. China as having been in her "normal state of health" until approximately a week earlier. *Id.* at 8, 10. At the hearing, Ms. China rejected the characterization of her health as having been "normal" until a week earlier. *Id.* at 60–61, 63–64. She stated that the notes were misleading or inaccurate except to the extent that they referred to "how [she] used to be" (i.e., before November 2012). *Id.* at 88; *see also id.* at 138–39 (testimony of Mr. China to the same effect).

Ms. China was intubated and placed on ventilator support after emergency room doctors diagnosed acute respiratory failure with upper airway edema and diffuse neuromuscular weakness. *Id.* at 7–8. During a February 1, 2013 emergency room consultation, neurologist Dr. Francisco Torres opined that Ms. China "could have a clinical picture compatible with [GBS] given [her] flu-like symptoms and then diffuse generalized weakness" in the days preceding her visit to the emergency room. *Id.* at 11.

Ms. China subsequently tested positive for the GQ1B antibody, which is an antiganglioside antibody associated with the Miller-Fisher variant of GBS. *Id.* at 1–2, 52, 71–72; *see* I. Nachamkin, et al., Anti-Ganglioside Antibody Induction by Swine (A/NJ/1976/H1N1) and Other Influenza Vaccines: Insights into Vaccine-Associated Guillain-Barre Syndrome, 198 J. Infect. Disease 226 (2008), filed as Pet'r's Ex. 39, Docket No. 32 ("Nachamkin"). As a result, she was treated with a five-day course of intravenous immunoglobulin ("IVIG"). Pet'r's Ex. 7, at 2, 72.

On February 15, Ms. China was extubated and monitored for treatment success. *Id.* at 2. She was discharged and transferred for acute inpatient rehabilitation on February 26 with a final hospital diagnosis of GBS, Miller-Fisher variant. *Id.*; *see also* Pet'r's Ex. 6, at 10, Docket No. 7 (Rehabilitation Discharge Summary).

The fact that Ms. Chinae had received a flu shot was noted by hospital personnel on the day she was admitted. See Pet'r's Ex. 7, at 4 (comments by Dr. Diane Li in medical history and physical report dated January 31, 2013, noting that Ms. Chinae "did receive a flu shot this season"). Ms. Chinae's hospital records contain no indication, however, that any of her treating physicians suspected that there was a connection between the vaccine and her GBS.²

Over the next few months, Ms. Chinae received further treatment for her GBS. See, e.g., Pet'r's Ex. 1, at 7–10; Pet'r's Ex. 3, at 11–14, Docket No. 7 (Neurologist Medical Report). Ms. Chinae's GBS symptoms substantially subsided by the end of 2013, though she continued to receive physical therapy through 2014. Pet'r's Ex. 3, at 15–17; Pet'r's Ex. 10, at 14. But see Pet'r's Ex. 9 (letter from Dr. Neira indicating that Ms. Chinae had not recovered completely as of July 2014).

III. The Vaccine Claim

On January 30, 2015, Ms. Chinae filed a petition for compensation under the Vaccine Act in the Court of Federal Claims. Pet'r's Pet. for Compensation, Docket No. 1. She alleged that the flu vaccination she received on October 31, 2012 caused her GBS. Pet'r's Decl. at 1. The case was assigned to Chief Special Master Denise Vowell on January 30, 2015. Docket No. 5. On February 17, 2015, both parties filed a Joint Statement of Completion, and thereafter filed additional medical records. Docket Nos. 10, 14–17, 22–24, 29–30, 34. The HHS Secretary filed a Rule 4(c) report asserting that Ms. Chinae was not entitled to compensation on December 1, 2015. Docket No. 41.

Ms. Chinae and the Secretary filed expert reports on August 21, 2015 and December 1, 2015, respectively. Docket Nos. 31, 42. Pursuant to the Special Master's request to supplement the record with additional expert support, Ms. Chinae filed a second report prepared by her expert, Dr. Lawrence Steinman, on February 16, 2017. Docket No. 64. The Secretary responded with a supplemental report from his expert, Dr. Peter Donofrio, on April 24, 2017. Docket No. 65. On January 16, 2018, the case was reassigned to Special Master Brian Corcoran. Docket Nos. 68–69.

² The Court notes that during a June 2013 appointment with Dr. Neira, Ms. Chinae told him that one of the hospital's doctors had told her that her GBS was an adverse reaction to the flu vaccine. Pet'r's Ex. 1, at 7. Then, in a report prepared during a follow-up visit in October 2013, Dr. Neira noted that the GBS "may have been caused by [the] flu vaccine" and advised that Ms. Chinae not receive any flu vaccinations in the future. Id. at 73, 77. Dr. Neira's final VAERS report similarly stated that Ms. Chinae had experienced fatigue and other symptoms before Thanksgiving 2012, and posited that the onset of GBS was connected to the October 2012 flu vaccine. Pet'r's Ex. 10, at 17, Docket No. 14 (VAERS Email Correspondence); see Pet'r's Ex. 9, at 1–5, Docket No. 8 (VAERS Supplemental Report). The onset date for Ms. Chinae's GBS symptoms, however, was reported as January 31, 2013. Pet'r's Ex. 2, at 2.

IV. The Expert Testimony

A hearing was held on Ms. Chinae's claim on August 6 and 7, 2018. See Docket No. 82. In addition to the testimony of Ms. Chinae and four other lay witnesses, each party presented expert testimony regarding the critical issue of whether Ms. Chinae's GBS was caused by the flu vaccination she received on October 31, 2012.

Dr. Lawrence Steinman testified as Ms. Chinae's expert.³ According to Dr. Steinman, Ms. Chinae exhibited symptoms of GBS as early as Thanksgiving 2012 when she experienced double vision, fatigue, taste disturbance, voice hoarseness, feelings of tingling/cold, and swallowing difficulties. Hr'g Tr. 234–40. He attributed these symptoms to inflammation of various nerves typically affected by GBS. Id. at 236, 240–41, 277–78. Dr. Steinman conceded that the relatively long gap between the vaccination and Ms. Chinae's hospitalization was "atypical," but proposed that her GBS "smoldered" for weeks before it became acute, resulting in Ms. Chinae's visit to the emergency room. Id. at 251–52. Alternatively, he testified, he could support the theory of an eleven- or twelve-week onset for GBS resulting from a flu vaccination. Id. at 256–57.

Dr. Peter Donofrio testified on behalf of the Secretary.⁴ Dr. Donofrio testified that GBS symptoms typically progress "fairly rapidly," and that common symptoms are numbness/tingling, weakness in upper and lower extremities, lower back pain, absent reflexes, and unsteady gait. Id. at 304–05, 311–12. In his view, generalized fatigue is a symptom that may result after a "full-blown" bout of GBS; it is not a pre-acute presenting symptom of GBS. Id. at 312. He thus disputed Dr. Steinman's assertion that Ms. Chinae's GBS "lurked" for months before reaching its nadir. Id. at 316, 353–55. Instead, Dr. Donofrio concluded, the likely onset of Ms. Chinae's GBS occurred closer to her January 2013 hospitalization, thus falling beyond the six- to eight-week period that he testified was the medically appropriate timeframe for the occurrence of vaccine-induced GBS. Id. at 322–23, 334; Resp't's Ex. A, at 8, Docket No. 42 ("Donofrio Report"); Resp't's Ex. F, at 3, Docket No. 65 ("Donofrio Supplemental Report").

³ Dr. Steinman obtained his medical degree from Harvard Medical School, where he completed a fellowship in chemical neurobiology. Hr'g Tr. at 214; see also CV, filed as Ex. 76 (Docket No. 74–1) ("Steinman CV") at 1. After medical school, Dr. Steinman went on to complete pediatrics and neurology residencies at Stanford University. Hr'g Tr. at 214; Steinman CV at 1. He then joined the faculty at Stanford in 1980, where he presently serves as the George A. Zimmerman Professor of Neurological Sciences, Neurology, Genetics, and Pediatrics. Hr'g Tr. at 216; Steinman CV at 1.

⁴ Dr. Donofrio is a professor of neurology and director of the MDA and ALS clinics at the Vanderbilt University Medical Center. Hr'g Tr. at 301. He received his B.S. at the University of Notre Dame, and then attended the Ohio State University School of Medicine for his M.D. Id. He is board certified in neurology, internal medicine, electrodiagnostic medicine, and neuromuscular disorders. CV, filed as Ex. B (Docket No. 42–2) ("Donofrio CV") at 3.

V. The Special Master's Decision

On March 15, 2019, the Special Master issued an opinion ruling that Ms. Chinae was not entitled to compensation under the Vaccine Act. SM Dec. at 45, Docket No. 89. In reaching his conclusion, the Special Master applied the three-prong test for establishing causation set forth by the Federal Circuit in Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Noting the “well-established” connection between the flu vaccine and GBS, the Special Master found preponderant evidence of a medical theory causally connecting the flu vaccine to GBS, thus satisfying prong one of Althen. SM Dec. at 40. The Special Master determined, however, that Ms. Chinae had not satisfied prong three of Althen because the onset date of her GBS (mid-to-late January 2013) was too long after the administration of her October 2012 flu vaccination. See id. at 41.

The Special Master noted that it was undisputed that Ms. Chinae did not see a medical professional about her alleged GBS symptoms between the time she received her vaccination on October 31, 2012 and late January 2013. Id. He further observed that contemporaneous medical records did not corroborate that Ms. Chinae had complained to any doctor about those symptoms until late January. Id. In that regard, he found that Dr. Lara's November 2014 letter purporting to document symptoms not recorded in her December 2012 report lacked credibility. Id. at 41–42.

The Special Master found “more persuasive,” however, the testimony of Ms. Chinae's witnesses (whom he characterized as honest and credible). Id. at 42. Based on that testimony he concluded that Ms. Chinae did in fact suffer from “overall fatigue/malaise” beginning in November 2012 through January 2013, and that the symptoms about which she complained “affected her professional and social life.” Id.

Nonetheless, the Special Master concluded that “in light of what is known regarding [] typical GBS,” Ms. Chinae did not establish that any of the symptoms she suffered in November and December of 2012 “represented the onset of her subsequently-diagnosed GBS.” Id. Dr. Donofrio's testimony, he explained, “persuasively established that GBS is understood to be an acute-onset monophasic disease.” Id. Therefore, although some of Ms. Chinae's reported symptoms, such as malaise and fatigue, “could be secondarily associated with GBS,” they were not “presenting symptoms of the illness.” Id. (emphasis added).

Further, the Special Master rejected as unsupported by the medical literature Dr. Steinman's theory, which he characterized as positing the existence of “a smoldering form of GBS that could not only begin with secondary symptoms but thereafter progressively meander, only becoming acute over an eleven-week period, and long after the antibodies he deemed essential to the condition would have first been produced in reaction to the flu vaccine.” Id. at 43. The Special Master opined that “despite his immense credentials as an immunologist,” Dr. Steinman “does not have a current, demonstrated expertise in studying or treating GBS sufficient to breathe life into this theory.” Id.

The Special Master also found Dr. Steinman's overall credibility “greatly undercut” by certain comments he had made at the hearing, which the Special Master characterized as “stepp[ing] out of his role as medical/scientific expert and into the shoes of judicial ‘color commentator,’ expressing views about the proper apportionment of legal burdens and standards

applicable in the Vaccine Program, or making asides about his responsibilities as an expert based upon his understanding of the applicable legal standards.” Id. at 26–27, 43. In particular, the Special Master cited Dr. Steinman’s statements that he could “probably structure a theory” identifying the vaccine as a substantial cause of Ms. Chinae’s GBS even if another cause was identified, and suggesting that the method by which he would diagnose the cause of GBS “in the real world” is different from how he would do so in a Vaccine Program case, where he is tasked by petitioners to propose a vaccine cause. Id. at 26 (citing Hr’g Tr. at 217, 234, 265–66, 285, 287–88).

For these reasons, the Special Master concluded that the record did not support the conclusion that Ms. Chinae’s fall 2012 symptoms were GBS-related. He therefore found that the onset of her GBS occurred no earlier than January 20–28, 2013. Id. at 43. Given that finding, the Special Master concluded that Ms. Chinae had failed to show a proximate temporal relationship between the vaccine and GBS as required under Althen prong three. See id. at 45. He noted that the “most reliable medical literature offered in this case” sets a reasonable timeframe for GBS onset post-vaccine administration at no more than six to eight weeks (which is also the timeframe set for the Table version of the claim). Id. at 44. He determined that Ms. Chinae’s arguments in support of a longer timeframe “lack[ed] reliable support in science or fact.” Id.

In short, the Special Master concluded that “the evidentiary record does not support Petitioner’s contention that the flu vaccine she received in October 2012 caused her GBS in the timeframe proffered, or that the symptoms she experienced in November and December 2012 were manifestations of that GBS.” Id. at 45. He therefore dismissed Ms. Chinae’s claim. Id.⁵

VI. The Motion for Review

On April 12, 2019, Ms. Chinae, proceeding pro se, filed the present motion for review. See generally Pet’r’s Mot. For Review (“Pet’r’s Mot.”), Docket No. 94. Ms. Chinae’s central argument is that the Special Master erred in crediting the opinion of Dr. Donofrio over that of Dr. Steinman regarding the onset date of her GBS.

The government timely filed its response to Ms. Chinae’s motion on May 15, 2019. Docket No. 105. The motion is now fully briefed and ripe for review.

DISCUSSION

I. Jurisdiction

Congress established the National Vaccine Injury Compensation Program in 1986 to provide a no-fault compensation system for vaccine-related injuries and deaths. Figueroa v. Sec’y of Health & Human Servs., 715 F.3d 1314, 1316–17 (Fed. Cir. 2013). A petition seeking

⁵ Because he determined that “the timeframe for onset of [Ms. Chinae’s] GBS was too remote to be medically reasonable,” the Special Master found it unnecessary to undertake a detailed Althen prong two analysis. SM Dec. at 44 n.43. He noted, however, that in his view the record did not support a conclusion that the flu vaccine caused Ms. Chinae’s GBS because “[h]er symptoms . . . likely caused her January illness.” Id.

compensation under the Vaccine Act is filed in the Court of Federal Claims, after which the Clerk of Court forwards it to the Chief Special Master for assignment to a special master. 42 U.S.C. § 300aa-11(a)(1). The special master to whom the petition is assigned “issue[s] a decision on such petition with respect to whether compensation is to be provided under the [Vaccine Act] Program and the amount of such compensation.” *Id.* § 300aa-12(d)(3)(A). That decision is subject to review in the Court of Federal Claims in accordance with 42 U.S.C. § 300aa-12(e)(1). This Court, therefore, has jurisdiction over Ms. Chinaea’s motion for review of the Special Master’s adverse decision regarding her entitlement to compensation under the Vaccine Act.

II. Standard of Review

On review of a special master’s decision in a vaccine case, the Court applies the “arbitrary and capricious” standard to factual findings and the “not in accordance with law” standard to legal rulings. *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). “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 & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). The Court “do[es] not reweigh the factual 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 those “are all matters within the purview of the fact finder.” *Porter v. Sec’y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010)).

In short, “as long as a special master’s finding of fact is ‘based on evidence in the record that [is] not wholly implausible,’” the Court must uphold it. *Id.* (quoting *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (alteration in original)). This standard of review is “uniquely deferential” to special masters’ decisions. *Milik v. Sec’y of Health & Human Servs.*, 822 F.3d 1367, 1376 (Fed. Cir. 2016) (quoting *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)). “If the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision,’ then reversible error is ‘extremely difficult to demonstrate.’” *Id.* (quoting *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

III. Merits

A petitioner must prove by a preponderance of the evidence that a vaccine caused the injury at issue to secure compensation under the Vaccine Act for a non-Table injury. See 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1)(A); see also *Broekelschen*, 618 F.3d at 1342 (citing *Moberly*, 592 F.3d at 1321). Specifically, a petitioner must establish that the vaccine was both the “but-for” cause of the injury and a substantial factor in bringing the injury about. *Moberly*, 592 F.3d at 1321.

To prove causation, a petitioner must satisfy all three of the elements set forth by the Federal Circuit in *Althen*. Those elements are “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278. “Once the petitioner has

demonstrated causation, she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine.” Broekelschen, 618 F.3d at 1342 (citing Doe v. Sec’y of Health & Human Servs., 601 F.3d 1349, 1351 (Fed. Cir. 2010); 42 U.S.C. § 300aa-13(a)(1)(B)).

The Special Master’s dismissal of Ms. Chinae’s petition was based on his conclusion that she failed to satisfy Althen prong three, which, as noted, required her to prove a proximate temporal relationship between the vaccine and her GBS. SM Dec. 44–45. He held that a reasonable timeframe for the onset of GBS after a vaccination is six to eight weeks. Id. at 44. He further found that the onset of Ms. Chinae’s GBS occurred outside that time period, in the last week or so of January 2013 (eleven or twelve weeks after the vaccination). Id. at 43.

In her motion for review, Ms. Chinae does not appear to challenge the Special Master’s determination that six to eight weeks is a reasonable timeframe for the onset of GBS caused by a flu vaccine. Instead, she asks the Court to set aside the Special Master’s factual determination that the onset date for her GBS occurred a week or two before she went to the emergency room on January 31, 2013, rather than in November 2012, a few weeks after she received the vaccine. Pet’r’s Mot. at 2. She relies upon Dr. Steinman’s theory that—although the symptoms of her GBS did not become acute until the end of January 2013—she had symptoms of GBS as early as November 2012 and those symptoms “smoldered” until they became acute in late January 2013. Id. at 1–2. She contends that the Special Master erred in failing to credit Dr. Steinman’s opinion regarding the “atypical” nature of her illness and instead relying upon what she characterizes as the “orthodox” views of Dr. Donofrio. Id. at 2.

In light of this Court’s extremely narrow scope of review with respect to special masters’ factual findings, Ms. Chinae’s arguments do not provide a sufficient basis for reversing the Special Master’s decision. Where—as here—each side offers conflicting expert testimony, the Special Master is empowered to make a decision “based on the credibility of the experts and the relative persuasiveness of their competing theories.” Broekelshen, 618 F.3d at 1347. That is precisely what the Special Master did in this case.

It bears noting that—notwithstanding the absence of contemporaneous medical records—the Special Master credited the testimony of Ms. Chinae and her witnesses that she experienced “overall fatigue/malaise, inter alia, beginning in November 2012 and running into January 2013, and that these symptoms affected her professional and social life.” SM Dec. at 42. Nonetheless, the Special Master ruled that Ms. Chinae was not entitled to compensation under the Vaccine Act because he found that the record was “not supportive of the conclusion that Petitioner was experiencing nascent GBS in November or December 2012 . . . or that any of these earlier symptoms had anything at all to do with Petitioner’s late-January 2013 symptoms.” Id. at 42–43.

In so holding, the Special Master found Dr. Donofrio’s opinion more persuasive than that of Dr. Steinman. SM Dec. at 42. He also found Dr. Steinman’s credibility undermined by certain statements he made at the hearing, in which (as described above) he offered commentary on the legal standards that govern proof of causation under the Vaccine Act. Id. at 43. Indeed, the Special Master noted that he had criticized Dr. Steinman in previous cases “for testifying in this manner,” which he characterized as “wholly unhelpful and irrelevant.” Id. at 43 n.42.

Thus, Dr. Donofrio characterized GBS as “an acute-onset, monophasic disease.” *Id.* at 42. He testified that GBS typically evolves “fairly rapidly” (i.e., over several days) and that common presenting symptoms are numbness/tingling, weakness in upper and lower extremities, lower back pain, absent reflexes, and unsteady gait. Hr’g Tr. at 304–05, 311–12. He noted that “ninety percent of GBS patients reach the nadir of their illness between two and four weeks following onset, with a plateauing of symptoms thereafter.” SM Dec. at 27 (citing Hr’g Tr. at 304).

The course of Ms. China’s symptoms from November through January did not fit the pattern Dr. Donofrio described. The Special Master found persuasive Dr. Donofrio’s testimony that the kind of generalized fatigue Ms. China experienced starting in November 2012 is not a pre-acute presenting symptom of GBS, but rather is a symptom that can follow a “full-blown” course. *Id.* (citing Hr’g Tr. at 312). Relying on Dr. Donofrio’s testimony, the Special Master placed the onset of Ms. China’s GBS in mid-to-late January 2013, one or two weeks before she went to the emergency room. *Id.* at 43.

The Special Master found Dr. Steinman’s testimony, on the other hand, unpersuasive. Dr. Steinman agreed that the literature showed that a typical course of GBS includes paresthesia, pain, generalized weakness, sensory disturbances, unsteady gait, and loss of bowel function. *See, e.g.,* J. Menze, et al., *Textbook of Peripheral Neuropathy*, 167 (1st ed. 2012), filed as Pet’r’s Ex. 80, Docket No. 74 (“Menze”). Dr. Steinman explained that the Miller-Fisher variant of GBS also results in eye movement abnormalities and ataxia. Hr’g Tr. at 218, 239. He posited that while the course of Ms. China’s symptoms during November and December was “atypical,” it reflected that she experienced what he called a “smoldering” form of GBS. *Id.* at 232, 240–41, 299, 357, 359.

The Special Master rejected Dr. Steinman’s theory for several reasons. First, he noted that the theory was not recognized in the medical literature before him, including the literature upon which Dr. Steinman relied. SM Dec. at 43. For example, the Special Master found unavailing Dr. Steinman’s reliance upon J. Wanschitz, et al., *Distinct Time Pattern of Complement Activation and Cytotoxic T Cell Response in Guillain-Barre Syndrome*, 126 *Brain* 2034 (2003) (“Wanschitz”). *See* Pet’r’s Ex. 69, Docket No. 64. He observed that “literature like Wanschitz discussed purportedly longer timeframes for GBS only after a presentation sufficiently acute for a diagnosis, and was thus unhelpful in establishing GBS’s course measured from the time of the proposed insult (in this case, vaccination).” SM Dec. at 43. The Special Master similarly found unpersuasive a GBS textbook excerpt that Dr. Steinman cited which stated that once GBS is diagnosed, it could “progress for more than four weeks until it really bottoms out.” *Id.* at 25 (quoting Hr’g Tr. at 252). This text, the Special Master observed, “applies only to the course of GBS following its onset (which in this case would mean that Petitioner’s nadir should have been reached by the end of December at the latest—a month before Petitioner sought emergency treatment).” *Id.*

Further, the Special Master explained that Dr. Steinman had no “current, demonstrated expertise in studying or treating GBS sufficient to breathe life into his theory.” *Id.* at 43. He concluded that Dr. Steinman’s theory that Ms. China’s GBS first manifested itself in November 2012 and subsequently “smoldered” beneath the surface was not grounded in medical evidence, but was “the product of his admitted goal: to ‘provide’ a theory that would be useful to the Petitioner.” *Id.* (emphasis added). And the Special Master determined that Dr. Steinman’s

statements to that effect, as well as Dr. Steinman's legal asides regarding the Vaccine Act, were "wholly inappropriate . . . at [a] hearing" and "greatly undercut [his] overall credibility." Id.

It is the province of the special master to make credibility determinations regarding the testimony of the witnesses before him, including expert witnesses like Dr. Donofrio and Dr. Steinman. The Court, accordingly, concludes that the Special Master's decision to give greater weight to Dr. Donofrio's opinion than Dr. Steinman's was not arbitrary or capricious but was instead a reasonable exercise of his discretion as the trier of fact.

Ms. China's remaining criticisms of the Special Master's decision also lack merit. She observes that Dr. Donofrio suggested that her GBS may have been caused by a pre-onset upper respiratory infection ("URI"), a theory she contends lacks any support in the evidence. Pet'r's Mot. at 1. But as the Special Master noted, Dr. Donofrio relied upon concerns expressed by at least two other physicians that Ms. China may have suffered from a URI in the two weeks immediately before she went to the emergency room. SM Dec. at 31 (citing Pet'r's Ex. 7, at 4-5). He also noted that there was other radiological evidence suggestive of a URI. Id. Such an infection provided a possible alternative cause for Ms. China's GBS according to Dr. Donofrio, who asserted that "[i]t is well known that [GBS] is often preceded by an upper or lower . . . respiratory tract infection or gastroenteritis in approximately 60-70% of patients." Id. (quoting Donofrio Report at 8).

In any event, the Special Master did not base his decision in any respect on the possibility that Ms. China's GBS was caused by a URI. Instead, his decision was based on his conclusion that Ms. China had failed to establish that it was caused by the flu vaccine. Further, "the absence of alternative causes for a condition does not alone suffice to ascribe causation to the vaccine." See, e.g., Lampe, 219 F.3d at 1361 (citing Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1149 (Fed. Cir. 1992)). Ms. China's challenge to Dr. Donofrio's theory of an alternative cause for her GBS therefore does not supply a basis for reversing the Special Master's determination.

In short, the Special Master based his decision on all of the evidence before him and on his assessment of the credibility of the witnesses. He provided an adequate and reasonable explanation for his finding that the October 2012 flu vaccine did not cause Ms. China's GBS. The inferences he drew and the conclusions he reached were well explained and grounded in the record. The Court, accordingly, must sustain his decision.

CONCLUSION

On the basis of the foregoing, Ms. China's motion for review is **DENIED** and the Special Master's ruling is **SUSTAINED**. The Clerk is directed to enter judgment accordingly. Each side shall bear its own costs.

IT IS SO ORDERED.



ELAINE D. KAPLAN
Judge