# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

Filed: January 27, 2021

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| PATRICIA A. SPAYDE, | * | PUBLISHED |
| Petitioner, | * | No. 16-1499V |
| v. | * | Special Master Nora Beth Dorsey |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | Entitlement; Influenza ("Flu") Vaccine; Guillain-Barré Syndrome ("GBS"). |
| Respondent. | * | |

Dan R. Mastromarco, Mastromarco Firm, PLLP, Annapolis, MD, for petitioner.
Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for respondent.

## RULING ON ENTITLEMENT[1]

## I. INTRODUCTION

On November 14, 2016, Patricia A. Spayde ("petitioner") filed a petition under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that as a result of an influenza ("flu") vaccine administered on November 13, 2013, she suffered from Guillain-Barré Syndrome ("GBS"). Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating that the

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

case was "not appropriate for compensation under the terms of the Vaccine Act." Respondent's Report ("Resp. Rept.") at 1 (ECF No. 38).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner provided preponderant evidence that the flu vaccine petitioner received caused her to develop GBS, which satisfies her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

## II. PROCEDURAL HISTORY

On November 14, 2016, petitioner filed her petition along with medical records, an affidavit from her treating physician, Dr. Douglas B. Forsyth, and an expert report of Dr. Damanhuri D. Alkaitis. ECF No. 1.[3] Petitioner filed additional medical records, an affidavit, and a statement of completion in February 2017 and June 2017. ECF Nos. 10, 28-30. On September 8, 2017, respondent filed his Rule 4(c) Report, recommending against compensation. Resp. Rept. at 1.

On March 23, 2018, respondent filed an expert report of Dr. Timothy Vartanian. Resp. Exhibit ("Ex.") A. Petitioner filed a supplemental expert report of Dr. Alkaitis on June 28, 2018. ECF No. 51. Thereafter, the undersigned held a Rule 5 conference on August 2, 2018, where she preliminarily found petitioner developed GBS. Rule 5 Order dated Aug. 7, 2018, at 1 (ECF No. 52). Although the undersigned observed that petitioner likely met her burden under Althen prong one, she did not believe petitioner could meet her burden under Althen prongs two and three, primarily due to the factual issue of onset. Id. The undersigned requested additional medical records and additional expert reports addressing onset and alternative causes. Id. at 2-3.

Petitioner filed additional medical records in October 2018. ECF Nos. 64, 66, 68. Respondent filed a supplemental expert report of Dr. Vartanian on November 9, 2018, and petitioner filed her supplemental expert report of Dr. Alkaitis on November 27, 2018. Resp. Ex. C; ECF No. 74.

The undersigned held a status conference on February 12, 2019, where she explained to the parties that onset remained an issue. Order dated Feb. 13, 2019, at 1 (ECF No. 76). Petitioner was ordered to file a motion to dismiss or a motion for a ruling on the record. Id. at 2. On May 14, 2019, petitioner filed a motion for a ruling on the record. Petitioner's Motion for a Ruling on the Record ("Pet. Mot."), filed May 14, 2019 (ECF No. 85). Respondent filed his response to petitioner's motion on June 21, 2019, and petitioner filed a reply on July 5, 2019. Resp. Response to Pet. Mot. ("Resp. Response"), filed June 21, 2019 (ECF No. 90); Pet. Reply to Resp. Response ("Pet. Reply"), filed July 5, 2019 (ECF No. 93).

[3] Before the entitlement hearing, petitioner relabeled and refiled her improperly labeled exhibits. See ECF Nos. 113-17. For clarity, the undersigned will refer to petitioner's filings by their docket entry numbers in this section.

The undersigned held a status conference on October 1, 2019. Order dated Oct. 2, 2019 (ECF No. 94). After reviewing all of the evidence, the undersigned determined that she would need to hold an entitlement hearing to resolve the factual issues, and the case was set for hearing. Id.; see Prehearing Order dated Nov. 19, 2019 (ECF No. 95).

An entitlement hearing was held on October 27 and 28, 2020. Order dated Oct. 28, 2020 (ECF No. 124). Additional documents were requested from both parties during the hearing, and were filed from November 2020 to January 2021. Resp. Ex. F; Pet. Exs. 48-51; Resp. Status Rept., filed Jan. 13, 2021 (ECF No. 138).

This matter is now ripe for adjudication.

## III. FACTUAL HISTORY

### A. Brief Summary of the Medical Records

Prior to receipt of the flu vaccination at issue here, petitioner's medical history was significant for breast cancer, for which she was undergoing radiation therapy, diabetes mellitus, hypertension, hyperlipidemia, obesity, and allergic rhinitis. Pet. Ex. 2 at 1-6.

On November 13, 2013, petitioner received a flu vaccination. Pet. Ex. 2 at 6. She presented to her primary care physician, Dr. Douglas B. Forsyth, on January 2, 2014, complaining of backache, nausea and vomiting, chills, and fever for one day. Id. at 7. Dr. Forsyth diagnosed petitioner with the flu and prescribed Tamiflu. Id. at 9-10.

Petitioner next sought treatment at Covenant HealthCare ("Covenant") Emergency Room ("ER") on January 8, 2014, where she was seen by Dr. Tiffany A. Weiss-Feldkamp. Pet. Ex. 2 at 11. Petitioner complained of generalized aches, cough, and fever. Id. Flu testing for flu antigens A and B were performed and were negative. Id. at 12. Petitioner was diagnosed was body aches and viral illness. Id. at 13.

On January 13, 2014, petitioner returned to Dr. Forsyth. Pet. Ex. 2 at 18-22. In his note from this visit, Dr. Forsyth documented that petitioner "ache[d] all over" and that "[h]er hands even tingle." Id. at 18. Petitioner saw Dr. Forsyth again on January 22, 2014. Id. at 33. At that visit, Dr. Forsyth charted that petitioner's "hands are picky, very weak all over, pain from the waist up. Mild numbness in her hands. She has mild nausea. No fever, no chills, no cough. She is very weak, not getting better at all." Id. Concerned that petitioner might have post-viral myocarditis, Dr. Forsyth sent her to the ER at St. Mary's of Michigan ("St. Mary's") for further testing. Id. at 38. Diagnostic testing at St. Mary's was performed and petitioner was admitted for continued IV hydration and diabetes control. Id. at 39-55.

On January 24, 2014, a neurological consult was performed by Dr. Barbara A. Jahnke, who noted that "[f]or the past week and a half, [petitioner] has been having a prickly feeling particularly of her upper arms, beginning [in] her fingers and moving up her forearms." Pet. Ex. 2 at 76. Physical examination revealed that petitioner had absent deep tendon reflexes throughout. Id. at 78. Dr. Jahnke's impression was "[p]rogressive weakness, paresthesias,

beginning in [petitioner's] upper extremities and now with evidence of lower extremity weakness, progressive over [three] weeks since upper respiratory tract infection 01/01/2014." Id. at 79. She noted that petitioner's electromyography ("EMG") was consistent with GBS, and that petitioner had reflex loss as well as decreased motor strength. Id. Dr. Jahnke ordered a lumbar puncture for cerebrospinal fluid ("CSF") analysis. Id. at 80. The lumbar puncture was performed, and CSF analysis was consistent with GBS. Id. at 83. CSF showed increased protein at 128 (normal 10-60). Id. at 103. Petitioner was diagnosed with GBS and plasmapheresis was ordered. Id. at 105-06.

On January 26, 2014, Dr. Jahnke observed that petitioner's overall strength had improved. Pet. Ex. 2 at 105. She was to continue plasmapheresis for five days. Id. Petitioner was also placed on acyclovir pending testing of the CSF for herpes virus. Id. Subsequent results showed that herpes simplex virus was not detected in the CSF. Id. at 103. Additionally, a gram stain and culture of the CSF showed no growth, indicating that bacterial and viral pathogens were not detected. Id. at 102.

Petitioner improved with treatment and was discharged from the hospital on February 8, 2014. Pet. Ex. 2 at 138. Dr. Forsyth's discharge note stated that petitioner's discharge diagnoses were GBS, intra-abdominal mass, and post-viral syndrome. Id.

On July 28, 2014, petitioner saw Dr. Jahnke for a follow up visit. Pet. Ex. 2 at 153. Petitioner continued to have sequela from her GBS; her toes felt like they were asleep, and her strength was not up to baseline. Id. However, she had made remarkable improvement and was able to perform the activities of daily living despite the surgery she had undergone for liposarcoma in April 2014. Id.

### B. Affidavits and Hearing Testimony

#### 1. Petitioner

On November 13, 2013, petitioner received a flu vaccine. Pet. Ex. 3 at ¶ 1; Transcript ("Tr.") 8. Petitioner testified that she had never experienced tingling in her fingers prior to receipt of her flu vaccination. Tr. 15. Petitioner described herself as someone who does not go to the doctor often. Tr. 12.

Petitioner testified that within two or three days after her vaccination, she began to feel tired, sore, and weak, and began experiencing generalized aching pain all over and tingling in her hands and feet. Tr. 10-11. She later testified she could not pinpoint when the tingling began. Tr. 15-16. On cross-examination, petitioner confirmed that she began to experience weakness a few days after vaccination. Tr. 23-24.

During the 2013-2014 holiday season, petitioner continued to feel very ill, tired, and weak, and she began having tingling in her hands and feet. Tr. 9. Petitioner testified that Dr. Forsyth's office closes over the holiday period, so she was unable to see him until January 2, 2014. Tr. 11-12. Around this time, petitioner was having trouble walking and driving. Tr. 21-22. After her January 2, 2014 appointment, she spent most of her time lying in bed and

continued to get worse. Tr. 13, 15. She testified that she does not remember much about what happened between January 2 and January 22, 2014, when she was admitted to St. Mary's. Tr. 12, 14, 16. Petitioner admitted "[her] memory is not good." Tr. 22.

After petitioner began her plasmapheresis treatments, she felt better within one to two weeks. Tr. 20. At the time of the hearing, petitioner testified that she continues to experience GBS sequalae. Tr. 21. She still has "tingling [] in [her] left foot, especially the toes. . . . [T]hen it will go to hurting if [she is] on [her] feet . . . . [B]oth [her] hands are weak." Id.

**2. Ms. Marylynn McPhail**

Ms. McPhail is petitioner's daughter. Pet. Ex. 10 at ¶ 3. Ms. McPhail testified that she is extremely close with petitioner and sees her daily. Tr. 88. She described petitioner as someone who is slow to complain about physical ailments. Id. Ms. McPhail averred that prior to petitioner's flu vaccination, petitioner was healthy and doing well. Pet. Ex. 10 at ¶ 8; Tr. 89.

During the Thanksgiving and Christmas period in 2013, Ms. McPhail averred that petitioner was tired and lethargic, and unable to drive or go grocery shopping. Pet. Ex. 10 at ¶ 7. She testified that within one or two weeks after petitioner's vaccination, petitioner "started to become lethargic and weak" and "started to deteriorate." Tr. 90. She thought petitioner's condition was due to her radiation treatments[4] "because she had gotten a flu shot every year" without any problem. Id.

On New Years Day of 2014, Ms. McPhail went to petitioner's house to watch the Michigan State Rose Bowl game. Tr. 90. Petitioner complained of weakness and prickly hands. Id. Petitioner also complained of nausea and muscle aches. Pet. Ex. 10 at ¶ 9. Ms. McPhail observed that petitioner had difficulty standing and walking. Id.

The next day, petitioner got very ill. Tr. 90. She was not getting out of bed, and complained of pain, hurting all over, and weakness. Tr. 90-91. Ms. McPhail tried to get her out of bed, but was unsuccessful. Tr. 91.

Ms. McPhail returned from a ski trip on January 5, 2014, and went to see petitioner. Tr. 94. She testified that petitioner could not get out of bed and was having trouble walking. Tr. 94-95. Petitioner complained that her foot hurt, her hands tingled, and her whole body hurt. Id.

On January 8, 2014, Ms. McPhail met petitioner at Covenant. Tr. 96-97. Ms. McPhail testified that after this visit, petitioner continued to decline. Tr. 99-100. "Over the next week[, petitioner] was still not improving and feeling very weak." Pet. Ex. 10 at ¶ 11.

Ms. McPhail testified that petitioner began complaining her about her pain, weakness, and numbness on January 1 or 2, 2014. Tr. 102-03. She added that petitioner "is not a complainer." Tr. 103.

[4] Petitioner was undergoing radiation treatment for breast cancer. Pet. Ex. 2 at 1.

Once petitioner presented to St. Mary's on January 22, 2014, Ms. McPhail visited petitioner every day. Tr. 103. Ms. McPhail testified that petitioner began to improve within five days of beginning plasmapheresis. Tr. 108. She was able to eat and walk on her own. Id.

**3. Dr. Douglas B. Forsyth**

Petitioner has been a patient of Dr. Forsyth's for over 20 years. Pet. Ex. 4 at ¶ 3. Dr. Forsyth testified that petitioner is not quick to complain about a medical condition and if ill, "would minimize it, if anything." Tr. 34.

Petitioner received a flu vaccine at his office on November 13, 2013. Pet. Ex. 4 at ¶ 7; Tr. 37-38. On November 13, 2013, petitioner informed Dr. Forsyth that she was feeling well and had no neurological complaints. Tr. 38-39.

Dr. Forsyth testified that he does not recall the exact dates in which his office closed for the holidays in 2013, but "at the very worst," his office would have been closed for one week. Tr. 67-68. He added that January 2, 2014 was probably his first day back, but he "would have been on call the whole time before that." Tr. 68.

Petitioner presented to Dr. Forsyth on January 2, 2014, complaining of backache, nausea and vomiting, chills, and fever for one day. Pet. Ex. 2 at 7. Dr. Forsyth diagnosed her with the flu and prescribed Tamiflu. Pet. Ex. 4 at ¶¶ 8-9; see also Tr. 41. He testified that he rarely prescribed Tamiflu, and since he did in this case, that would mean that petitioner "was quite ill" and "not really doing that well." Tr. 41. On cross-examination, Dr. Forsyth conceded that none of petitioner's complaints documented in his record from this visit were neurological. Tr. 68-69. He added, however, that he could not guarantee that he would have noted neurological symptoms in his record. Tr. 69.

On January 8, 2014, petitioner presented to Covenant with complaints of generalized body aches, non-productive cough, and fever. Pet. Ex. 4 at ¶¶ 10-11. He testified that these symptoms are consistent with the flu or another viral illness. Tr. 70-71. A flu antigen test, which he testified is about 70% accurate, was negative for antigens A and B. Pet. Ex. 4 at ¶ 12; Tr. 43-44. Dr. Forsyth testified that the negative flu test cast doubt on his initial diagnosis of flu. Tr. 44. He explained that petitioner "had a very bad viral illness," which Tamiflu did not help, but that his flu diagnosis "may have been premature." Tr. 44-45.

Petitioner followed up with Dr. Forsyth on January 13, 2014. Pet. Ex. 4 at ¶ 14. She "continued to complain of severe body aches, sore throat, sores in her mouth, and the development of tingling in her hands," so he ordered bloodwork. Id. at ¶¶ 15-16; see also Tr. 46. These symptoms were still consistent with a viral illness. Tr. 72. He explained that he knew petitioner did not have the flu but still left it as a diagnosis in the record. Tr. 73.

On January 22, 2014, petitioner presented to Dr. Forsyth with continued complaints of "aches, back pain, bilateral hand tingling, nausea, and weakness." Pet. Ex. 4 at ¶ 18. Since he first saw petitioner on January 2, 2014, her symptoms of weakness, tingling, and numbness progressed. Tr. 74. Dr. Forsyth averred that "over the course of the prior month, petitioner

continued to complain of increased weakness, tingling and numbness in her hands" and had lost 24 pounds. Pet. Ex. 4 at ¶ 20; see also Tr. 54. Because her condition did not improve, and because her weakness had increased, he referred her to St. Mary's where she was admitted. Pet. Ex. 4 at ¶¶ 19, 21; Tr. 51.

Thereafter, on January 24, 2014, petitioner underwent an EMG[5] and a neurology consult with Dr. Jahnke. Pet. Ex. 4 at ¶¶ 22-25; Tr. 56-57. Dr. Jahnke diagnosed petitioner with GBS. Pet. Ex. 2 at 105. Dr. Forsyth agreed with the diagnosis. Pet. Ex. 4 at ¶¶ 30-31.

Dr. Forsyth testified that petitioner's symptom of hand tingling began before her January 13, 2014 visit, even though his prior records do not document complaints of tingling. Tr. 47, 82-83. He testified that petitioner was experiencing neurologic symptoms as early as the first week of January 2014, but was unable to state the specific date her hand tingling began. Tr. 47, 60, 82-83.

Dr. Forsyth opined that petitioner's "flu vaccination [was] proximally consistent with the timing of the onset of the GBS" and thus, the flu vaccine was the likely cause of petitioner's GBS. Pet. Ex. 4 at ¶¶ 33-36. He testified that petitioner's GBS is the only case of GBS he has seen in his career. Id. at ¶ 34; Tr. 34.

### C. Expert Reports

#### 1. Petitioner – Dr. Damanhuri D. Alkaitis

##### a. Background and Qualifications

Dr. Alkaitis is board-certified neurologist, with board certifications in neurology, electrodiagnostic medicine, and clinical neurophysiology. Pet. Ex. 5 at 1; Pet. Ex. 48 at 4. He received a Ph.D. in organic chemistry from University of California, Berkeley in 1970 and an M.D. from Johns Hopkins School of Medicine in 1975. Pet. Ex. 48 at 2. Thereafter, he completed an internal medicine internship, a residency in neurology, and a fellowship at the Muscular Dystrophy Association Clinic. Id. Since 1979, he worked as a neurologist in various hospitals in New York, Connecticut, and Maryland, and taught clinical neurology at Columbia University from 1981-1990. Id. at 3. Dr. Alkaitis currently works as a neurologist at National Jewish Health in Denver, Colorado. Id. at 2. He has authored or co-authored numerous publications. Id. at 4-5.

[5] After the hearing, Dr. Forsyth provided a copy of petitioner's second EMG performed on September 19, 2017, along with his comments about the study. See Pet. Ex. 49. He wrote, "[petitioner's] EMG in 2017 showed no signs of diabetic neuropathy several years after the first one showed the GBS changes . . . . [T]his [] strongly argue[s] that her findings were GBS." Id. at 1.

**b. Opinion**

Dr. Alkaitis opined that "to a reasonable degree of medical certainty" but for the flu vaccination on November 13, 2013, petitioner would not have developed GBS and the vaccination was a substantial factor in petitioner's development of GBS. Pet. Ex. 5 at 3.

**i. Diagnosis**

Examining petitioner's clinical course and laboratory data, Dr. Alkaitis found petitioner suffered from GBS. Tr. 132-35, 154. He opined that petitioner's constellation of symptoms, clinical course, laboratory data, and response to treatment were diagnostic of GBS. Pet. Ex. 7 at 6-7; see Pet. Ex. 51 at 4-5.

Dr. Alkaitis opined that petitioner's treatment plan of plasmapheresis and IVIg and petitioner's response was also compatible with GBS. Pet. Ex. 7 at 9; Tr. 138-39. He testified that he has personally seen GBS patients rapidly improve with plasmapheresis and IVIg as petitioner did and it was usual to see rapid improvement with treatment. Tr. 139-40; see also Pet. Ex. 7 at 10. Dr. Alkaitis conceded that "it is true that . . . steroids, in acute inflammatory polyneuropathy, do not have a place," but argued that "the fact that [petitioner was] given plasmapheresis, IVIg[,] and steroids [did] not negate in any way, shape[,] or form [the] diagnosis of [GBS]." Tr. 149. He concluded that he attributed petitioner's improvement to either the plasmapheresis or IVIg. Id.

In response to Dr. Vartanian's opinion that petitioner had characteristics inconsistent with GBS, Dr. Alkaitis pointed out that (1) ascending paralysis is not often found in GBS patients, (2) petitioner's CSF findings were consistent with GBS, and (3) the "[l]ack of conduction block[s] [on EMG did] not negate the diagnosis of GBS." Pet. Ex. 7 at 10; see also Tr. 143-47; Pet. Ex. 51 at 4. He added that petitioner's " weakness and areflexia [were] definite[ly] consistent with GBS." Pet. Ex. 7 at 10.

Dr. Alkaitis noted that CSF in GBS patients can often show an elevation in protein like petitioner's CSF.[6] Pet. Ex. 5 at 2; see Pet. Ex. 51 at 4. Dr. Alkaitis opined that petitioner's elevated CSF lymphocytes, weakness, areflexia, and prolonged H reflex on EMG were all compatible with GBS, and not present in viral meningitis, as suggested by Dr. Vartanian. Pet. Ex. 7 at 9. He testified that "there was no other explanation for [petitioner's] elevated white cell except it was part of the [GBS]." Tr. 147.

In response to Dr. Vartanian's proposal of diabetic neuropathy as an alternative diagnosis, Dr. Alkaitis opined that petitioner's diagnostic tests and clinical picture did not support that alternative diagnosis. Pet. Ex. 7 at 7, 9-10; Tr. 147-48; Pet. Ex. 51 at 3. While he explained that petitioner's January 24, 2014 EMG "could be consistent with diabetic neuropathy," this would not explain the F and H wave latencies found. Pet. Ex. 7 at 5. Additionally, although the EMG was nondiagnostic, it was "consistent with a diagnosis of [GBS]

[6] Petitioner CSF proteins obtained on January 24, 2014 were elevated at 128 (normal 10-60). Pet. Ex. 2 at 103.

since the prolongation of the F and H waves could be due to demyelination at the root level typical for [GBS]." Id. at 5, 7; see also Tr. 137-38. In summary on this point, petitioner's EMG was not in and of itself diagnostic of GBS, but was not inconsistent with GBS. Tr. 138.

Also in response to Dr. Vartanian's opinion that petitioner may have had diabetic neuropathy, Dr. Alkaitis opined that petitioner's follow up EMG, performed September 19, 2017, showed no evidence of a diabetic neuropathy. Pet. Ex. 51 at 3 (citing Pet. Ex. 49).

At the hearing, Dr. Alkaitis discussed other differential diagnoses but explained how each were ruled out. Tr. 140-42. He opined that "[n]o other diagnosis fits the clinical picture as completely as the diagnosis of [GBS]." Pet. Ex. 51 at 5.

### ii. Althen Prong One

Dr. Alkaitis opined that the theory of molecular mimicry is a medically accepted theory as to how the vaccine causes GBS. Pet. Ex. 5 at 3; Pet. Ex. 7 at 2. Dr. Alkaitis acknowledged that GBS is associated with multiple etiologies, including viral and bacterial infections, but he noted that vaccines are also associated with GBS. Pet. Ex. 7 at 2; Tr. 125-26.

Dr. Alkaitis cited a 2012 article by Souayah et al.,[7] where the authors examined 802 cases of GBS reported after flu vaccination between 1990 and 2009. Tr. 227-28. He agreed with the authors that "[t]he immunological mechanisms leading to the occurrence of GBS after vaccination are not well understood, although molecular mimicry and other mechanisms of immune system stimulation may be responsible." Pet. Ex. 38 at 6; see also Tr. 228.

### iii. Althen Prong Two

Dr. Alkaitis opined that after petitioner received a flu vaccine on November 13, 2013, "antibodies against the vaccine . . . produce[d] an immune response" that "cross-react[ed] with components of the myelin . . . and produce[d] an immunological reaction to myelin." Pet. Ex. 5 at 3.

Dr. Alkaitis testified that GBS is difficult to diagnose due to the variation of symptomology. Tr. 126. He added that "while the classic manifestation of [GBS] may not yet be observable, the antigen or antigens may have induced the immune system to respond[,] initiating a complex reaction within the entire immune system of the body." Pet. Ex. 7 at 3. "Many of these adverse reactions are nonspecific and may be incorrectly attributed to a number of causes." Id.

Dr. Alkaitis opined that petitioner's January 2, 2014 symptoms of chills, fever, nausea, vomiting, backache, and headaches were most likely an adverse reaction to the flu vaccine. Pet. Ex. 5 at 1; see Pet. Ex. 7 at 8. "[T]hese symptoms [were] not the manifestation of a viral illness

[7] Nizar Souayah et al., Guillain-Barré Syndrome After Influenza Vaccination in the United States: A Report from the CDC/FDA Vaccine Adverse Event Reporting System (1990-2009), 14 J. Clinical Neuromuscular Disease 66 (2012).

nor [were] they indicative of an induced viral illness from a vaccine, but rather an immunological response to the complex antigens presented to the body in a vaccine." Pet. Ex. 7 at 3. He conceded that these symptoms were not a manifestation of GBS, "but rather the initial reaction to the vaccination" that caused the autoimmune process to manifest into GBS. Id. at 3, 8.

At the hearing, he testified that petitioner exhibited "clear unequivocal weakness by January 1," which eventually progressed to a point where Dr. Jahnke noted the weakness. Tr. 137. He found petitioner's symptoms documented on January 2, 2014 consistent with GBS, not a viral illness, especially after looking at petitioner's clinical course. Tr. 169-73. On cross-examination, he conceded that many of these symptoms were not listed as adverse effects to the flu vaccine nor were petitioner's symptoms of fever, chills, nausea, vomiting, and back ache listed as Brighton criteria for GBS. Tr. 179-81, 203; see also Pet. Ex. 39 at 4.[8] However, he maintained that petitioner's clinical picture was consistent with GBS, and not a viral illness. Tr. 198-202.

Dr. Alkaitis opined that petitioner did not have the flu, in part because (1) she received the flu vaccine, which is 60-70% effective, and (2) her flu test was negative. Tr. 173. Thus, he concluded that "[m]ore likely than not, she did not have the flu." Tr. 173-74. On cross-examination, he agreed that even with negative flu results, a flu infection can still be considered if clinical suspicion is high. Tr. 204-05. As for other causes, Dr. Alkaitis found no evidence that petitioner had *Campylobacter jejuni*,[9] nor were any tests ordered or performed to determine if petitioner had *Campylobacter jejuni*. Tr. 177. Of note, petitioner did not have any gastrointestinal symptomology prior to the onset of her illness. Id.

Dr. Alkaitis acknowledged that there is nothing in the medical records indicating that any of petitioner's treating physicians opined that her flu vaccine caused her GBS.[10] Tr. 217.

### iv. Althen Prong Three

Dr. Alkaitis opined that "there [was] a proximal temporal relationship between the [flu] vaccination and [petitioner's GBS]." Pet. Ex. 5 at 3. He testified that petitioner's GBS symptoms began on or about January 1, 2014, which is 49 days post-vaccination. Tr. 179; see Pet. Ex. 8 at 2; Tr. 158.

Citing medical literature, Dr. Alkaitis noted the timing of GBS post-vaccination can be variable. Pet. Ex. 7 at 2. In a study using 1000 Vaccine Adverse Event Reporting System

[8] Christiaan Fokke et al., Diagnosis of Guillain-Barré Syndrome and Validation of Brighton Criteria, 137 Brain 33 (2014).

[9] *Campylobacter jejuni* is "a species that is a common cause of enteric campylobacteriosis in humans." Campylobacter Jejuni, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=62516 (last visited on Jan. 21, 2021).

[10] However, as described earlier, petitioner's treating physician, Dr. Forsyth, opined that petitioner's flu vaccine was the likely cause of her GBS. See Pet. Ex. 4 at ¶¶ 33-36.

("VAERS") reports from 1990 to 2005, 77.4% of GBS cases reported an onset within six weeks of vaccination and 10.1% reported an onset more than six weeks post-vaccination. Id. at 2-3; Pet. Ex. 50 at 2.[11] Of these 1000 cases of GBS, 63.2% followed a flu vaccination, with nearly 81% developing GBS within six weeks of flu vaccination and 8.4% developing GBS more than six weeks after flu vaccination. Pet. Ex. 50 at 3. In another study examining 802 cases of GBS reported after flu vaccination between 1990 and 2009, 77.8% developed GBS within six weeks of vaccination and 9.7% developed GBS after six weeks. Pet. Ex. 38 at 3.

Relying on Dr. Forsyth's records, Dr. Alkaitis testified that petitioner's neurological symptoms began with back pain documented on January 2, 2014. Tr. 156. He opined that "muscle aches and pains" are neurological symptoms. Id. (citing Resp. Ex. E-1 at 4 ("Muscle pain or radicular pain, which precedes the weakness in about 30% of patients, is another frequent initial sign [of GBS].")).[12] Thus, by at least by January 1, 2014, she exhibited neurological symptoms. Id. Additionally, "she most likely had . . . tingling in the hands on January 2" although it is not noted until the January 13 visit to Dr. Forsyth. Tr. 156-57, 211.

For further support, Dr. Alkaitis cited Dr. Jahnke's note that it was her impression that petitioner's condition had progressed since January 1, 2014. Tr. 160-61 (citing Pet. Ex. 2 at 79). Additionally, he noted that both petitioner and Ms. McPhail testified that petitioner's weakness began in early January. Tr. 163.

**2. Respondent – Dr. Timothy Vartanian**

**a. Background and Qualifications**

Dr. Vartanian is a board-certified neurologist who specializes in inflammatory demyelinating diseases. Resp. Ex. A at 1. He received a Ph.D. and M.D. from University of Chicago. Resp. Ex. F at 2. He then completed an internship in internal medicine, neurology residency, and fellowships at Beth Israel Hospital and Harvard Medical School. Id. at 3. Dr. Vartanian held academic positions at Harvard Medical School from 1992-2009, and has been a professor at Weill Cornell Medicine since 2009. Id. He has also worked as an attending neurologist at New York Presbyterian Hospital since 2009. Id. Dr. Vartanian has received various honors and awards and authored or co-authored over 50 publications. Id. at 4, 12-24.

**b. Opinion**

Dr. Vartanian opined that petitioner did not likely suffer from GBS, but even assuming she did, her GBS was not likely caused by her flu vaccination. Resp. Ex. A at 8-12; Tr. 256, 300.

[11] Nizar Souayah et al., Guillain-Barré Syndrome After Vaccination in United States: Data from the Centers for Disease Control and Prevention/Food and Drug Administration Vaccine Adverse Event Reporting System (1990-2005), 11 J. Clinical Neuromuscular Disease 1 (2009).

[12] Susanna Esposito & Maria Roberta Longo, Guillain-Barré Syndrome, 16 Autoimmunity Revs. 96 (2017).

**i. Diagnosis**

Dr. Vartanian testified that he did not know what petitioner suffered from in January 2014. Tr. 271, 342. He opined that she "clearly suffered a viral illness and clearly had an abnormal spinal fluid, [and] had a borderline electrophysiologic study." Tr. 271. However, he did not believe that she had "ancillary studies or a clinical presentation that was characteristic of either classic GBS or even atypical GBS." Tr. 271-72. Although he agreed that the diagnosis of GBS was "a possibility," it was "not supported by the electrophysiologic findings" and "unusual clinical presentation." Tr. 342, 345.

Dr. Vartanian testified that based on the data available, it is likely that petitioner did not develop GBS following her November 2013 flu vaccination due to characteristics inconsistent with GBS. Resp. Ex. A at 9; Tr. 300. These included the lack of ascending paralysis, the absence of conduction blocks on EMG,[13] and the CSF findings.[14] Resp. Ex. A at 9; Tr. 332.

Of particular note, Dr. Vartanian observed that "[petitioner] did not exhibit ascending paralysis, nor did she have flaccid weakness—both of which are classic symptoms for GBS."[15] Resp. Ex. A at 9. On cross-examination, Dr. Vartanian conceded that ascending paralysis is not necessary in order to diagnose GBS. Tr. 313-14. Dr. Vartanian also agreed that weakness, muscle aches, and tingling are all symptoms seen in GBS patients. Tr. 321. Even though petitioner exhibited generalized fatigue and weakness, he found those symptoms were most likely due to other causes.[16] Resp. Ex. A at 9.

Additionally, Dr. Vartanian noted petitioner's CSF studies showed no indication of albuminocytologic dissociation. Resp. Ex. A at 9; Tr. 322. Since GBS patients would typically show an albuminocytologic dissociation, he argued this is another reason supporting his opinion that petitioner likely did not develop GBS. Tr. 322, 324-25. At the hearing, however, he backed off this position when he testified that while petitioner's CSF results were not typical of GBS, they were "not wholly incompatible." Tr. 325.

Instead of agreeing that petitioner's EMG was consistent with GBS, Dr. Vartanian found it to be consistent with diabetic neuropathy. Resp. Ex. A at 9. He conceded, however, that

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[13] Petitioner's January 24, 2014 EMG showed decreased F and H wave responses. Pet. Ex. 2 at 71. The impression was "somewhat confusing" as the EMG "could be consistent with a diabetic neuropathy. . . but diabetes alone would not explain the F and H wave latency changes." Id. at 72.

[14] On January 24, 2014, petitioner's CSF showed elevated protein at 128 (normal 10-60) and elevated glucose at 109 (normal 40-70). Pet. Ex. 2 at 102-03. Petitioner's CSF cultures were negative. Id. at 101-03.

[15] With regard to petitioner's prickly sensations "beginning [in] her fingers and moving up her forearms" that were noted during a consultation with Dr. Jahnke on January 24, 2014, Dr. Vartanian described this as an ascending sensory symptom, not ascending paralysis. Tr. 314-17.

[16] Dr. Vartanian did not specify these "other causes." Resp. Ex. A at 9.

petitioner's loss of H and F wave responses on her January 24, 2014 EMG and her areflexia were features consistent with GBS. Id.; Tr. 330. He agreed with Dr. Jahnke that petitioner could not be diagnosed with GBS based on her EMG results alone. Resp. Ex. A at 9. He argued that if petitioner had GBS, the EMG should have been more abnormal than it was, instead of being nondiagnostic. Tr. 331-33. He opined that if the EMG had shown a loss of H wave responses and evidence of segmental conduction blocks, in combination with the right clinical picture, it would have been diagnostic of GBS. Tr. 333.

Dr. Vartanian added that the timing of the EMG in relationship to the onset of petitioner's symptoms was a factor in determining whether petitioner had GBS. Tr. 334. For the EMG to be diagnostic, it should have been done more than two or three weeks after onset. Id. "If there are clinically relevant symptoms, then the electrophysiology should be abnormal." Id. Petitioner's EMG showed abnormalities, but Dr. Vartanian found the EMG nondiagnostic, confusing, and conducted too early, if her neurologic symptoms began on January 13, 2014. Tr. 335. If petitioner's onset was in the first week of January 2014, "[t]hen the EMG was done at the correct time, and you would expect it to be much more abnormal." Tr. 336, 340.

Additionally, Dr. Vartanian argued that patients with GBS usually do not improve as quickly as petitioner did. Resp. Ex. A at 9; Tr. 326-28. Dr. Vartanian also noted petitioner improved after receiving a high dose of steroids, treatment contraindicated for GBS. Resp. Ex. A at 9. Dr. Vartanian testified that in his experience, patients who receive plasmapheresis do not recover as rapidly as petitioner did, but he conceded that it was still possible. Tr. 327. He added that plasmapheresis is not used to treat a viral infection due to associated complications, and is therefore used only when indicated. Tr. 329-30. However, in petitioner's case, if she had "a persistent viral infection with inflammatory mediators, she could feel better after plasma exchange."[17] Id.

With diabetic neuropathy, neurologic deficits typically "resolve days to weeks after the toxic metabolic insult has resolved." Resp. Ex. A at 9. Thus, he found the most probable explanation for petitioner's improvement in symptoms to be due to "the aggressive treatment of [petitioner's] metabolic syndrome (hyperglycemia and hypokalemia) during her hospitalization in Jan[uary] 2014." Id. at 9-10.

### ii. Althen Prong One

Dr. Vartanian testified that molecular mimicry is not a disputed theory, "it is a part of a mechanism to describe autoimmune illnesses." Tr. 300. However, he maintained that GBS cannot result from a flu vaccine. Tr. 303. He later clarified that the current flu vaccines, or those not associated with the 1976 vaccination program, "have no clear association with GBS." Tr. 308.

Dr. Vartanian opined that the most common cause of GBS is a viral or bacterial antecedent infection, the most common of which is *Campylobacter jejuni*. Tr. 238; see Resp. Ex.

[17] Petitioner was not tested for inflammatory mediators. Tr. 330.

E-6 at 2;[18] Resp. Ex. E-10 at 2.[19] A number of other viral infections, including cytomegalovirus, Epstein-Barr virus, and flu A have also been identified as antecedent infections associated with GBS. Tr. 238-39; Resp. Ex. E-6 at 1, 5. Dr. Vartanian testified that about 70% of GBS cases develop after an antecedent infection. Tr. 302; Resp. Ex. E-6 at 1, 3.

Dr. Vartanian opined that the onset of neurological symptoms in GBS cases is typically between one to two weeks after an infection or vaccination. Tr. 240, 243; see Resp. Ex. E-6 at 2. He added that "an infection is a more dramatic inciting event for autoimmunity than is immunization." Tr. 246.

### iii. Althen Prong Two

Assuming petitioner suffered from GBS, Dr. Vartanian opined there is no "persuasive evidence that it was likely caused by a reaction to the [November 13, 2013] flu vaccination." Resp. Ex. A at 10; see also Tr. 240. Dr. Vartanian disagreed with Dr. Alkaitis' theory that molecular mimicry led to petitioner developing GBS. Resp. Ex. A at 10-11; Tr. 269. He maintained that "if [petitioner] had GBS, then [the viral] infection [was] by far the most likely cause of [her] GBS." Tr. 256; see also Tr. 301.

Dr. Vartanian disagreed with Dr. Alkaitis' opinion that petitioner's January 2, 2014 symptoms were an immunological response to the flu vaccine. Tr. 261-62. He explained that petitioner "undeniably suffered from a viral illness," documented by a low-grade fever, oral sores, myalgias, and CSF findings consistent with viral meningitis,[20] on January 2, 2014. Resp. Ex. A at 11; see also Tr. 248. At the hearing, Dr. Vartanian maintained that it was very clear from the medical records and Dr. Forsyth's testimony that petitioner had a viral illness on January 2, 2014, and those symptoms raised no suspicion of GBS. Tr. 256, 263-64, 356-57.

Even though petitioner tested negative for flu antigens A and B, Dr. Vartanian argued the negative antigen test did not prove that petitioner did not have the flu because (1) the rapid antigen test is "notoriously problematic," especially during flu season when the false negative rate is high, and (2) the rapid antigen test was conducted on January 8, six days after petitioner presented to Dr. Forsyth with viral symptoms, and past the CDC recommendation of three to four days. Tr. 257, 260-61; see Pet. Ex. 44 at 1, 3-5.[21]

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[18] B.C. Jacobs et al., The Spectrum of Antecedent Infections in Guillain-Barré Syndrome: A Case-Control Study, 51 Neurology 1110 (1998).

[19] Jeremy H. Rees et al., *Campylobacter Jejuni* Infection and Guillain-Barré Syndrome, 333 New Eng. J. Med. 1374 (1995).

[20] Dr. Vartanian conceded that there was not enough data to say whether petitioner had viral meningitis. Tr. 347.

[21] Influenza (Flu): Rapid Influenza Diagnostic Tests, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm (last reviewed Oct. 25, 2016).

With regard to petitioner's January 13, 2014 symptoms, he opined that her symptoms remained consistent with a viral illness. Tr. 264. Although tingling is a symptom consistent with GBS and was documented at this visit, Dr. Vartanian maintained that petitioner's constellation of symptoms documented on January 13, 2014 did not raise suspicion for GBS and that some of petitioner's symptoms are not associated with GBS. Tr. 264-65.

Dr. Vartanian found petitioner's January 22, 2014 symptoms, in general, consistent with a viral illness. Tr. 266. However, if petitioner's weakness was in specific muscle groups, instead of all over, that would raise his suspicion of GBS. Tr. 265-66. He opined that "the distribution and localization of [petitioner's] numbness and weakness" would determine whether petitioner's symptoms were "part . . . of a viral infection or . . . an evolving neurologic syndrome," but it was impossible to make such determination by looking at the history of present illness note from that visit. Tr. 266.

#### iv. Althen Prong Three

Dr. Vartanian's testimony as to onset was contradictory. He opined that petitioner's first neurologic symptom (tingling hands) began on January 13, 2014, which is more than eight weeks after vaccination and beyond the medically acceptable timeframe. Resp. Ex. A at 4, 10. He added that petitioner had a viral illness that began on January 2, 2014, 11 days prior to the onset of her hand tingling, which he opined was an appropriate time frame for attributing causation to a viral illness. Id. at 11; see Tr. 255-56, 356-57.

However, on cross-examination, he testified that "hand tingling is nonspecific" and "[he] wouldn't call [petitioner's] hand tingling necessarily or definitely the onset of her neurological symptoms." Tr. 354-55. Dr. Vartanian conceded that hand tingling can be a symptom associated with GBS, but noted that it can occur due a number of reasons, including a systemic viral infection. Id. Dr. Vartanian added that he would find her nausea on January 22 and weakness on January 24 to be "her hard neurological findings." Tr. 355.

## IV. DISCUSSION

### A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the

vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

**B. Factual Issues**

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

### C. Causation

To receive compensation through the Program, petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that she suffered a Table Injury, she must prove that a vaccine she received caused her injury. To do so, she must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and her injury ("Althen Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and her injury ("Althen Prong Three"). § 13(a)(1); Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

"Expert medical testimony which merely expresses the possibility—not the probability—of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred." LaCour v. Sec'y of Health & Hum. Servs., No. 90-316V, 1991 WL 66579, at *5 (Fed. Cl. Spec. Mstr. Apr. 15, 1991); accord Burns v. Sec'y of Health & Hum. Servs., No. 90-953V, 1992 WL 365410, at *6 (Fed. Cl. Spec. Mstr. Nov. 6, 1992), aff'd, 3 F.3d 415 (Fed. Cir. 1993). The Federal Circuit has likewise made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Id.; see also de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008).

## V. ANALYSIS

### A. Diagnosis

The first issue that requires resolution is whether or not petitioner had GBS. Petitioner asserts that GBS is the correct diagnosis, and respondent disagrees. Based on the record as a whole, the medical records, and the opinions of petitioner's treating neurologist, Dr. Jahnke, as well as the expert reports and testimony of Dr. Alkaitis, the undersigned finds that petitioner had GBS.

Petitioner's treating neurologist, Dr. Jahnke, performed her initial evaluation on January 24, 2014. She suspected that petitioner had GBS based on the progression of her symptoms over the prior two to four weeks, petitioner's increasing weakness, and absent deep tendon reflexes. Dr. Jahnke also noted that petitioner's EMG was consistent with acute GBS. Petitioner had prolonged distal latencies and F and H wave latency changes. Dr. Jahnke confirmed the diagnosis of GBS after a lumbar puncture showed elevated protein in the CSF.

Notably, petitioner improved after treatment for GBS, including plasmapheresis and IVIg. Additionally, there are numerous progress notes in petitioner's medical records from her hospitalization that note the diagnosis of GBS, including Dr. Forsyth's discharge summary. See Pet. Ex. 2 at 76, 79, 83, 123, 131, 135-36, 138-39.

Further, Dr. Alkaitis explained in his expert reports the basis for his opinion that petitioner suffered from GBS. He also testified on this issue at the hearing. The undersigned found Dr. Alkaitis' expert reports and testimony on the issue of petitioner's diagnosis of GBS to be persuasive.

In contrast, respondent's expert, Dr. Vartanian, testified that he did not know what illness petitioner had. Dr. Vartanian's opinion conflicts with the opinions of petitioner's treating physicians, and all of those who saw and treated petitioner during her hospitalization for GBS. Thus, the undersigned finds Dr. Vartanian's opinion unpersuasive, especially given the weight of the evidence presented by petitioner to support her diagnosis of GBS.

For all of these reasons, the undersigned finds that petitioner has proven by preponderant evidence that she suffered from GBS.

### B. Causation

There are two issues related to causation: (1) onset and (2) whether there is an alternative cause, other than the flu vaccination, of petitioner's GBS.

#### 1. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain,

but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

As for Althen Prong One, the undersigned finds that petitioner has provided preponderant evidence that the flu vaccine can cause GBS and that molecular mimicry is a sound and reliable causal theory. There are several reasons for this finding. First, GBS is a Table Injury following flu vaccination. See 42 C.F.R. § 100.3(a). When proposing the addition of GBS to the Table, respondent discussed the mechanism by which this injury is caused, specifically stating, "[i]t is not fully understood why some people develop GBS, but it is believed that stimulation of the body's immune system, as occurs with infections, can lead to the formation of autoimmune antibodies and cell-mediated immunity that play a role in its development." National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45145 (July 29, 2015).

The undersigned takes judicial notice of the fact that respondent added GBS after receipt of a flu vaccine to the Table. Such recognition of the causal association between vaccine and injury has been held to support the establishment of the theory required by the first Althen prong. See Doe 21 v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 178, 199 (2009), rev'd on other grounds, 527 F. App'x 875 (Fed. Cir. 2013). The undersigned also notes that prior decisions found petitioners had met Althen prong one even before GBS was added to the Table. See, e.g., Stitt v. Sec'y of Health & Hum. Servs., No. 09-653V, 2013 WL 3356791, at *8-10 (Fed. Cl. Spec. Mstr. May 31, 2013); Stewart v. Sec'y of Health & Hum. Servs., No. 06-777V, 2011 WL 3241585, at *16 (Fed. Cl. Spec. Mstr. July 8, 2011); Barone v. Sec'y of Health & Hum. Servs., No. 11-707V, 2014 WL 6834557, at *8-9 (Fed. Cl. Spec. Mstr. Nov. 12, 2014).

Second, respondent has conceded entitlement to compensation in many cases where petitioners have had GBS following the flu vaccination. See, e.g., Morgan v. Sec'y of Health & Hum. Servs., No. 19-1105V, 2020 WL 4725625 (Fed. Cl. Spec. Mstr. June 15, 2020); Robinson v. Sec'y of Health & Hum. Servs., No. 18-0088V, 2019 WL 2383530 (Fed. Cl. Spec. Mstr. Apr. 2, 2019); Martinez v. Sec'y of Health & Hum. Servs., No. 20-0709V, 2020 WL 7054282 (Fed. Cl. Spec. Mstr. Oct. 27, 2020). Even after GBS was added to the Table, respondent conceded or did not contest cases which may not have met the Table criteria. See, e.g., Johnson v. Sec'y of Health & Hum. Servs., No. 16-1356V, 2017 WL 7513282 (Fed. Cl. Spec. Mstr. Sept. 22, 2017 ); Hinton v. Sec'y of Health & Hum. Servs., No. 16-1140V, 2018 WL 4391071 (Fed. Cl. Spec. Mstr. May 29, 2018).

Third, petitioner's expert, Dr. Alkaitis, provided expert reports, testimony, and medical literature to explain and support the theory of molecular mimicry as it relates to GBS. See Pet. Ex. 38 at 6; Pet. Ex. 50 at 5. Medical literature filed by the respondent also supports molecular mimicry as a sound and reliable theory. See, e.g., Resp. Ex. E-15 at 2-4;[22] Resp. Ex. E-16 at 2;[23] Resp. Ex. E-17.[24] Souayah et al. wrote "[t]he immunological mechanisms leading to the occurrence of GBS after vaccination are not well understood, although molecular mimicry and other mechanisms of immune system stimulation may be responsible." Pet. Ex. 38 at 6. Willison et al. noted that GBS is preceded by infection or immune stimulation, such as vaccination, "that induces an aberrant autoimmune response targeting peripheral nerves and their spinal roots. Molecular mimicry between microbial and nerve antigens is clearly a major driving force behind the development of the disorder." Resp. Ex. E-16 at 2. Likewise, van den Berg et al. wrote molecular mimicry is "involved in the pathogenesis of GBS." Resp. Ex. E-15 at 3.

Lastly, respondent's expert, Dr. Vartanian, agreed that molecular mimicry is not a disputed theory and added that "it is a part of a mechanism to describe autoimmune illnesses." Tr. 300.

For all of these reasons, undersigned finds that petitioner has provided preponderant evidence of a sound and reliable causal theory, satisfying Althen Prong One.

### 2. Althen Prong Two

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and

[22] Bianca van den Berg et al., Guillain-Barré Syndrome: Pathogenesis, Diagnosis, Treatment and Prognosis, 10 Nature Revs. Neurology 469 (2014).

[23] Hugh J. Willison et al., Guillain-Barré Syndrome, 338 Lancet 717 (2016).

[24] Robert K. Yu et al., Ganglioside Molecular Mimicry and Its Pathological Roles in Guillain-Barré Syndrome and Related Diseases, 74 Infection & Immunity 6517 (2006).

effect." Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

The undersigned finds that petitioner has provided preponderant evidence of a logical sequence of cause-and-effect, as required by Althen Prong Two. Here, petitioner's clinical course as described in the medical records, and specifically the records of Dr. Jahnke, show a time course consistent with the mechanism and the timeframe within which GBS can occur following vaccination.

To summarize, petitioner received a flu vaccination on November 13, 2013. On January 2, 2014, she presented to Dr. Forsyth with complaints of backache, nausea and vomiting, chills, and fever for one day. On January 8, 2014, petitioner was seen at Covenant for complaints of generalized aches, cough, and fever. Petitioner tested negative for flu antigens A and B. Petitioner returned to Dr. Forsyth on January 13, 2014. Dr. Forsyth documented that petitioner "ache[d] all over" and that "[h]er hands even tingle." Pet. Ex. 2 at 18. Petitioner saw Dr. Forsyth again on January 22, 2014, where Dr. Forsyth charted that petitioner's "hands are picky, very weak all over, pain from the waist up. Mild numbness in her hands. She has mild nausea. No fever, no chills, no cough. She is very weak, not getting better at all." Id. at 33. On January 24, 2014, petitioner presented to Dr. Jahnke who noted that "[f]or the past week and a half, [petitioner] has been having a prickly feeling particularly of her upper arms, beginning [in] her fingers and moving up her forearms." Pet. Ex. 2 at 76. Dr. Jahnke found petitioner's EMG and CSF to be consistent with GBS. Id. at 39, 83.

Additionally, petitioner was worked up for alternative etiologies and none were found. Specifically, CSF testing for herpes simplex virus was negative. Gram stain and culture on the CSF was also negative. During her illness, petitioner was tested for flu A and B, and these results were also negative. Both parties devoted substantial testimony to the issue of the validity of the petitioner's flu testing, but the most persuasive testimony as to whether or not petitioner had wild virus flu came from Dr. Forsyth. Dr. Forsyth articulated three reasons that he did not believe petitioner suffered from the flu. First, she received a flu shot to prevent her from contracting flu. Secondly, the flu A and B tests were both negative. Further, Dr. Forsyth testified the flu test results were probably about 70% accurate. The third reason that Dr. Forsyth did not believe petitioner had the flu virus was based on the fact that petitioner took Tamiflu and it did not improve her condition. The undersigned finds these three reasons to be compelling evidence that petitioner did not have the flu, and that the flu virus did not cause her GBS.

Respondent asserts that even if petitioner had GBS, it was caused by a viral illness. While her treating physicians suspected that she had an antecedent viral illness before the onset of her GBS, diagnostic testing did not reveal any evidence of a viral illness. Dr. Vartanian essentially conceded this point at the hearing. In his expert report, Dr. Vartanian's stated that petitioner had CSF findings consistent with viral meningitis. Resp. Ex. A at 7. At the hearing, however, Dr. Vartanian conceded that he "[did not] have enough data" to conclude that petitioner had viral meningitis. Tr. 347. Petitioner's CSF testing did not reveal a viral etiology.

Moreover, where there are two potential causes for an illness, the petitioner is not required to eliminate the other potential cause in order to be entitled to compensation. In

Walther v. Secretary of Health & Human Services, petitioner received four vaccinations, but only one was included in the Vaccine Injury Table. 485 F.3d 1146, 1149 (Fed. Cir. 2007). The special master found petitioner not entitled to compensation because petitioner was unable to prove her illness was caused by the covered vaccine, in part because she did not eliminate other potential causes. Id. at 1147. The Federal Circuit ruled petitioner does not bear the burden of eliminating alternative independent potential causes. Id. at 1150-52. The Walther Court

> looked to the Restatement (Second) of Torts, explaining that for purposes of causation a petitioner is treated as the equivalent of a tort plaintiff and the government as the equivalent of a tort defendant. The [Walther] court noted that the Restatement (Second) of Torts § 433B(3) provided that in cases involving multiple independent potential causes, where harm has been caused by only one of them but there is uncertainty as to which one, "the burden is upon each such actor [tort defendant, or respondent in this case] to prove that he has not caused the harm."

Goring v. Sec'y of Health & Hum. Servs., No. 16-1458V, 2019 WL 3938705, at *18 (Fed. Cl. Spec. Mstr. May 6, 2019) (quoting Walther, 485 F.3d at 1151). Thus, applying the Restatement to the Vaccine Act, the Walther Court determined "the government bears the burden of establishing alternative causation by a preponderance of the evidence once the petitioner has established a prima facie case." Walther, 485 F.3d at 1151.

Here, because petitioner's clinical history presents a logical sequence of cause and effect consistent with vaccine causation, she need not eliminate a viral illness as an alternative cause. See Walther, 485 F.3d at 1151. While respondent has argued that petitioner's illness was caused by an antecedent virus, he has failed to provide evidence that she had a viral illness, and therefore, has failed to prove that petitioner's GBS was caused by something other than her flu vaccination.

For the above reasons, the undersigned finds that petitioner has proven by preponderant evidence a logical sequence of cause-and-effect, satisfying Althen Prong Two.

### 3. Althen Prong Three

Althen Prong Three requires petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. The phrase has also been referred to as a "medically acceptable temporal relationship." Id. The petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

Here, the fundamental issue with regard to causation is onset—whether the onset of petitioner's GBS occurred within a timeframe which was appropriate given the causal theory of molecular mimicry. For a Table claim of GBS following the flu vaccine, onset must fall within three and 42 days of vaccination. 42 C.F.R. § 100.3(a). However, for non-Table claims, or causation-in-fact claims, special masters have generally found that petitioners are entitled to causation where onset occurs up to two months, eight weeks or 56 days, following the flu vaccination.[25] Barone v. Sec'y of Health & Hum. Servs., No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) ("[S]pecial masters have never gone beyond a two-month (meaning eight week) interval in holding that a vaccination caused a demyelinating illness.").

The undersigned finds that onset of petitioner's GBS occurred sometime on or after January 1, 2014, but before her visit to Dr. Forsyth on January 13, 2014.

This finding is based on Dr. Forsyth's medical records and testimony. On January 13, 2014, Dr. Forsyth noted that petitioner's "hands [] tingle." Pet. Ex. 2 at 18. At the hearing, Dr. Forsyth explained that the way he wrote the note indicated that the symptom of hands tingling did not begin on that day, but started at some point in the past, although he was unable to say when the symptom began. Tr. 47, 82-83. The notes from petitioner's prior visit to Dr. Forsyth on January 2, 2014, and her visit to Covenant on January 8, 2014, do not mention the symptom of hand tingling. See Pet. Ex. 2 at 7-17. Looking back at his notes, Dr. Forsyth testified that he hopes that he would have documented the symptom of tingling hands prior to petitioner's January 13, 2014 visit if petitioner had mentioned it. Tr. 69, 73. However, he also admitted that he may not have documented it due to difficulties he had typing into the electronic medical record system at that time. Tr. 47. Reflecting back to earlier visits, Dr. Forsyth testified that the onset of petitioner's hand tingling could have begun as early as January 1, 2014, although again, he did not document the symptom when he saw petitioner on January 2, 2014. Tr. 60.

In summary, Dr. Forsyth testified that petitioner's symptom of tingling hands occurred as early as January 1, but before January 13, 2014.

Petitioner's symptom of tingling hands can be a neurological symptom, and tingling and numbness of the feet and hands can be a symptom of GBS. The treating physicians, as well as the experts focused on the symptom as a marker for petitioner's onset of GBS. Assuming that the petitioner's hand tingling began on January 1, 2014, then onset of her GBS was seven weeks

[25] See, e.g., Barone v. Sec'y of Health & Hum. Servs., No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (noting two months is the longest reasonable timeframe for a flu/GBS injury); De La Cruz v. Sec'y of Health & Hum. Servs., No. 17-783V, 2018 WL 945834, at *1 (Fed. Cl. Spec. Mstr. Jan. 23, 2013) (finding an onset of GBS more than two months after flu vaccination not compensable); Aguayo v. Sec'y of Health & Hum. Servs., No. 12-563V, 2013 WL 441013, at *3 (Fed. Cl. Spec. Mstr. Jan. 15, 2013) (rejecting an onset of three-and-one-half months in a flu/GBS case); Corder v. Sec'y of Health & Hum. Servs., No. 08-228V, 2011 WL 2469736, at *27-29 (Fed. Cl. Spec. Mstr. May 31, 2011) (finding petitioner failed to prove that the flu vaccine can cause GBS four months after vaccination).

or 49 days after vaccination, which is within eight weeks or two months after vaccination. That timeframe is appropriate given the causal mechanism of molecular mimicry.

Assuming, however, that onset was as late as January 12, 2014, the day before Dr. Forsyth documented the symptom of hand tingling, onset was approximately 60 days. While 60 days is four days outside the generally accepted timeframe of eight weeks, it is exceedingly close, and within a two-month calendar period. See Paluck v. Sec'y of Health & Hum. Servs., 786 F.3d 1373, 1383-84 (Fed. Cir. 2015) (finding the "special master [] erred in setting a hard and fast deadline . . . between vaccination and [] onset"). Therefore, it reasonable and appropriate to find that the onset of petitioner's GBS is within the appropriate timeframe given the mechanism of molecular mimicry.

Moreover, Dr. Alkaitis gave persuasive testimony based on medical literature showing that while most cases of GBS occur within the first several weeks after vaccination, up to ten percent develop GBS after six weeks. See Pet. Ex. 50; see also Pet. Ex. 38.

The undersigned finds Dr. Vartanian's testimony as to onset inconsistent and contradictory, and thus, finds it less persuasive. In his first report, Dr. Vartanian opined petitioner's first neurologic symptom (tingling hands) began on January 13, 2014. However, during the hearing, he testified that "hand tingling is nonspecific" and "[he] wouldn't call [petitioner's] hand tingling necessarily or definitely the onset of her neurological symptoms." Tr. 354-55. He found her nausea on January 22 and weakness on January 24 to be "her hard neurological findings." Tr. 355.

### C. Alternative Causation

Because the undersigned concludes that petitioner has established a prima facie case, petitioner is entitled to compensation unless respondent can put forth preponderant evidence "that [petitioner's] injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther, 485 F.3d at 1151. In order to meet his burden, respondent must demonstrate by preponderant evidence "that a particular agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor)." de Bazan, 539 F.3d at 1354 (emphasis omitted).

Significantly, the Federal Circuit has rejected the contention that the presence of a viral infection can *per se* be considered a factor unrelated to vaccination so as to bar compensation. Knudsen, 35 F.3d at 548-50. Rather, respondent bears a burden of proving not only that there was a viral infection, but also that the infection was principally responsible for causing petitioner's injury. Id. at 549. As discussed above in the analysis related to Althen Prong Two, the undersigned found the respondent failed to establish evidence to show that petitioner's GBS was caused by a source other than her vaccination—here, a viral illness. Thus, respondent did not prove by a preponderance of evidence that her injury was "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

## VI. CONCLUSION

For the reasons discussed above, the undersigned finds that petitioner has established by preponderant evidence that she is entitled to compensation. A separate damages order will issue.

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**
Nora Beth Dorsey
Special Master