In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-853V

Filed: March 19, 2025

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SANELA REDZEPAGIC,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

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Maximillian Muller, Esq., Muller Brazil LLP, Dresher, PA, for petitioner.
Catherine Stolar, Esq., U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

Roth, Special Master:

On June 10, 2019, Sanela Nicocevic filed a petition on behalf of her minor child, S.R., for compensation pursuant to the National Vaccine Injury Compensation Program.[2] Petition, ECF No. 1. Sanela Redzepagic was substituted as petitioner when she reached the age of majority. ECF No. 30-31. Petitioner alleges that she developed Guillain-Barré Syndrome ("GBS") as a result of the influenza ("flu") vaccine she received on January 29, 2018. Petition, ECF No. 1.

In his initial Rule 4(c) Report, respondent argued that petitioner had not established a Table GBS claim following her flu vaccine because her onset was 46 days after vaccination. ECF No. 21 at 7-8. However, in an amended Rule 4(c) Report, respondent stated that he would not continue to defend the case and requested a ruling on the record regarding entitlement based on the record as it currently existed. *See* ECF No. 26 at 1. Petitioner then filed her Motion for Ruling on the Record and respondent responded thereto. ECF Nos. 33, 35.

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

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

Based on the medical records, affidavits, expert report of Dr. Simpson and medical literature causally connecting petitioner's diagnosis of GBS with the flu vaccination that she received and for the reasons expressed below, I find petitioner's evidence sufficient to meet her burden in establishing entitlement to compensation.

I. Procedural History

The petition was filed on June 10, 2019, along with medical records and the affidavit of petitioner's mother, Sanela Nicocevic. Petitioner's Exhibits ("Pet. Ex.") 1-6. The case was assigned to me on June 11, 2019, and an initial order was issued on the same date. ECF No. 4. Petitioner filed a statement of completion on June 12, 2019. ECF No. 5.

Additional medical records and a statement of completion were filed on September 10, 2019. ECF Nos. 9-10. Respondent filed a status report on December 9, 2019, advising that he was willing to entertain a demand from petitioner. ECF No. 11. The parties engaged in settlement negotiations for several months. *See* ECF Nos. 13-14, 16, 18. Petitioner continued filing updated medical records during that time. Pet. Ex. 8-10, ECF No. 15; Pet. Ex. 11, ECF No. 17.

On August 10, 2020, the parties advised the Court that they had reached an impasse. ECF No. 19. Respondent was directed to and thereafter filed his Rule 4(c) Report on November 20, 2020. ECF No. 20; Non-PDF Scheduling Order, issued Sept. 21, 2020; ECF No. 21.

Petitioner then filed an expert report, curriculum vitae, and medical literature from Dr. David Simpson. Pet. Ex. 12-24, ECF No. 23.

Following an initial request to file an expert report, respondent instead filed an amended Rule 4(c) Report on August 9, 2021, stating that "he will not continue to defend this case during further proceedings on entitlement before the Office of Special Masters, and requests a ruling on the record regarding petitioner's entitlement to compensation" while reserving "his right to a potential appeal of the entitlement decision." ECF Nos. 24-25; ECF No. 26 at 1.

A status conference was held thereafter on October 26, 2021 for clarification of respondent's position. The parties agreed to move forward with the filing of a motion for ruling on the record. ECF No. 27. Petitioner was also noted to have reached the age of majority, and an affidavit was ordered from her detailing the events in this case. *Id*.

On December 9, 2021, petitioner filed her affidavit and copies of text messages she sent to her mother. Pet. Ex. 25-26, ECF No. 29. Sanela Redzepagic was substituted as petitioner on December 17, 2021. ECF No. 30-31.

Petitioner filed a Motion for Ruling on the Record on January 24, 2022. ECF No. 33. Respondent filed a response on April 25, 2022. ECF No. 35.

I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. *See* Vaccine Rule 8(d);

Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record."). Accordingly, this matter is now ripe for resolution.

II. Background

A. Petitioner's Medical History

Petitioner presented to her primary care physician ("PCP") on January 29, 2018 for a physical. She was a healthy 15 year old with no prior medical history, who received all her childhood vaccinations without event. Pet. Ex. 3 at 35. An examination was normal, and she received the subject influenza vaccine. *Id*. at 37-38.

On March 20, 2018, petitioner presented to the Stamford Health Emergency Room ("Stamford ER") for generalized body aches that began on Saturday[3] and were worse in her legs than in her upper body. Pet. Ex. 9 at 136. She had no fever, was not sick, and had not traveled. She described pain in her lower back to lower legs that was sharp, mild to moderate, and intermittent, aggravated by movement and ongoing for three to four days. She reported that the symptoms started after she was vigorously exercising. *Id*. The impression was myositis, and she was prescribed NSAIDs and discharged. *Id*. at 138-39.

Three days later, on March 23, 2018, petitioner returned to the Stamford ER. Pet. Ex. 9 at 104. She reported that her weakness and body aches were unchanged since she presented two days ago. She was now unable to walk without calf pain, and she had some dizziness and blurred vision since taking the Motrin prescribed when she presented previously. *Id*. Her blood work was normal. She had a headache that resolved after eating. The impression was leg cramps. *Id*. at 104-06. She was discharged and walked out of the ER, but she felt weak while waiting for her mother to get the car and was found lying on her side. She refused reevaluation. *Id*. at 107.

The following day, March 24, 2018, petitioner presented to Optimus Health Care Clinic reporting "[t]otal body weakness." Pet. Ex. 3 at 31. Her mother reported that petitioner had been sick since getting the flu vaccine at the end of January and had presented to the ER twice for generalized body aches and weakness. Her mother expressed concern for GBS. *Id*. She reported no family history of muscle disorders, and that petitioner began having difficulty walking last week then became unable to walk and had to be picked up from school. Petitioner denied leg pain but reported toe numbness and tingling and weakness in her feet mainly when walking. She reported tingling in her fingertips, jaw pain, difficulty eating, and headaches. She had dizziness when rising, felt unsteady, and was experiencing "room spinning sensation." *Id*. On examination, she had tenderness in the back of her legs, leg weakness, and unstable gait, but normal reflexes and strength. The assessment was myalgias and headache. *Id*. at 33. She was prescribed muscle relaxers for leg pain and advised to continue over the counter NSAIDs. *Id*.

On March 25, 2018, petitioner returned to the Stamford ER reporting continued bilateral lower extremity weakness and difficulty walking. Pet. Ex. 9 at 80. She reported no fever,

[3] The Saturday prior to this presentation was March 17, 2018.

shortness of breath, or pain, and had been seen in the ER numerous times for the same complaints since receiving the flu vaccine in January. Pet. Ex. 9 at 80. The weakness in petitioner's lower extremities had progressed over the past 24 hours. Her mother reported she was receiving IVIG for "peripheral neuropathy" herself. Pet. Ex. 9 at 80. Petitioner had weakness in the lower extremities on examination. *Id*. at 81-82. The differential diagnosis included GBS, myalgia, myositis, post viral weakness, ADEM, and transverse myelitis. *Id*. at 82. A head CT was unremarkable but for a probable pineal cyst. *Id*. at 83. Petitioner was transferred to Yale New Haven Children's Hospital ("Yale") at the recommendation of pediatric neurology. *Id*. at 83-84.

Upon arrival at Yale, petitioner's extremity weakness was noted, and was the concern for GBS versus cord compression from the Stamford ER. Pet. Ex. 4 at 29. Petitioner reported headaches relieved with Advil, dizziness on standing, and blurry and double vision in her left eye that began two days ago. *Id*. She reported that she had flu-like symptoms three weeks ago and presented to the Stamford ER three times for bilateral lower extremity weakness. Her blood work and CT had been normal, and her bilateral lower extremity weakness was attributed to over-exhaustion from working out. *Id*. at 11, 29. During a neurology consultation, she reported that she received a flu shot in January 2018 and developed flu-like symptoms which resolved but then reoccurred several weeks later. She then developed lower extremity pain and weakness, that was greater on the right than on the left. The weakness had gotten worse over the past few days. Her mother had recently been diagnosed with "peripheral burning neuropathy," but was not sure what kind of neuropathy. The mother had no weakness but had shooting pain down her legs and had a recent IVIG infusion. *Id*. at 10, 29.

Petitioner was admitted and a lumbar puncture was ordered. Pet. Ex. 4 at 15. Extensive viral labs were ordered, which were negative for viruses. *Id*. at 22-23, 58-59. The neurology assessment noted an otherwise healthy teen with asymmetrical weakness, diffuse hyporeflexia, and intermittent blurry/double vision. GBS, transverse myelitis, neuromyelitis optica, and other demyelinating processes or cord compression were noted as concerns. *Id*. at 43. The lumbar puncture showed albuminocytologic dissociation, with CSF protein at 162 and 9 WBCs, consistent with GBS. *Id*. at 44. Brain and spine imaging revealed enhancement of the cauda equine nerve root with no other abnormalities, also consistent with GBS. *Id*. at 35-36, 44. There was no bladder or bowel involvement. *Id*. at 33. The record documented "[c]urious infectious component possible with mother impacted with b/l LE neuropathy without diagnoses of diabetes." *Id*. at 32. Two days of IVIG was ordered, with PLEX to be considered if she worsened, and she was to be closely monitored. *Id*. at 44.

Petitioner experienced significant improvement with two days of IVIG. She could ambulate and demonstrated improved muscle strength. She was discharged home on March 28, 2018, and was to attend outpatient rehabilitation. Pet. Ex. 4 at 48-49.

At a follow-up visit with her pediatrician on April 2, 2018, petitioner continued to report poor appetite, nausea, blurred vision, and headache. She started physical therapy, and her bilateral leg weakness was slowly improving. Pet. Ex. 3 at 27. She returned on April 5, 2018, after fever the day prior but no upper respiratory symptoms. She reported continued improvement and was walking without assistance. She still felt some weakness in her arms and

legs. *Id*. at 23. There were no sensory abnormalities noted, and her gait, stance, and reflexes were normal. *Id*. at 25.

A physical therapy note from April 25, 2018 documented a 15 year old with GBS that started around March 10 or 11 after receiving a flu shot. She started feeling tingling in her hands and feet then started walking funny due to weakness. She went to the ER multiple times and received two days of IVIG after the GBS diagnosis. Her symptoms were a lot better, but she felt uncomfortable walking and was not 100% confident, and she was getting a lot of headaches. Pet. Ex. 3 at 57; Pet. Ex. 8 at 69.

At a follow-up visit on April 27, 2018, the neurologist noted steady improvement. She was attending physical therapy and able to walk but was not entirely back to baseline. Pet. Ex. 5 at 7. Petitioner reported suffering her first headache more than a year ago, but her headaches had worsened since the lumbar puncture. She reported frontal and temporal bilateral headaches with photophobia. Her headaches were better when laying down in a dark room. She had no nausea or vomiting or aura or warning. She was taking Advil daily. *Id*. She was in high school and did well academically. She had resolving GBS and had regained the reflexes she lost during the acute phase of her illness, but had migraines without aura and chronic daily headache. She was to continue with physical therapy, stop taking Advil, and return in three months. *Id*. at 7-8.

Petitioner attended 12 PT sessions and was discharged on June 25, 2018 with an at-home exercise program. She had made gains in strength, coordination, and balance with reduced fatigue and improved functional mobility. Pet. Ex. 9 at 43-44.

Petitioner returned to the neurologist on September 27, 2018. She reported no weakness or tingling and had finished physical therapy, but she continued to report headaches with photosensitivity. Pet. Ex. 5 at 9. It was noted that she did not eat well and was not doing the at-home exercises provided by physical therapy. She expressed anxiety over schoolwork. *Id*. The neurologist's impression on that day was a 15 year old with a history of GBS and migraine headaches. Her neurological exam was normal. She was overusing Advil, had poor nutrition during the day, and was not sleeping enough at night and napping frequently after school. Migraine prevention was discussed in detail. *Id*. at 11-12.

Petitioner returned to the neurologist on November 15, 2018 for continued headaches. Pet. Ex. 5 at 13. She reported improvement since her last visit, with headaches only occurring a couple of times a month. She was now eating breakfast, which was helping. She was often stressed; sleep was still problematic, and she was often up until 2:00 am. She was not exercising but her strength continued to improve. *Id*.

On February 2, 2019, petitioner presented to the pediatrician with a rash on her face for about a month that worsened a few days before. Pet. Ex. 3 at 20. She also had a rash on her left elbow and upper chest. The rash was slightly itchy, and she felt fatigued. Her mother was concerned about lupus. *Id*. The examination was normal but for mild urticaria on her cheeks, mild eczema on her left elbow, and pale erythematous light rash on her chest. *Id*. at 21. Blood work was ordered, and she was prescribed Cephalexin for her rash and advised to do a "bleach bath" once a week for the eczema. *Id*. at 22.

At a follow-up visit on February 8, 2019, she reported improvement of the rash on her face, chest, and arms, but it was still itchy. She had no history of fever, no upper respiratory symptoms, and no sick contacts or recent travel. The findings were otherwise normal. Pet. Ex. 3 at 12-15.

Petitioner was seen in the Stamford ER on March 24, 2019 for knee pain. She was dancing in heels at a party and her knee "popped out." She had significant pain with weight bearing. Pet. Ex. 9 at 8. X-rays were negative but she had some soft tissue swelling. She was encouraged to take Tylenol or Motrin and told to ice the knee. *Id*. at 9.

Petitioner presented to a rheumatologist on March 28, 2019 for evaluation of her facial rash. She described waxing and waning itchy red patches on her cheeks, nose, and chin that felt dry and bumpy or raised. She used Aquaphor, which helped the dryness and itching. Pet. Ex. 7 at 6. She reported a history of chronic headache, an oral ulcer that resolved a month ago, fatigue, and a recent knee injury. She also reported she may have color changes in her hands with cold exposure. Her mother expressed concern about lupus. Petitioner's ANA was low positive, which is a nonspecific finding and seen in up to 20% of the healthy pediatric population, and her other labs were normal. *Id*. She was wearing makeup making the rash difficult to see, but it did not appear to be the classic malar rash of lupus. Her fatigue seemed to be related to sleep hygiene. The assessment was pruritic rash of unclear etiology, and no further testing was recommended. *Id*. at 10.

Petitioner presented to urgent care on July 3, 2019 for facial swelling and rash. Pet. Ex. 10 at 2. She had large urticaria on her cheeks and was told to use Benadryl or Claritin for itching. *Id*. at 3.

Petitioner presented for her annual physical on July 22, 2019. Pet. Ex. 8 at 6. She reported a rash that would come and go, usually on her face and torso. Her examination was normal, and she was assessed with a rash. *Id*. at 6-9.

B. Affidavit of Sanela Nicocevic

Ms. Nicocevic is petitioner's mother. She submitted an affidavit that affirmed petitioner's receipt of an influenza vaccine on January 29, 2018, and that petitioner developed GBS, which is recognized by the Vaccine Injury Table. She further affirmed that petitioner suffered the residual effects of GBS in excess of six months. Pet. Ex. 6 at 1.

C. Affidavit of Petitioner

Petitioner affirmed that she went to the doctor on January 29, 2018 for a checkup and received a flu shot. Pet. Ex. 25 at 1. "Right after the shot, I started experiencing flu-symptoms. I couldn't go to school for a few days because I had a fever, started throwing up, and was sore." She felt better after about a week and returned to school. *Id*.

Petitioner affirmed that she got sick again for a few days around March 7, 2018, with flu-like symptoms, fatigue, and nausea. Pet. Ex. 25 at 1. She then began getting sharp cramps in the

legs, but was "still going to school with all that pain and trying to be present." She would have to call her mother to pick her up because she was unable to go up the stairs at school. *Id*. Petitioner believes this occurred between March 10 and March 20, 2018. Pet. Ex. 25 at 1. She stopped going to school because the symptoms were getting worse. *Id*.

According to petitioner, she then started to have numbness and tingling in her toes and feet, and she could not walk. Her mother took her to the ER multiple times, but there was no diagnosis. Pet. Ex. 25 at 1-2. She was told it was muscle cramps and was given ibuprofen, which did not help. *Id*. at 2.

Petitioner affirmed that she stayed home in bed and could not walk, stand, or do anything. Her mother took her to a clinic begging for answers, but none were given. Pet. Ex. 25 at 2. The next morning, the ER called and told them to come back right away. She was then transferred to Yale New Haven Children's Hospital, where she underwent a spinal tap and other testing. *Id*. She was diagnosed with GBS, received three days of IVIG, and was in the hospital for a week. She couldn't go to school because she was weak and could not walk properly. She went to physical therapy for three months after her hospitalization. *Id.*

According to petitioner, she also started to have bad migraines at this time and had to see a neurologist. She missed a lot of school and transferred schools because she was so behind. Pet. Ex. 25 at 2. About two and half years ago, she dislocated her knee and had to use crutches for a week. She thinks this was partially because her legs were still weak. She still gets tired, cannot walk or stand for long periods of time, and feels her legs are weaker. *Id*.

D. Petitioner's School Attendance Record

Petitioner was referred to Stamford Academy from her district school, Stamford High School, due to extensive absences. The record shows her absence from school in early 2018 for short- and long-term illness. However, petitioner was routinely tardy or absent prior to and after the dates of her GBS illness. *See generally* Pet. Ex. 11.

E. Other Evidence

Petitioner filed some text message exchanges with her mother from February 1, 2018 through April 2018 from instances when she did not feel well. Pet. Ex. 26.

III. Petitioner's Expert, Dr. David Simpson

A. Qualifications

Dr. Simpson is a Professor of Neurology and the Director of the Neuromuscular Division and Clinical Neurophysiology Laboratories at the Icahn School of Medicine at Mount Sinai, where he has worked as an attending neurologist since 1984. He is board-certified in neuromuscular and electrodiagnostic medicine, psychiatry, and neurology, with subspecialties in clinical neurophysiology and neuromuscular medicine. Pet. Ex. 12 at 1. Dr. Simpson has published and lectured extensively about neurological disorders, including peripheral neuropathy

and Guillain-Barré Syndrome, and electrodiagnosis. He maintains a clinical neurology practice based in the Icahn School of Medicine at Mount Sinai, an academic medical center, where he supervises and trains medical students, residents, and fellows. His specialty is neuromuscular disorders, which covers a wide range of peripheral nerve and muscle diseases, with Guillain-Barré Syndrome and CIDP being an important part of that spectrum. Pet. Ex. 12 at 1; Pet. Ex. 13.

B. Opinion

Dr. Simpson detailed petitioner's medical history following her receipt of the flu vaccine on January 29, 2018. Pet. Ex. 12 at 2-4.

He explained that acute inflammatory demyelinating polyneuropathy ("AIDP"), also known as GBS, is a disorder characterized by progressive limb weakness, reduced reflexes, and sometimes autonomic impairment. Pet. Ex. 12 at 4. Cerebral spinal fluid ("CSF") may show elevated protein and a low white blood cell count, which is known as albumino-cytologic dissociation. *Id*. Nerve conduction and EMG studies typically reveal generalized sensory motor demyelinating polyneuropathy. Symptoms generally reach nadir within four weeks of onset. *Id*.

Dr. Simpson proposed various biologic mechanisms by which vaccines may lead to neurologic illness, including molecular mimicry, neurotoxic effect, immune complex formation, and loss of self-tolerance. He proposed that molecular mimicry is "the most likely biologic mechanism" in this case: "[t]his concept suggests that epitopes of a virus or vaccine, results in the development of immune antibodies and/or T cells that could cross-react with epitopes on myelin or axonal glycoproteins of nerves, leading to neuronal damage." Pet. Ex. 12 at 4; Pet. Ex. 15.[4]

Dr. Simpson provided medical literature to show the connection between vaccines and the occurrence of demyelinating neuropathy. Pet. Ex. 12 at 4; Pet. Ex. 17[5]; Pet. Ex. 18[6]; Pet. Ex. 19.[7] Dr. Simpson further proposed that the most compelling example of vaccines causing

[4] Michael C. Levin et al., *Neuronal Molecular Mimicry in Immune-Mediated Neurologic Disease*, 44 ANNALS OF NEUROLOGY 87 (1998), filed as "Pet. Ex. 15." This is a study on multiple sclerosis, a central nervous system disease. It studied patients infected with human T-lymphotropic virus type I who developed HTLV-1 associated myelopathy/tropical spastic paraparesis, an immune disease of the CNS. The results implicated molecular mimicry as a potential pathogenic mechanism in immune-mediated damage to the CNS, suggesting that it may occur when an immune response mounted against an environmental antigen cross-reacts with a host antigen, which in turn leads to autoimmunity, organ-specific damage, and possibly disease. Pet. Ex. 15 at 8. The study did not involve GBS or damage to the peripheral nervous system.

[5] J. Pritchard et al., *Risk of relapse of Guillain-Barré syndrome or chronic inflammatory demyelinating polyradiculopathy following immunization*, 73 J. NEUROLOGY NEUROSURGERY & PSYCHIATRY 348 (2002), filed as "Pet. Ex. 17." This is a 2002 study of patients already suffering from GBS and CIDP who experienced relapses with increased fatigue, weakness, numbness, and paresthesia after vaccination. The authors acknowledged that their conclusions were based on questionnaires filled out by the patients, with more patients who experienced symptoms after vaccination responding than those who did not, thus overestimating the frequency of relapses.

[6] Lawrence B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States 1976-1977*, 110 AM. J. EPIDEMIOLOGY 105 (1979), filed as "Pet. Ex. 18." *Schonberger* is a 1979 epidemiologic study of the increase in GBS following the A/New Jersey influenza vaccine that supports the hypothesis that GBS was an immunopathologic reaction triggered by recent exposure to an exogenous agent which leads to certain cellular changes triggering an attack on the nerve root and peripheral nerves.

[7] INST. OF MED., ADVERSE EFFECTS OF VACCINES: EVIDENCE & CAUSALITY (Kathleen Stratton et al. eds., 2012),

demyelinating disease was the outbreak of cases of GBS following the federal government-sponsored National Influenza Immunization Program for the 1976 swine flu, but numerous case reports have also documented the development of GBS following flu vaccination. Pet. Ex. 12 at 4; Pet. Ex. 14[8]; Pet. Ex. 18[9]; Pet. Ex. 19.[10]

Dr. Simpson discussed a survey done by questionnaire in the United Kingdom, which focused on relapses within six weeks of vaccination in those who already had GBS and CIDP. Pet. Ex. 12 at 4; Pet. Ex. 17.[11] He noted that 1114 patients, or 37.1% of those asked, filled out the questionnaire, and of those, 927 patients had GBS and 179 had CIDP.[12]

Relying on *Nachamkin*, Dr. Simpson stated that molecular mimicry is the proven mechanism leading to the development of GBS, particularly in the setting of campylobacter jejuni infection, and the accepted causal mechanism in the medical community for causing autoimmunity in general: "[t]hus, it is generally accepted in the medical community that vaccinations can serve as a causal antecedent to the occurrence of GBS and CIDP." Pet. Ex. 12 at 4-5; Pet. Ex. 20[13] at 2.

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filed as "Pet. Ex. 19." The 2012 IOM Adverse Effects of Vaccines: Evidence and Causality, published in 2012, contained the findings of an association between the flu vaccine and GBS.

[8] Thomas J. Safranek et al., *Reassessment of the Association between Guillain-Barré Syndrome and Receipt of Swine Flu Vaccine in 1976-1977: Results of a Two-State Study*, 133 AM. J. EPIDEMIOLOGY 940 (1990), filed as "Pet. Ex. 14." This was a reassessment of the *Schoenberger* study. It examined the methods used and the relationship of the swine flu vaccine to the development of GBS, demonstrating the association between the receipt of the swine flu vaccine and subsequent GBS with consistency to two prior nationwide studies, suggesting that further epidemiologic studies would not reverse the findings.

[9] Schonberger et al., *supra* note 6.

[10] INST. OF MED., *supra* note 7.

[11] Pritchard et al., *supra* note 5.

[12] *Pritchard* further discusses that of the GBS patients, 311 patients had received vaccinations since having GBS. 11 patients or 3.5% reported symptoms of increased fatigue, weakness, numbness, and paresthesia, but these were usually mild and did not require hospitalization or treatment. In three cases, onset was within 24 hours and all but one case reported onset within one week of vaccination. One patient reported being unable to walk or drive for six weeks. Pet. Ex. 17 at 1. Influenza, tetanus, and typhoid were the vaccinations most commonly associated with relapse of GBS. Of the 311 patients who received vaccines after having GBS, 29 patients also received a vaccine within six weeks before the onset of their initial GBS, and two had a recurrence after receiving a different vaccine. *Id*. Of the 179 CIDP patients, 65 had been vaccinated after disease onset. Five reported worsening symptoms after vaccination, with three of these patients having a typical relapse of CIDP, but only one required treatment within two months of vaccination. The two others were vaccinated while already experiencing neurologic symptoms, which worsened and caused them to become dependent on a cane and unable to drive. Two out of 23 patients with CIDP experienced a relapse after the tetanus vaccine, two out of 46 after the flu vaccine, one after simultaneous flu and pneumococcus vaccines, and two out of six after the pneumococcus vaccine. *Id*. 14 patients with CIDP had no symptoms of relapse after the typhoid vaccine, and between one and seven patients with CIDP had no symptoms after yellow fever, diphtheria, meningococcus, oral polio, BCG, hepatitis A, hepatitis B, cholera, or rubella vaccines. The study concluded that for those with GBS and CIDP, the risk of relapse from vaccines was low. They also noted that more people who had symptoms responded to the questionnaire than those who did not. Pet. Ex. 17 at 1-2.

[13] Irving Nachamkin et al., *Campylobacter Species and Guillain-Barré Syndrome*, 11 CLINICAL MICROBIOLOGY REV. 555 (1998), filed as "Pet. Ex. 20." *Nachamkin* discusses in detail campylobacter jejuni, a gastrointestinal illness, as well as the various forms of GBS. It details the structural features of Campylobacter that can elicit an autoimmune attack against host nerve tissue due to similarities between the structures of C. jejuni and those present on relevant sites of the peripheral nerve fibers. Pet. Ex. 20 at 7-8. *Nachamkin* notes, however, that while "certain types of Campylobacter may be implicated in GBS, host factors may play an even more important role in developing GBS." *Id*. at 8. Since some patients with C. jejuni with the similarities discussed do not develop antiganglioside

According to Dr. Simpson, petitioner was neurologically asymptomatic prior to the January 29, 2018 flu vaccine. Pet. Ex. 12 at 5. The evolution of her clinical presentation was notable for a constellation of neurological symptoms including gait impairment, muscle weakness, and muscular pain. Neurological examinations revealed bilateral lower and upper extremity sensory impairment and hypo-/areflexia. She had elevated protein on CSF testing. Her presentation was classic for GBS, which was her ultimate diagnosis by all her providers. *Id*. Petitioner was treated with IVIG with improvement in symptoms, further supporting the diagnosis of an immunologically mediated peripheral neuropathy like GBS. *Id*.

Dr. Simpson proposed that while the Table specifies 3-42 days for onset of GBS following influenza vaccine, *Schonberger* demonstrates that the true range of attributable risk is longer than 42 days and up to ten weeks. Pet. Ex. 12 at 5; Pet. Ex. 18.[14]

Dr. Simpson then discussed respondent's suggestion that an upper respiratory infection was an alternative cause of petitioner's GBS. Pet. Ex. 12 at 6-7. He addressed the medical records documenting petitioner's report of flu-like symptoms following her receipt of flu-like symptoms that resolved then returned several weeks later, prior to the onset of her neurological symptoms. *Id*. However, Dr. Simpson argued that it cannot be inferred that this indicates a causative relationship between an upper respiratory infection and GBS, but rather it is more likely that both the upper respiratory symptoms and GBS are causally related to the flu vaccine. *Id*.

Further, Dr. Simpson cited to several studies that support the association between flu vaccination and upper respiratory symptoms within the following weeks, including one study that showed a 4.4-fold increase in non-influenza upper respiratory illnesses in the nine months following receipt of a flu vaccine when compared to a placebo injection. Pet. Ex. 12 at 7; Pet. Ex. 22[15]; Pet. Ex. 23[16]; Pet. Ex. 24.[17]

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antibodies, how these antibodies develop may depend on the interaction between the microbe and the immune system. However, it is unclear whether host genetic factors are important in GBS, which raises the question of whether solely host factors determine the outcome of GBS. Pet. Ex. 20 at 8-9. *Nachamkin* concluded that the association of Campylobacter and the development of GBS is firmly established, but how it induces the disease is unclear. A better system of surveillance is needed since most Campylobacter infections go unrecognized. *Id*. at 9-10.

[14] Schonberger et al., *supra* note 6. *Schonberger* noted that the period of increased risk was concentrated within the 5-week period after vaccination, but it lasted for approximately 9 to 10 weeks. Pet. Ex. 18 at 7.

[15] Benjamin J. Cowling et al., *Increased Risk of Noninfluenza Respiratory Virus Infections Associated With Receipt of Inactivated Influenza Virus*, 54 CLINICAL INFECTIOUS DISEASES 1778 (2012), filed as "Pet. Ex. 22." *Cowling* conducted a randomized study of 115 children over the nine months after they received the inactivated trivalent flu vaccine or a placebo, with recipients of the flu vaccine having an increased risk of non-influenza infections, suggesting that influenza vaccine recipients may lack temporary non-specific immunity against other respiratory viruses.

[16] Alexa Dierig et al., *Epidemiology of respiratory viral infections in children enrolled in a study of influenza vaccine effectiveness*, 8 INFLUENZA & OTHER RESPIRATORY VIRUSES 293 (2014), filed as "Pet. Ex. 23." This was a follow-up study to *Cowling*. The study found an increase in adeno and rhinovirus in children vaccinated against influenza, but the biological mechanism by which the flu vaccine induced immunity to influenza but decreased immunity to other respiratory viruses was unknown. The authors concluded that it should be a priority to determine whether a causal association exists, whether it is consistent across populations, and whether an increase in the rate of non-influenza respiratory illnesses outweighs the benefits of seasonal flu vaccines in children. Pet. Ex. 23 at 1, 7.

[17] Sharon Rifkin et al., *Assessment of temporally-related acute respiratory illness following influenza vaccination*, 36 VACCINE 1958 (2018), filed as "Pet. Ex. 24." *Rifkin* studied the risk of non-influenza caused respiratory

Dr. Simpson concluded that GBS was the correct diagnosis based on petitioner's symptoms and testing, the evidence supporting an association between influenza vaccine and the onset of GBS, and the onset occurring within an appropriate medical time frame following the flu vaccine. Pet. Ex. 12 at 7. Further, "[t]here is no alternative explanation for causation of this neurological syndrome in this patient's medical history." *Id*. The intervening upper respiratory infection is unlikely to be causative of her GBS, because evidence supports an increased risk of upper respiratory infection in the several weeks following influenza vaccination. *Id*.

IV. The Parties' Arguments

A. Petitioner's Argument

Petitioner maintains that she has presented a medical theory causally connecting her GBS to the influenza vaccine. Petitioner's Brief ("Pet. Br.") at 8. She submits that GBS resulting from a flu vaccine is a "Table" injury, and "[t]herefore, a reputable medical theory causally connecting the vaccination and injury is clearly established and accepted by the government." Pet. Br. at 8.

Further, petitioner submitted that her expert Dr. Simpson discussed the generally accepted theory regarding GBS resulting from flu vaccination: "[t]he theory is based upon molecular mimicry, where epitopes of a virus or vaccine, results in development of immune antibodies and/or T cells that could cross-react with epitopes on myelin or axonal glycoproteins of nerves, leading to neuronal damage." Pet. Br. at 8; Pet. Ex. 12 at 4-5. Petitioner continued that molecular mimicry is the accepted mechanism when viral or bacterial antigens share homology with host antigens, and the resulting immune response is directed at both the injected antigens and host antigens. Pet. Br. at 8. (citing *Barone v. Sec'y of Health and Human Servs*., 2014 WL 6834557, at *3 (Fed. Cl. Spec. Mstr. Nov. 12, 2014).[18]

Petitioner submitted that she has presented evidence of a specific biological mechanism that explains how the flu vaccine provoked an autoimmune response which caused GBS by molecular mimicry, and has therefore satisfied her burden under Prong I. Pet. Br. at 8.

Petitioner further argued that she was healthy prior to January 29, 2018, and developed GBS 46 days after the flu vaccine "consistent with post-vaccination GBS. Pet. Br. at 9; Pet. Ex. 3 at 35-40; Pet. Ex. 12 at 5. Petitioner asserts that Dr. Simpson "demonstrated a theory, based on molecular mimicry, where the flu vaccine results in development of immune antibodies and/or T cells that could cross-react with epitopes on myelin or axonal glycoproteins of nerves, leading to GBS." Pet. Br. at 9; Pet. Ex. 12 at 4-5. Therefore, petitioner has satisfied her burden under Prong II. Pet. Br. at 9.

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infections in post-influenza vaccinated children when compared with unvaccinated children. The study found an increased hazard of acute respiratory infection caused by non-influenza pathogens in the influenza vaccinated population, and concluded this warranted further investigation, which could correct the misperception that all acute respiratory infections occurring after vaccination were caused by influenza.

[18] Petitioner cites to a case involving GBS after a flu vaccine prior to flu/GBS being recognized as an on-Table injury. *See Barone*, 2014 WL 6834557 at *6.

In addressing respondent's argument that petitioner suffered from an intervening upper respiratory infection that was an alternative cause of her GBS, petitioner argued that Dr. Simpson addressed this, citing to studies that demonstrated an increased risk of upper respiratory infection in the weeks following flu vaccine and suggesting that both petitioner's upper respiratory symptoms and GBS were caused by the flu vaccine. Pet. Br. at 9; Pet. Ex. 12 at 7; Pet. Ex. 22[19]; Pet. Ex. 23[20]; Pet. Ex. 24.[21]

Regardless, petitioner argued that even if it was determined that the upper respiratory infection was a factor, petitioner is not required to show that the flu vaccine was the sole cause or even a predominant cause of her GBS. Rather, demonstrating that the vaccine was a "substantial factor" and a "but for" cause of the injury is sufficient. Pet. Br. at 9 (citing *Pafford v. Sec'y of Health & Human Services.*, 452 F. 3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Services.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)).

Finally, petitioner maintains that onset in this case was approximately 46 days after her receipt of the flu vaccine. Pet. Br. at 10. While the Table criteria for GBS and flu vaccine is 3-42 days, Dr. Simpson relied on *Schonberger* to explain that studies have shown the risk period to be up to 10 weeks. Pet. Br. at 11; Pet. Ex. 12 at 5; Pet. Ex. 18 at 8.[22] Petitioner noted that respondent has not offered any evidence to demonstrate that 46 days is not within a medically acceptable timeframe, and other Program cases have found eight weeks or 56 days to be a reasonable timeframe for the onset of GBS symptoms following flu vaccination. Pet. Br. at 11-12 (citing *Barone*, No. 11-707V, 2014 WL 6834557, at *13).

Petitioner concluded that she has satisfied all three *Althen* Prongs and is therefore entitled to compensation under the Vaccine Act. Pet. Br. at 12.

B. Respondent's Argument

Respondent briefly reviewed the relevant procedural history, referencing his initial Rule 4(c) Report. In this report, respondent recommended against compensation because petitioner's onset of 46 days was outside the 3-42 day window required for a Table injury of GBS following the flu vaccine, and petitioner had failed to establish a cause-in-fact claim. Respondent's Brief ("Resp. Br.") at 2; ECF No. 21.

Respondent further noted that after petitioner filed the report of Dr. Simpson, respondent filed an amended Rule 4(c) Report, maintaining his position that petitioner failed to meet her burden under the Vaccine Act, but stating that "in light of petitioner's expert report and the evidence filed therewith . . . he no longer wished to defend against petitioner's entitlement claim before the Office of Special Masters and requested a ruling on the record regarding petitioner's entitlement to compensation." Resp. Br. at 2; ECF No. 26 at 7-9.

[19] Cowling et al., *supra* note 15.
[20] Dierig et al., *supra* note 16.
[21] Rifkin et al., *supra* note 17.
[22] Schonberger et al., *supra* note 6.

Respondent detailed petitioner's arguments and responded that "[a]s noted in respondent's Amended Rule 4(c) Report, respondent maintains that petitioner has not met her burden of proof under the Vaccine Act but no longer wishes to defend against petitioner's entitlement claim before the Office of Special Masters." Resp. Br. at 7; ECF No. 26 at 9.

Respondent concluded that the Special Master should decide the issue of entitlement based on the record as filed. In the event that entitlement is decided in petitioner's favor, respondent recommended further proceedings be scheduled to determine the type and amount of damages to be awarded, and reserved his right to request additional information in support of a damages award. Resp. Br. 7-8.

V. Legal Standard

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. 42 U.S.C. § 300aa-11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an "off-Table" injury, which requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii); *see also Wright v. Sec'y of Health & Human Servs*., 22 F.4th 999, 1006 (Fed. Cir. 2022) (defining the term "residual effects" in the Act, as "detrimental conditions within the patient, such as lingering or recurring signs and symptoms" of the alleged vaccine injury, which are compensable). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Petitioners are not required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Human Servs*., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Human Servs*., 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes"). Once a petitioner has proven causation by preponderant evidence, "the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs*., 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing 42 U.S.C. § 300aa-13(a)(1)(B)).

To prove causation, a petitioner must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that a petitioner show by preponderant evidence that a vaccination they received caused their injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id*. at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53).

Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

Each *Althen* prong requires a different showing. Under the first prong, a petitioner must provide a "reputable medical theory" demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, a petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id*. at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). Even if the vaccination can cause the injury, a petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs*., 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *Id*. at 961 (citation omitted), and "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," *Paluck v. Sec'y of Health & Human Servs*., 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

The third *Althen* prong requires that a petitioner establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id*. However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id*.; *see also Locane v. Sec'y of Health & Human Servs*., 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Finally, although this decision discusses some but not all the literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence

even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Discussion

It is undisputed that petitioner received a flu vaccination, that she suffered from GBS, and that she suffered the sequela of GBS in excess of six months. Respondent raised two issues: the onset of GBS 46 days after receipt of the flu vaccination, and petitioner's "flu-like illnesses" reported as occurring between her receipt of the flu vaccination and the onset of her GBS. *See* Resp. Br. at 7; ECF No. 21 at 7-9. Therefore, this case is one of causation-in-fact, and petitioner must prove by preponderant evidence the three prongs of *Althen*. Based on the existing medical records, expert opinion, and medical literature filed, I find petitioner has satisfied her burden.

A. Petitioner Has Satisfied *Althen* Prong I

The first *Althen* prong requires petitioner to provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379 (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). This standard was recently clarified by the Federal Circuit. *See Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d at 1351, 1359-60 (Fed. Cir. 2019) (stating that the correct standard for *Althen* prong one is "reputable," and "sound and reliable" not a "lower reasonable standard" (internal quotations omitted)). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde*, 746 F.3d at 1341.

Following a review of the 2012 Institute of Medicine ("IOM") report, which was developed after the IOM conducted a comprehensive review of the scientific literature on vaccines and adverse events, the committee charged with this review agreed to proposed changes to the Vaccine Table. In accordance with Section 312(b) of the National Childhood Vaccine Injury Act of 1986, Title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and Section 2114(c) of the Public Health Service Act as amended (PHS Act) (42 U.S.C. 300aa-14(c)), the following change, *inter alia,* to the Vaccine Table became effective on February 21, 2017: "XIV. Seasonal influenza vaccine…(D) Guillain-Barre Syndrome within 3-42 days (not less than 3 days and not more than 42 days)." National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294-01 (Jan. 19, 2017) (codified at 42 C.F.R. § 100.3 (2022)).

Because this is not a Table case, petitioner is required to prove the *Althen* Prongs despite the Program's recognition that flu vaccine can cause GBS. To that end, citing to medical literature, Dr. Simpson explained how viral illnesses and vaccinations can cause acute demyelinating illnesses in the nervous system in general, and how the flu vaccine can cause GBS

specifically. Pet. Ex. 12 at 4; Pet. Ex. 15.[23] He proposed molecular mimicry as the biological mechanism to explain how the flu vaccine can cause GBS. He relied on the epidemiological study by *Schonberger* showing the increased risk of developing GBS following the swine flu vaccine in the 1970s, as well as other studies concluding that molecular mimicry was accepted in the medical community as a plausible theory for how the flu vaccination can cause GBS. Pet. Ex. 12 at 4-5; Pet. Ex. 17[24]; Pet. Ex. 18[25]; Pet. Ex. 19[26]; Pet. Ex. 20.[27]

Petitioner presented a sound and reliable medical theory supported by medical literature and an expert opinion for how flu vaccine can cause GBS that is sufficient to satisfy *Althen* Prong I. While the depth of Dr. Simpson's opinions may be insufficient in other contexts, the acceptance by the IOM that the flu vaccine can cause GBS weighs in favor of petitioner having satisfied her burden under Prong I. Further, respondent's lack of effort in rebutting Dr. Simpson's opinions with an expert report of his own and claiming only that petitioner has not satisfied the *Althen* prongs also weighs in favor of petitioner. There are occasions where this approach may be appropriate and sufficient for respondent to be successful, but the evidence offered herein along with the medical community's acceptance of the connection between flu vaccine and GBS amounts to preponderant evidence in favor of petitioner on Prong I.

B. Petitioner Has Satisfied *Althen* Prong II

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccinations can cause the injury, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "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," *Paluck*, 786 F.3d at 1385 (quoting *Andreu*, 569 F.3d at 1375). Petitioner is not, however, required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes").

It is undisputed that petitioner received a flu vaccine and suffered GBS. However, respondent argued that petitioner had an upper respiratory infection after her receipt of the flu vaccine and prior to her onset of GBS. Therefore, the upper respiratory infection was the cause of her GBS, not the flu vaccine. *See* ECF No. 21 at 8-9.

It is unclear what petitioner suffered following the flu vaccine and prior to the onset of her GBS. Petitioner affirmed that she started experiencing flu-like symptoms right after the flu

[23] Levin et al., *supra* note 4.
[24] Pritchard et al., *supra* note 5.
[25] Schonberger et al., *supra* note 6.
[26] INST. OF MED., *supra* note 7.
[27] Nachamkin et al., *supra* note 13.

vaccine and could not go to school for about a week because she had a fever and was sore and throwing up. Pet. Ex. 25 at 1. She further affirmed that around March 7, 2018, she had flu-like symptoms, fatigue, and nausea again and was sick for a few days. *Id*. She never described symptoms of an upper respiratory infection, but rather only non-descript "flu-like symptoms." *See id*.

The medical records show that when petitioner presented to the ER on March 20, 2018, she reported generalized body aches that were worse in her legs than in her upper body, but denied fever, sick contact, or recent travel. Pet. Ex. 9 at 136. When she returned to the ER three days later, she reported weakness and body aches unchanged from two days ago, but she was now unable to walk without pain and had some dizziness and blurred vision. No illness of any kind was reported. *Id*. at 104. On March 24, 2018, when petitioner presented to Optimus Health Care Clinic for "[t]otal body weakness," her mother reported that she had been sick since getting the flu vaccine in January. There was no explanation of what symptoms she had since then, other than a fever twice. Pet. Ex. 3 at 31. Upon arrival at Yale on March 25, 2018, she reported "flu like symptoms" that resolved, reoccurred several weeks later, and resolved again. She then started developing lower extremity pain and weakness. Pet. Ex. 4 at 10. *Id*. at 10, 29. Petitioner underwent extensive viral panels, all of which were negative for viruses. *Id*. at 22-23, 58-59.

Petitioner did not report suffering from an upper respiratory infection at any time throughout her treatment. One medical record documented that petitioner "…endorses a flu-like syndrome (fever, chills, myalgias, nausea, emesis x 1) roughly 3.5 weeks ago that subsided within a week." Pet. Ex. 4 at 41. However, petitioner never explained with specificity what she meant by "flu-like symptoms" when she experienced them either right after her receipt of the flu vaccine or again several weeks later. Further, it is unclear if petitioner provided the details of fever, chills, myalgias, nausea, and one episode of emesis included in that history, or if it was provided by the person taking the history. *See id.*

Petitioner's text messages to her mother show that on February 1, 2018, petitioner texted her mother that she was "so sick I wanna die" and that she should never have gotten the flu shot. Pet. Ex. 26 at 2. On March 7, 2018, petitioner texted her mother at 1:35 am and 11:01 am that she threw up, her stomach hurt, and she was afraid to eat because she didn't want to throw up. *Id*. at 3. On March 19, 2018 at 8:26 am, she asked her mother to pick her up because she was in so much pain. *Id*. at 4. Other than the text message on February 1, 2018 when petitioner mentioned the flu vaccine, the details of petitioner's illnesses when these text messages were sent is not known.

Petitioner's school record shows that she did not go to school on February 2 or February 5, 2018, but she was not absent again until March 19, 2018. Pet. Ex. 11 at 2. Therefore, whatever "flu-like symptoms" she suffered in March were not significant enough to keep her out of school.

While there is no definitive proof that petitioner suffered from an upper respiratory infection or that the symptoms she referred to as flu-like symptoms would qualify as an upper respiratory infection, Dr. Simpson seemingly accepted respondent's reference to an upper respiratory infection in rendering his opinion regarding the potential involvement of the upper respiratory infection in her GBS. Pet. Ex. 12 at 6-7. Dr. Simpson argued that a causative

relationship between an upper respiratory infection and GBS cannot be inferred, but rather that the symptoms of each were causally related to the flu vaccine. *Id*. He then cited several cases which studied the increase in non-influenza upper respiratory illnesses in children in the months following receipt of the flu vaccine. Pet. Ex. 12 at 7; Pet. Ex. 22[28]; Pet. Ex. 23[29]; Pet. Ex. 24.[30]

Further, respondent did not rebut Dr. Simpson's opinions or interpretation of her medical history. He offered no expert opinion or other support for his claim that an alternative cause existed for her GBS, other than the unsupported possibility that she suffered from an upper respiratory infection after the flu vaccine but prior to the onset of GBS. Additionally, respondent did not offer any evidence to establish how an upper respiratory infection, if petitioner did have one, could cause GBS.

Between March 20, 2018 and March 25, 2018, petitioner's mother relentlessly sought medical attention for petitioner's unexplained symptoms while her condition progressively worsen. Had petitioner been sick with an upper respiratory or other illness of any significance prior to the onset of her GBS, her mother certainly would have reported that to the various doctors at the many visits over those five days rather than simply saying she had been sick since the flu vaccine.

Based on Dr. Simpson's opinion that petitioner's GBS and other symptoms were all causally related to the flu vaccine and the lack of any definitive evidence of an upper respiratory infection in petitioner's records, I find that petitioner has satisfied Prong II.

C. Petitioner Has Established *Althen* Prong III

To satisfy the third *Althen* prong, petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires prepondrant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Dr. Simpson opined that 46 days was a medically appropriate timeframe for the onset of GBS following petitioner's flu vaccine. Pet. Ex. 12 at 5. In support of his opinion, he relied on *Schonberger* which provided that the increased risk period was within 5 weeks but could last up to 10 weeks. *Id.*; Pet. Ex. 18.[31]

[28] Cowling et al., *supra* note 15.
[29] Dierig et al., *supra* note 16.
[30] Rifkin et al., *supra* note 17.
[31] Schonberger et al., *supra* note 6.

The Vaccine Table provides for onset of GBS within 3 to 42 days of the flu vaccine. Petitioner's onset was 46 days, though there was a report early in her presentation where she reported onset as March 10 or 11, which would have placed onset on the 40th or 41st day after the flu vaccine. *See* Pet. Ex. 3 at 57; Pet. Ex. 8 at 69. Decisions in the Vaccine Program have gone out as far as two months or 60 days for vaccine-caused demyelinating illness. *See, e.g.*, *Spayde v. Sec'y of Health & Human Servs.*, No. 16-1499V, 2021 WL 686682, at *19 (Fed. Cl. Spec. Mstr. Jan. 27, 2021).

Respondent provided no evidence to argue against the 46-day onset in this matter. I therefore find that petitioner offered sufficient evidence to support the 46-day onset of GBS following flu vaccination and has therefore satisfied Prong III.

D. Burden Shifting: Alternative Causation

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Human Servs*., 98 Fed. Cl. 719 (2011). Consequently, the burden then shifts to the government to prove that an alternative cause unrelated to the administration of the vaccine was the "sole substantial factor" in causing the alleged injury. *De Bazan*, 539 F.3d at 1354; *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" 42 U.S.C. § 300aa-13(a)(2); *see also Doe/11 v. Sec'y of Health & Human Servs.*, 83 Fed. Cl. 157 (2008) (holding that an idiopathic diagnosis cannot be a "factor unrelated," as it is idiopathic).

As the foregoing confirms, it is unclear what petitioner meant by "flu-like symptoms" following her receipt of the flu vaccine and again several weeks later. Further, respondent did not provide any evidence to show how a virus such as an upper respiratory infection could cause GBS. Rather, he appears to rely only on the temporal association of petitioner's complaint of "flu-like symptoms" prior to the onset of her GBS to demonstrate alternative causation. Just as the word of petitioner alone is insufficient to support a claim, respondent simply claiming that petitioner suffered some sort of illness between the receipt of a vaccination and the onset of GBS is insufficient to satisfy his burden in proving alternative cause.

VII. Conclusion

Having considered all the evidence filed in this matter, I am persuaded that petitioner has carried her burden of proof. Despite respondent's objections to the contrary, he provided no expert report or other evidence to rebut the evidence presented by petitioner. The record sufficiently establishes that petitioner's flu vaccine was the substantial factor in her development of GBS. Accordingly, this matter shall proceed to damages. A separate damages order will be issued.

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master