In the United States Court of Federal Claims OFFICE OF SPECIAL MASTERS

No. 17-487V

Filed: January 8, 2021

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BARBARA PERKINS,					*	To Be Published
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Petitioner,					*	
V.					*	Finding of Facts; Onset; Tetanus-
					*	diphtheria-acellular pertussis ("Tdap")
SECRETARY OF HEALTH					*	Vaccine; Guillain-Barre Syndrome
AND HUMAN SERVICES,					*	("GBS"); Miller-Fisher Variant ("MFV")
					*	
Respondent.					*	
L.					*	
					*	
* * * * * * * * * *	*	*	*	*	*	

Lawrence Michel, Esq., Kennedy Berkley, et al., Salina, KS, for petitioner. *Mallori Openchowski, Esq.*, U.S. Department of Justice, Washington, DC, for respondent.

<u>RULING ON ONSET¹</u>

Roth, Special Master:

On April 6, 2017, Barbara Perkins ("petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*² ("Vaccine Act" or "the Program"). Petitioner alleged that as a result of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine she received on November 2, 2015 she developed the Miller-Fisher variant ("MFV") of Guillain-Barré syndrome ("GBS"). Petition at 1, ECF No. 1. As explained below, I find that petitioner's symptoms of dizziness, double vision, and ataxia, associated with her diagnosis of Miller-Fisher variant GBS, began after January 4, 2016.

¹ This Ruling has been designated "to be published," which means I am directing it to be posted on the Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public. *Id*.

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 (2012).

I. Procedural History

The petition was filed on April 6, 2017, along with an affidavit from petitioner as an attachment. ECF No. 1. On April 7, 2017, petitioner's affidavit was again filed; neither filing of the affidavit was designated as an exhibit. ECF No. 4. Petitioner filed medical records on May 8, 2017. Petitioner's Exhibits ("Pet. Ex.") 1-7, ECF No. 8.

The initial status conference was held on May 17, 2017. Respondent was ordered to file a status report identifying any missing medical records and provide his position by July 17, 2017. Scheduling Order at 1, ECF No. 9. That same day, petitioner's affidavit was refiled designated as "Pet. Ex. 8." ECF No. 10.

After requesting and receiving multiple extensions of time, respondent filed a status report on October 19, 2017, requesting a deadline for his Rule 4(c) Report. *See* Respondent's Status Report ("Resp. S.R."), ECF No. 12; Non-PDF Order, issued July 17, 2017; Resp. S.R., ECF No. 13; Non-PDF Order, issued Sept. 15, 2017; Resp. S.R., ECF No. 14.

Respondent filed his Rule 4(c) Report ("Resp. Rpt.") on December 4, 2017, recommending against compensation. ECF No. 15. Respondent postured that "petitioner has not offered any evidence to show that the onset of her alleged vaccine injury (at least eight weeks after vaccination) occurred in a time frame within which vaccine causation could be ascribed." Resp. Rpt. at 8. Respondent pointed out that when petitioner presented for a mammogram on November 9, 2015, she "completed a fall risk questionnaire, in which she noted that she had no difficulty with walking or balance." *Id.* at 2 n.2 (citing Pet. Ex. 2 at 274). Further, petitioner identified the onset of her symptoms as January 1, 2016 and January 2, 2016 when seeking treatment. *Id.* at 4 n.3 (citing Pet. Ex. 1A at 32); *id.* at 4 n.4 (citing Pet. Ex. 2 at 86). Respondent pointed out that her symptoms began in mid-December 2015. *Id.* at 5. Respondent also noted concerns regarding the six-month requirement and alternative causes of petitioner's condition. *Id.* at 4 n.4, 5, 6, 8.

Petitioner filed additional medical records on January 17, 2018. Pet. Ex. 9-11, ECF No. 21. A status conference was held on January 18, 2018, during which the issues raised in the Rule 4(c) Report were discussed. Scheduling Order at 1, ECF No. 23. Petitioner's counsel requested the opportunity to consult with an expert, and if appropriate, file an expert report addressing the onset issue, six-month requirement, and suggestion of alternate causes. *Id.* at 1-2.

Petitioner filed an expert report and CV from Dr. David Axelrod, an immunologist, on February 9, 2018. Pet. Ex. 12-13, ECF No. 24. In Dr. Axelrod's initial report, he placed the onset of petitioner's symptoms one week prior to January 6, 2016 consistent with the contemporaneous medical records filed in this matter. Pet. Ex. 12 at 1640. He then later concluded that the onset was in mid-December, approximately 42 days after her receipt of the Tdap vaccine based on petitioner's affidavit. *Id*.

Following several extensions of time, on July 2, 2018, respondent filed an expert report from Dr. Timothy Vartanian, a neurologist. *See* Motion for Extension of Time ("MFET"), ECF No. 26; Non-PDF Order, issued Apr. 9, 2018; MFET, ECF No. 27; Non-PDF Order, issued May

24, 2018; MFET, ECF No. 28; Non-PDF Order, issued June 22, 2018; Resp. Ex. A, ECF No. 29. Dr. Vartanian opined that petitioner's clinical picture fit with an onset in early January. Resp. Ex. A at 12-13.

Petitioner filed a supplemental expert report from Dr. Axelrod on July 12, 2018. Pet. Ex. 19, ECF No. 31. Dr. Axelrod wrote that petitioner reported an onset of loss of balance, double vision, weakness, and difficulty with speech on December 15, 2015. *Id.* at 1790. However, this information is contained in petitioner's affidavit with no support found in any of the contemporaneous medical records and no citation by Dr. Axelrod to any medical record.

Respondent filed medical literature on October 1, 2018, and a responsive expert report from Dr. Vartanian on October 10, 2018. Resp. Ex. A, Tabs 1-9, ECF No. 34; Resp. Ex. A, Tabs 10-12, ECF No. 35; Resp. Ex. C, ECF No. 36.

A Rule 5 status conference was held on December 19, 2018. Scheduling Order, ECF No. 37. During the conference, the discrepancies in onset presented in petitioner's affidavit and Dr. Axelrod's reports, in contrast with the contemporaneous medical records were discussed. *Id.* at 3-4. Petitioner's counsel admitted that Dr. Axelrod's opinion was predicated on an onset in mid-December and requested time to confer with Dr. Axelrod about whether Dr. Axelrod could support an onset of symptoms beginning in January. *Id*.

Petitioner filed a status report on February 4, 2019 advising that Dr. Axelrod could only support a theory of causation if petitioner's symptoms began in mid-December 2015. ECF No. 38 at 1. Petitioner requested "the opportunity to provide live testimony to the Court addressing the inconsistency between her affidavit and medical records regarding the onset of symptoms." *Id.*

A status conference was held on April 18, 2019. Scheduling Order, ECF No. 39. During the conference, petitioner's counsel advised that petitioner sincerely believed that she experienced an onset of symptoms in mid-December. *Id.* at 1. Petitioner was ordered to file a status report advising the Court on how she intended to proceed, and to suggest dates for an onset hearing, if appropriate. *Id.* at 2.

Petitioner filed a status report on June 18, 2019, suggesting November 5, 2019, as the date for the onset hearing. ECF No. 46. A prehearing order was issued. ECF No. 47.

On September 12, 2019, petitioner filed affidavits from Kim Perkins, her husband; Kistine Uffens, her daughter; Matt Uffens, her son-in-law; and Kyle Perkins, her son. *See* Pet. Ex. 23-26, ECF No. 48. Petitioner's counsel advised that all witnesses would be testifying on November 5, 2019.

On November 4, 2019, petitioner filed the following: petitioner's credit card bill showing the purchase of Southwest airline tickets on September 28, 2015; petitioner's airline tickets for her

trip to and from Seattle;³ petitioner's bank statement;⁴ text messages between petitioner and Kistine Uffens;⁵ Kyle Perkins' credit card statement;⁶ and a bank statement for Kistine and Matt Uffens.⁷ See Pet. Ex. 27-32, ECF No. 51.

An onset hearing was held on November 5, 2019, in Washington, DC. Petitioner and her witnesses appeared via videoconference from Utah. Following the hearing, a discussion was had with counsel to address the discrepancies in the facts as testified to by the various witnesses. An Order was issued for petitioner to file the records of Google search histories conducted by petitioner and her son as well as additional evidence to corroborate the affidavit of Mr. Uffens regarding a family trip to Discovery Park. *See* Scheduling Order, ECF No. 52.

On December 19, 2019, petitioner filed a response to the Court's order following the hearing, in which she stated that she and her son Kyle could not find any Google search history on their computers or phones. Response at 1, ECF No. 55. Further, upon reflection, Mr. Uffens was mistaken in recalling a trip to Discovery Park in December 2015; he was actually thinking of a trip to Chambers Bay, as documented in the photographs discussed during the hearing. *Id.* The Response also stated, "Attached hereto as Exhibit "A" is a social media post of petitioner's grandchildren by her daughter at the water park on December 24, 2015. Although petitioner was with her son's family on that particular date, this is the same water park they attended the day after Christmas, which was two days later. No documentation of payment of the entrance fee has been found and petitioner assumes they paid cash to visit the facility." *Id.* There was no attachment A filed with this response.

On December 20, 2019, respondent filed a status report requesting that any change to affidavits or testimony be made via sworn statement, and not through counsel. ECF No. 56.

On February 14, 2020, petitioner filed a "Response to Order" attaching as Exhibit A an affidavit of Matt Uffens, correcting and clarifying his recollections in this matter. According to

⁶ Between December 23, 2015 and January 2, 2016, Mr. Perkins purchased Delta Airline tickets, admission to Point Defiance Zoo on December 28, and admission to Lucky Strike Bellevue, a bowling alley, also on December 28, 2015. Pet. Ex. 31 at 1-2.

³ Petitioner's flight left Denver at 4:10 p.m. on December 23, 2015 and left Seattle at 10:05 a.m. on Saturday, January 2, 2016. Pet. Ex. 28 at 2.

⁴ Petitioner made various purchases in Washington state between December 23, 2015 and December 31, 2015, including Wal-Mart, Rudloof's United Pacific, Café Rio, Regal Cinemas, and admission at Point Defiance Zoo. Pet. Ex. 29 at 2.

⁵ On December 3, 2015, Ms. Uffens texted petitioner to confirm the plans for December 24, 2015 through January 2, 2016. Pet. Ex. 30 at 1. On December 21, 2015, Ms. Uffens sent petitioner a photo of petitioner's grandchildren. *Id.* at 2. On December 26, 2015, Ms. Uffens sent petitioner photos of petitioner with her grandchildren in front of a lake or other body of water. *Id.* at 3.

⁷ Mr. and Ms. Uffens' bank statements show purchases between December 24, 2015 and January 4, 2016, at various stores and Leavenworth Winter Peshastin, which appears to be a property fronting the Wenatchee River with a ski area, golf course, and trails. Pet. Ex. 32 at 2.

Mr. Uffens, while recalling memories from four years ago, he confused petitioner's visit to Seattle in December 2015 with her visit to Seattle in July 2016. Pet. Ex. A at 1. Upon looking at pictures with time stamps on them provided by his wife Kistine, Mr. Uffens affirmed that he recalled walking with petitioner at Chambers Bay golf course in December 2015 and provided details about the train tracks near the water, the old quarry, and the lone tree near the water. *Id.* at 2. Mr. Uffens also recalled his son and family members playing with a Nerf bow and arrow his son received for Christmas. *Id.* However, Mr. Uffens provided generalized statements with no specific details relating to any specific observances of petitioner other than to say, "I recall it took us some time to complete the loop, and specifically coming up the hill as you complete the walk." *Id.*

On February 21, 2020, an order was issued for petitioner to file any additional information in support of onset by March 23, 2020. Non-PDF Order, issued Feb. 21, 2020. Petitioner responded on February 24, 2020, advising that no further evidence would be submitted. ECF No. 58.

An Order was issued on February 25, 2020, closing the record on evidence to be considered in this ruling. ECF No. 59.

II. The Factual Record

A. Petitioner's History Prior to the Tdap Vaccine

Petitioner was born on October 12, 1962. Pet. Ex. 4 at 1593. She is married with five children and works as a piano teacher. *Id.* Her previous medical history is significant for recurrent sinusitis and seasonal allergies.

Petitioner presented to Siena Medical Clinic on February 20, 2014 with a sinus infection ongoing for one month. Pet. Ex. 4 at 1593. She had been taking Allegra without any improvement. *Id.* She reported that "she usually winds up with a sinus infection about every winter." *Id.* She was prescribed amoxicillin for 14 days for sinusitis. *Id.* at 1594. Petitioner reported a family history of colon cancer; her last colonoscopy was approximately five years before and she wanted to schedule another one. *Id.* at 1593. Petitioner had moved from Pennsylvania to Garden City about eight or nine months before. *Id.* She wanted to establish care with a D.O. in Garden City, specifically noting she did not want to see an M.D. or nurse practitioner. *Id.* She was advised that Dr. Hunsberger was the only D.O. in Garden City; attempts were made to establish care without success. *Id.*

Two months later, on April 24, 2015, petitioner returned to Siena Medical Clinic with complaints of sinus pressure, "ears feeling plugged up," mild cough, and runny nose. Pet. Ex. 4 at 1592. She was advised to try a daily antihistamine but declined. *Id*. She insisted on antibiotics for sinusitis; "[s]he states she is sure she has a sinus infection and an antibiotic is the only thing that will help it." *Id*. She was prescribed a ten-day course of amoxicillin. *Id*.

In September 2015 and on November 2, 2015, petitioner presented for and underwent treatment unrelated to this matter.⁸ *See generally* Pet. Ex. 2; Pet. Ex. 4. At the November 2, 2015 visit, petitioner was administered a Tdap vaccination. Pet. Ex. 4 at 1591.

⁸ This care is unrelated to petitioner's chronic sinusitis and ear infections and is not provided in detail herein as it is irrelevant to the matter.

B. Petitioner's History After the Tdap Vaccine

On January 4, 2016, two months after the November 2, 2015 Tdap vaccination, petitioner presented to Siena Medical Clinic with complaints of ear and sinus problems. Pet. Ex. 4 at 1587. She reported being ill for about a week.⁹ "[S]he recently flew back to Garden City from Seattle and her symptoms became worse." *Id*. An exam revealed a 53-year-old female in no acute distress. *Id*. She was neurologically intact, moved her extremities well, and did not have joint heat, redness, swelling, or gross deformity. *Id*. The impression was "Acute suppurative bilateral otitis media without rupture." *Id*. She was prescribed a Z-Pak for five days. *Id*. at 1586. The record documents, "[S]he does request this type of antibiotic due to past experience with good effectiveness." *Id*.

Two days later, on January 6, 2016, petitioner presented to the emergency room at St. Catherine's Hospital ("St. Catherine's"). Pet. Ex. 2 at 1298. She complained of ear pain, dizziness, and double vision. *Id.* She reported her "[s]ymptoms began approximately one week ago with a sore throat while she was traveling in Seattle. Approximately 5 or 6 days ago she began to experience bilateral ear pain...[which] has worsened over the past several days."¹⁰ *Id.* She saw her primary doctor who diagnosed her with otitis media and prescribed azithromycin. *Id.* She started the antibiotics but reported "tonight" she had symptoms of dizziness, ataxia, worsening ear pain, subjective fevers, double vision, retro-orbital pain, and diffuse tingling throughout her body. *Id.* She denied focal weakness or numbness. Cranial nerves were intact. *Id.* A head CT was performed and showed bilateral mastoid effusions, possibly consistent with mastoiditis. *Id.* at 1299-1300; Pet. Ex. 3 at 1554-55. The assessment was bilateral mastoiditis and otitis media with labyrinthitis; she was admitted for IV antibiotics. Pet. Ex. 2 at 1316.

While in the hospital on January 6, 2016, petitioner developed increased numbness of her entire body, particularly her face and jaw. Pet. Ex. 2 at 1414. She started to have trouble eating as compared to earlier that morning. *Id*. Upon exam, she was alert and oriented with no confusion noted and sensation intact in all extremities. *Id*. Continued monitoring and neurologic checks were ordered. *Id*.

A brain MRI conducted on January 7, 2016 showed no acute intracranial abnormality. Pet. Ex. 2 at 1324-25. However, there was moderate to severe inflammatory mucosal thickening in the sphenoid sinus¹¹ and mild to moderate inflammatory mucosal thickening at the right mastoid air

⁹ This would place onset of ear and sinus problems on or about December 28, 2015.

¹⁰ Assuming that "several days" refers to the five or six days reported by petitioner, this history would place onset of sore throat on or about December 30, 2015, and onset of ear pain on December 31, 2015 or January 1, 2016.

¹¹ The sphenoid sinus is one of the paranasal sinuses in the sphenoid bone, an irregular, wedge-shaped bone at the base of the skull. *Sphenoid sinus*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1692 (33d ed. 2020) [hereinafter "DORLAND'S"]; *os sphenoideum*, *id*. at 1323.

cells¹² and probable partial opacification¹³ of the right middle ear. Id.

A progress note for January 7, 2016 documented petitioner as afebrile, with stable vital signs and no leukocytosis. Pet. Ex. 2 at 1379. Her dizziness and ear pain had improved, but she was "still wobbly." *Id.* Later that day, she was noted to be responding to treatment and would be continued on steroids, Rocephin, and Vancomycin. *Id.* at 1378. There was concern about her ataxia; the plan was to discuss her case with radiology and order an MRI with IV contrast. *Id.* Her diagnosis remained bilateral mastoiditis. *Id.*

On January 8, 2016, petitioner was transferred to Porter Adventist Hospital ("Porter"). Pet. Ex. 2 at 1414. The discharge summary on transfer noted that petitioner had "a 3-day history of some peculiar neurologic changes."¹⁴ *Id.* at 1290. She had been dizzy, and unable to drive a car. *Id.* Her vision was doubled, her speech did not "feel normal," and on examination, she could not deviate her eyes to the left. *Id.* Due to eye movements and "fairly significant neurological changes," petitioner needed to be transferred to a place with a neurologist, and "[g]iven the significance of the mastoiditis," she "probably needs to be evaluated by ENT." *Id.* St. Catherine's did not have a neurologist or an ENT, and thus petitioner was transferred to Porter. *Id.*

Petitioner was admitted to Porter on January 8, 2016 with double vision and mastoiditis. Pet. Ex. 1A at 493. Her complaints started two weeks ago with a sore throat that progressed to ear pain.¹⁵ *Id*. She reported being out of town for the holidays and returning last Monday. *Id*. She went to her primary care provider when she came back to town, and, by then, she "was already starting to have a little bit of dizziness and some double vision." *Id*. She was diagnosed with otitis media and prescribed azithromycin. *Id*. She reported taking two of the azithromycin that day and one the next morning; by that afternoon, she began having neurological symptoms. *Id*. That afternoon, she had progressed to the point that she could not walk. *Id*.

She describes it as more of an ataxia and feeling like she was a noodle, she does note some associated weakness but she feels it is more ataxia and that the weakness is more in her hands and arms although her legs may be a little weak as well. That night, she made it home and to bed; however, by the morning the symptoms were so bad she went to the emergency room in Kansas... She feels that her vision is worsening and her weakness has progressed significantly over the last 48 hours...yesterday while in the hospital her temperature got as high as 99.5, but she has had no diarrhea or vomiting or abdominal pain...at times she has shaking with uncontrollable twitches...she has a little bit of a lisp that she does not usually

¹² Mastoid air cells are cavities containing air within the mastoid process, a projection of bone from the temporal bone just posterior to the bony external acoustic meatus, which is colloquially referred to as the "ear canal." *Air cell*, DORLAND'S at 310; *mastoid*, *id*. at 1097; *processus mastoideus ossis temporalis*, *id*. at 1496; *meatus acusticus externus osseus*, *id*. at 1101.

¹³ "Opacification" means becoming opaque. "Opaque" means impervious to light rays; neither transparent nor translucent. *Opacification*, DORLAND'S at 1305; *opaque*, *id*.

¹⁴ This would place onset of neurological changes on January 5, 2016.

¹⁵ This would place onset of sore throat on or about December 25, 2015.

have... yesterday afternoon she was having a little trouble swallowing, but at 1:30 this morning prior to transfer here, she was able to eat a sandwich without difficulty.

Id. The assessment was otitis media and sinusitis "associated with rather prominent neurologic changes." *Id.* at 495.

Examination at Porter showed 4/5 strength in both upper extremities and bilateral lower extremity weakness in her hip flexors and quadriceps. Pet. Ex. 1A at 508. She could not move her eyes in either direction or look up or down. *Id.* The record noted, "Given the patient's triad of symptoms, including ataxia, areflexia and ophthalmoplegia, consideration that this is a Guillain-Barre syndrome with Miller Fisher variant." *Id.* The plan was to start her on IVIG for five days and monitor her for worsening symptoms. *Id.*

A toxicology consult for botulism was also ordered following petitioner's report that she does home canning. Pet. Ex. 1A at 511. Petitioner reported to the toxicologist that she was in her usual state of health until January 2, 2016 when returning home to Kansas on a flight from Seattle. Id. at 510. She complained that she sat next to somebody who was ill and sneezed in her direction "quite a number of times" on the flight. Id. Shortly thereafter, she developed a sore throat and some ear pain and saw her primary care provider, who felt she had otitis media and started her on azithromycin. Id. She was admitted to St. Catherine's for ataxia and double vision. Id. Her weakness progressed, and by January 8, 2016, she was transferred to Porter. Id. The toxicologist noted that "the most recent thing that she ate that was home canned were tomatoes, which she put in a goulash just before this started...her husband and her daughter ate the same food and they are well." Id. at 511. Botulism antitoxin was ordered from the CDC, as petitioner's home canning and clinical presentation were "consistent with botulism." Id. at 511-12. A nursing note from January 10, 2016 stated that Porter received a call from an epidemiologist to research possible botulism exposures. Pet. Ex. 1B at 1153. "Answered questions with the help of the patient who is very alert and exhibits very precise memory of past few weeks events." Id. Petitioner's daughter and son-inlaw were called to discover the name and phone number of the restaurant that the family ate at on New Year's Eve as well. Id.

On January 19, 2016, petitioner was transferred from Porter to an inpatient rehabilitation facility. The discharge summary from Porter documented likely Miller-Fisher GBS treated with antitoxin as well as IVIG. Pet. Ex. 1A at 485. She had slow improvement with five doses of IVIG and an additional booster dose prior to discharge to rehabilitation. *Id.* Petitioner was discharged from inpatient rehabilitation on February 6, 2016; outpatient physical and occupational therapy was recommended. Pet. Ex. 1 at 8-11.

On February 8, 2016, petitioner was examined at Garden City Vision for double vision. Pet. Ex. 5 at 1603. She was diagnosed with bilateral hypermetropia.¹⁶ *Id*. at 1604.

Petitioner presented for outpatient physical therapy on February 8, 2016. Pet. Ex. 2 at 86. She reported her onset of symptoms as January 1, 2016. *Id*.

¹⁶ "Hypermetropia" is farsightedness. *Hypermetropia*, DORLAND'S at 881; *hyperopia*, *id*.

On February 12, 2016, petitioner presented to Siena to establish treatment with Dr. Rosin. Pet. Ex. 4 at 1582. She reported attending physical therapy three times per week and complained of continued diplopia and generalized weakness. *Id*. On examination, she had abnormal extraocular movements with a dysconjugate gaze, deemed consistent with ophthalmoplegia as noted by her records from Porter. *Id*. at 1583. Dr. Rosin increased petitioner's physical therapy to five times per week and recommended a follow-up appointment in two months. *Id*.

On February 27, 2016, petitioner presented to the ER with left ear pain that "started [T]uesday." Pet. Ex. 3 at 1231. She reported in early January that she had a double ear infection and approximately two days after being diagnosed with a double ear infection "ended up with" a variant of GBS. *Id*. She has been home for approximately three weeks and has had no other chronic illnesses. *Id*. The impression after examination was acute suppurative otitis media without spontaneous rupture of the ear drum in the left ear. *Id*. at 1232. Ciprodex was prescribed and over the counter nasal saline spray was recommended. *Id*.

On February 29, 2016, petitioner returned to Siena with left-sided otalgia and resolving GBS. Pet. Ex. 4 at 1579. "She is quite anxious because she believes that bilateral otitis media was the cause of her Guillain-Barre syndrome a few months ago." *Id.* She had been diagnosed with an ear infection on February 27, 2016 and was still having ear pain. *Id.* Examination revealed some otitis externa in her left ear. *Id.* at 1580. Dr. Rosin noted recent trauma on examination and petitioner admitted to using Q-Tips. Dr. Rosin advised that the use of Q-tips probably aggravated her external otitis media. *Id.* She was instructed to keep foreign bodies out of her ears and finish the prescribed Ciprodex. *Id.* She was noted to be "steadily improving" from GBS and required no other treatment. *Id.*

On March 11, 2016, petitioner presented to Siena with a complaint of nosebleeds. Pet. Ex. 4 at 1576. She reported four in the "last year and a half." *Id.* Her nasal examination was normal; fiberoptic examination in an ENT clinic was recommended. *Id.* Otherwise, she was doing well; she was noted to have resolving GBS and no longer needed to use a walker. *Id.*

On April 13, 2016, petitioner presented to Siena for a routine follow-up. Pet. Ex. 4 at 1573. "I'm doing better and I'm still in physical therapy and occupational therapy." *Id*. She had no new neurological concerns. *Id*. She reported occasional diplopia but no further episodes of epistaxis.¹⁷ *Id*.

The records filed confirm petitioner sought no further medical care for the next 15 months. The next medical records filed were for massage therapy visits on May 15, May 25, July 7, July 17, July 25, and September 7, 2017, for neck, back, and rib pain and numbness, and chiropractic treatment on September 19, 2017, following a car accident on September 16, 2017 with complaints of neck, back, and hip pain. Pet. Ex. 10 at 1636-37; Pet. Ex. 11 at 1641-42. Petitioner presented for 14 chiropractic visits from September 20 through October 19, 2017. *Id.* at 1644-71.

The medical records show no further treatment for GBS after April 13, 2016, approximately five and a half months post-Tdap vaccination on November 2, 2015.

¹⁷ "Epistaxis" means nosebleed. *Epistaxis*, DORLAND'S at 628.

C. Affidavit and Testimony of Petitioner, Barbara Perkins

Petitioner submitted an affidavit, filed as Pet. Ex. 8, and testified at hearing.

Petitioner lives in Orem, Utah. She previously lived in Garden City, Kansas. Tr. 5-6. In 2015, she lived with her husband and her daughter, Jaclyn, who was 15 years old at that time. Tr. 24-25. She also has three older children, Devin, Kistine, and Kyle. Tr. 34. Petitioner's typical activities included grocery shopping, cooking meals, cleaning the house, and driving Jaclyn around. Tr. 25. Petitioner was also the organist at her church and would drive to church to practice. Tr. 25.

Petitioner testified that she did not have a primary care physician in Garden City. Tr. 6. When she needed care, she "would just go to [Siena Medical Clinic] and have to sit and wait along with a lot of other people until [they] could get in." Tr. 6. "If we weren't there early in the morning, we couldn't get in to be seen. There's a shortage of doctors there." Tr. 6.

Petitioner affirmed being a healthy 52-year-old prior to November 2, 2015. Pet. Ex. 8 at 1. She had worn over-the-counter reading glasses since 2007 to read sheet music while playing the piano but had no other vision issues. Tr. 8-9, 26-27. Petitioner testified to seeing an optometrist in Colorado and an ophthalmologist in New Mexico for vision checks as preventative care. Tr. 27-28.

Petitioner affirmed receipt of a flu vaccine on September 11, 2015 at Dillions Pharmacy and a Tdap vaccine on November 2, 2015 at Siena Medical Clinic. Pet. Ex. 8 at 1. Petitioner stated she received the Tdap vaccine because her daughter had just had a baby, she planned to go to Seattle to visit and wanted "to prevent whooping cough for the baby." Tr. 7.

In her affidavit, petitioner claimed that, in mid-December 2015, she developed dizziness, loss of balance, double vision, progressive weakness, and difficulty with speech. Pet. Ex. 8 at 1. She testified to "periods of wobbliness or like not steadiness [which] began on approximately December 15th." Tr. 8-9. She described difficulty with balance and "unsteadiness sometimes when I would be walking, such as going down the stairs, up the stairs, just like turning around to go do something and I would feel a little off balance." Tr. 10, 31. She described difficulty with her vision where she had to move her head and move her eves upward in order to focus on something, but did not see an optometrist for these vision problems, because Garden City is very rural and getting an appointment "would be six months out." Tr. 8, 29. She was still playing the organ at church between December 15th and December 23rd and could not recall whether she had trouble seeing the sheet music while practicing. Tr. 30. She further described slurred speech where her words would not form correctly. Tr. 10. "It wasn't like every word I said was slurred or anything. It was just now and then." Tr. 26. Petitioner stated these symptoms were completely new to her in December 2015. Tr. 32. When asked if these symptoms affected her ability to drive, she stated, "Well, I didn't feel dizzy when I was driving", and she lived in a small town, so all of the places she drove were within four miles. Tr. 31.

Petitioner denied any falls or other possible triggering events and did not seek any medical care for these symptoms, though "I may have looked it up on Web MD or something. I don't

remember." Tr. 10, 32. Further, she did not mention these symptoms to her husband in mid-December 2015, nor did her husband mention observing any of these symptoms to her, but he was very busy at work every day from about 7:00 or 7:30 a.m. to 5:00 p.m., even though he did come home for lunch. Tr. 32-33.

According to petitioner, her husband noticed her vision problems when they took the fivehour drive from Garden City to Denver on December 23, 2015 so they could fly to Seattle. Tr. 11, 33. According to petitioner initially, Mr. Perkins was driving, but he needed to make a phone call, so she took over the driving. Tr. 11-12. Petitioner claimed, "I was driving a little bit erratically. And I was having kind of a hard time seeing, and I pulled out in front of a car. And he got upset and he said, you need to pull over now; you can not drive. So I pulled over and let him drive." Tr. 12.

Petitioner stated she, her husband, and daughter Jaclyn were going to Seattle to spend the holiday with her son Devin and her daughter Kistine, who both live in the greater Seattle area, a few hours apart. Tr. 34. Petitioner's other son, Kyle, flew to Seattle as well. Tr. 34. Petitioner stayed at Devin's house first for a few days and then stayed with Kistine. Tr. 35. On December 30, 2015, petitioner, her husband, Kistine and her family, Kyle, and Jaclyn went on an overnight trip to Leavenworth. Tr. 35. Devin and his family did not go. Tr. 35.

Petitioner described difficulty reading recipes while in Seattle and cooking with Kistine even though she had her reading glasses on. Tr. 12. She had to move her head and hold her eyes at an angle to read things like street signs or business signs. Tr. 28-29. Petitioner stated her vision changes were "on and off." Tr. 45. "I noticed it in the middle of December, but I noticed it a lot more constantly while we were on our trip to Seattle." Tr. 46. She did not drive in Seattle; her husband or her son-in-law drove. Tr. 46.

Petitioner also described difficulty with walking and balance, and the need to steady herself on kitchen counters. Tr. 12-13. She detailed a visit to Chambers Bay where she struggled to walk from the parking lot to the beach area. Tr. 12-13. "I was very weak...I didn't want to make a big deal out of it, but some of my family just said, I'll get the car. I said, no, I'll make it, but it was just very, very hard for me." Tr. 13. She described difficulty walking around logs, "I had to really, really be careful, more than I normally do and get assistance from family members that were around." Tr. 13. She described a trip to an aquatic center, where she went on the water slides, even though she did not feel like it, because she wanted to participate with her grand kids. Tr. 13. Petitioner stated that her husband told her she should go to the doctor, but she responded, "I'm not going to do that while I'm here. I'll just do it when I get home." Tr. 13. Petitioner testified that she did not have enough energy or stamina to get around while shopping with her daughter at Bath & Body Works. Tr. 13-14.

Petitioner further stated that this was the first time that she was meeting Kistine's new baby, and she could only hold the baby while seated because she "wasn't feeling great." Tr. 35-38. Petitioner said she did not discuss this with Kistine, but "I think that was a mutual understanding because she was aware of how I was feeling," and "[b]ecause she just saw me around the kitchen and stuff, walking around and kind of steadying myself, and she knew I wasn't

feeling very good, and I was weak. So she could tell." Tr. 38. Kistine did not suggest that she see a doctor, but petitioner planned to when she got home, if she could get an appointment. Tr. 38-39.

Petitioner denied having cold symptoms while in Seattle, only ear pain on her flight to Seattle on December 23, 2015, as "flying always bothers me anyway." Tr. 40. She added that her ear pain was intermittent while in Seattle and she "probably" took some Tylenol, "if that at all. I'm not one to try to take meds. I don't pop a lot of pills." Tr. 16, 40-41. Petitioner then remembered having a sinus infection while in Seattle, but she did not take any medication, because she does not take sinus medicine. Tr. 41-42. She does take over the counter allergy medicine for the dust and hay in Kansas. Tr. 42.

Petitioner stated that she returned from Seattle on January 2, 2016 and saw the doctor on January 4, 2016 because she felt terrible. She drove herself early in the morning; she did not recall having any trouble driving to the appointment. Tr. 39, 46. Petitioner agreed that she had sinus and ear problems when she presented to Siena that day. Tr. 16-17; Pet. Ex. 8 at 1. She stated the ear pain was there for about a week and became worse on the flight back from Seattle. Tr. 17. "I think maybe the flight made my ears feel worse. I'm always sensitive to flying, so with my ears hurting, it probably just made it worse." Tr. 17. Petitioner stated that she saw a nurse practitioner and was prescribed a Z-pack. Tr. 17-18. Petitioner stated her vision was not checked at this appointment. Tr. 44. When presented with the record documenting "pupils are equal and reactive to light," she responded the nurse practitioner did shine a light in her eyes but did not give her a vision test. Tr. 45; *see also* Pet. Ex. 4 at 1587.

Petitioner testified she mentioned only her ear and sinus problems at this appointment. She did not mention her vision problems, dizziness, or balance issues, because the "person that I was seeing was not a medical doctor, and I didn't think that she would be able to help with that anyway. So I didn't even bring it up. I was just there for the ear pain." Tr. 42-43. According to petitioner, Siena has doctors on staff, but none were taking new patients. Tr. 43. She conceded that she made no effort to make an appointment with a physician that day. Tr. 43-44.

Petitioner then described a three-hour drive she took on January 5, 2016 from Garden City to Wichita to buy Jaclyn a violin. Tr. 18, 46-47. According to petitioner, she was fine driving to Wichita, but when she got out of the car, she "was walking like [she] was drunk pretty bad." Tr. 18. She claimed she had to sit and close her eyes in the music store. Tr. 18-19. When she walked back to her car, she was "very dizzy and couldn't walk straight." Tr. 19. She recalled stopping for gas and having to steady herself to put gas in the car. Tr. 19. "And then I pulled out and I almost ran into a semi. It was terrible. And Jaclyn swerved the wheel and said, Mom, stop the car. So I had to let her drive. But she had already been doing drive[r]'s ed training, so she drove us on home." Tr. 19. Petitioner stated she had double vision, particularly with her peripheral vision on the left side. Tr. 47.

Petitioner affirmed she was admitted to St. Catherine's Hospital on January 6, 2016 "once paralysis and double vision set in." Pet. Ex. 8 at 1-2. Petitioner was presented with the medical record for that date documenting "...a three-day history of some peculiar neurological changes. She has been dizzy, been unable to drive a car, her vision has been doubled....". Tr. 18; *see also* Pet. Ex. 2 at 1290. Initially, petitioner stated the three-day history of neurological changes was not

accurate because she "had been experiencing those since the middle of December really." Tr. 18-19. She then stated she could not recall if she told the ER doctor how long she had been having the symptoms of dizziness, double vision, and balance problems. Tr. 20. She then admitted, the history of three days would have come from her. "[W]ell, he would have gotten it probably from me, but I don't remember saying it." Tr. 20. She later stated, "Well, I may have told them that my present symptoms of being unable to walk and my – the symptoms that I was experiencing right then were, you know, the severity of it was three days." Tr. 48-49. She ultimately conceded that she provided the history and was asked by the doctor how long she had been having symptoms. Tr. 48, 53.

Petitioner affirmed being transferred to Porter Adventist Hospital in Denver on January 8, 2016. Pet. Ex. 8 at 2. She agreed that her symptoms got progressively worse between the time that she presented to the ER and the time that she was transferred to Porter. Tr. 54, 76. She recalled telling her doctors that the onset of her double vision and "severe wobbliness was that day, January 2^{nd} ." Tr. 54. She later stated, "I may have told them that I had symptoms that were before then, but it got a lot worse on January 2^{nd} ." Tr. 55.

Petitioner agreed that she saw many specialists while at Porter and provided them with her medical history. Initially she stated, "I couldn't really speak very well at that time. I was very sick. I was crashing rapidly, and they were just all standing around me talking amongst themselves." Tr. 57. When it was pointed out to her that the medical records consistently documented her reporting to various doctors an onset of symptoms about a week to ten days prior to her presentation to Porter on January 8, 2016. Petitioner stated:

I was specifically just telling them when those symptoms began, the ones of my ataxia, the very bad symptoms that I was experiencing. But at the time I didn't tell them that I had the symptoms before. Like mid December, like the little one where it was hard to see and I was having to tilt my head, I didn't think about telling them all that stuff. I didn't think about telling them that I was dizzy at times. I was just more confused on what was happening right then and how bad I was and how bad it was when I first went to the hospital.

Tr. 58.

Petitioner recalled meeting with the toxicologist about the possibility of her having botulism. Tr. 55. During the hearing, the toxicologist's record was read to her, documenting that she reported being in perfect health until January 2nd when she returned home from a flight during which the person next to her was ill and sneezed in her direction several times. Shortly thereafter, she developed a sore throat and ear pain which sent her to the medical clinic. Petitioner responded, "I don't think that the toxicologist got all those stories straight. I mean, I was just mentioning that I sat by somebody on the plane who was sick, very sick. And I recall...telling the toxicologist that my ear pain got worse on the flight, because it did." Tr. 56; *see also* Pet. Ex. 1A at 510-12; Pet. Ex. 1B at 1153. Though petitioner was in the ICU at that point, she agreed with the medical records that she was very alert and exhibited very precise memory of the past week's events; "Yeah, I had my mind with me." Tr. 59-60.

When asked whether her reporting of January 2, 2016 as the onset of her illness to various treating physicians was accurate, petitioner responded, "No. The onset, I would say, would be mid-December." Tr. 60. Petitioner was asked if she was being as precise as possible with the doctors so they could figure out what was wrong with her. She responded, "I didn't really correlate it all. I don't know why, but I just didn't." Tr. 60. Petitioner was asked if, after being diagnosed with Miller-Fisher GBS, it occurred to her to advise the doctors of vision problems since mid-December. She stated, "I may have told them. I don't know if they didn't note it or - I don't remember telling them that." Tr. 61. Petitioner then added that she probably told a lot of her doctors that she had problems with walking and balance while on her trip to Seattle. Tr. 62. When asked if it was her belief that the doctors failed to write down that her symptoms started in mid-December, petitioner responded, "That could be true.... I don't know. I mean, I have searched the records all the way through to see if any of them wrote it all down or not." Tr. 62.

Petitioner affirmed being discharged from Porter and sent to inpatient physical therapy and occupational therapy on January 19, 2016. Pet. Ex. 8 at 2. She was discharged from inpatient rehabilitation on February 6, 2016 and continued to receive occupational and physical therapy through her primary care provider. *Id.*

D. Affidavit of Kim Perkins, Petitioner's Husband

Kim Perkins is petitioner's husband; he submitted an affidavit but did not testify at hearing.¹⁸ Pet. Ex. 23 at 1. He affirmed "with exactness the onset of Guillain Barre/Miller Fisher syndrome (sic)" that Gail experienced was in mid-December 2015. *Id*.

According to Mr. Perkins they had a family trip to Seattle in the middle of December, and "I remember vividly that a couple of days before we left, [petitioner] made the comment she was experiencing blurriness of vision and dizziness." Pet. Ex. 23 at 1. Mr. Perkins affirmed the morning they left for Seattle, petitioner was driving to the airport and he asked her pull over because she was driving erratically. *Id.* at 2. Petitioner told him that her "vision was a little blurry, but thought it was because of the late night with not much sleep." *Id.* Mr. Perkins recalled that, when petitioner exited the car, she had to steady herself by holding onto the side of the car, and once in the airport, petitioner needed to hold his arm to steady herself. *Id.* She said she needed some rest. *Id.*

According to Mr. Perkins, petitioner "just wasn't herself" in Seattle. Pet. Ex. 23 at 2. He recalled a dinner where petitioner complained that "the menu was blurry and she couldn't read it." *Id.* "It wasn't but two days into our visit when she was complaining to me that her vision was getting worse. She also expressed that she was experiencing more and more dizziness. I recommended we go to the ER, but she declined." *Id.* Mr. Perkins affirmed that petitioner's energy level and ability to interact with the family was diminished significantly. *Id.* He again suggested that she see a doctor, but she declined and said she would get checked out when they returned home. *Id.*

Mr. Perkins affirmed that, on the way home, he noticed petitioner shielding her eyes; she stated that "the light was irritating her eyes and the blurriness was intensifying even though she

¹⁸ No reason was given for Mr. Perkins not testifying.

was wearing sunglasses." Pet. Ex. 23 at 3. Mr. Perkins affirmed that petitioner had "full blown Guillan (sic) Barre and Miller Fisher syndrome." *Id*.

E. Affidavit and Testimony of Kistine Uffens, Petitioner's Daughter

Kistine Uffens, petitioner's daughter, lives in Lake Stevens, Washington, a suburb of Seattle. Tr. 90; Pet. Ex. 24 at 1.

Ms. Uffens affirmed having a baby in November 2015 and petitioner receiving a Tdap vaccine to protect the baby from the disease. Pet. Ex. 24 at 1. Petitioner and Mr. Perkins traveled to Seattle for Christmas in December 2015. Tr. 91.

According to Ms. Uffens, petitioner's symptoms weren't "as evident" when they first arrived in Seattle. Tr. 96. "[I]t was as the vacation went on where we were out doing things more, like five six days into the trip" when petitioner complained of dizziness.¹⁹ Tr. 96.

While staying with her brother Devin and his family, they visited Chambers Bay. Tr. 102-03. Ms. Uffens recalled petitioner walking slowly and gingerly along the beach at Chambers Bay. Tr. 93. Ms. Uffens confirmed that the photographs of petitioner filed were taken on December 26, 2015 at Chambers Bay. Tr. 104-05. One photograph shows petitioner holding Ms. Uffens' baby. Tr. 105.

Ms. Uffens affirmed thinking during this trip that petitioner had aged a bit and her eyesight was "extremely off." Pet. Ex. 24 at 1. Petitioner "would move her head right then left in a cocking motion" when trying to read street signs, TV, or labels while out shopping, and kept asking Ms. Uffens if she could see something clearly. *Id.* at 1-2. Ms. Uffens recalled joking with petitioner, saying "Mom are you serious?! You gotta get that checked out!" *Id.* Ms. Uffens testified that petitioner had difficulty reading signs while driving and reading a menu at a restaurant, even with her reading glasses on. Tr. 92-93. Ms. Uffens then admitted never having any conversations with petitioner about her vision but recalled telling Mr. Perkins that petitioner could not see well and needed "to go get that checked out." Tr. 105-06.

Ms. Uffens affirmed that petitioner seemed slower than usual, walked more carefully, and would not get on the floor with the kids as she usually would. Pet. Ex. 24 at 2. However, at hearing, Ms. Uffens stated during that trip, petitioner held the baby, played on the playground equipment, and played games on the floor with the kids. Tr. 101. Ms. Uffens stated petitioner was not unable to do any activities, she was "just not as like a hundred percent like she usually was." Tr. 101. She got down on the floor with the kids, but she would not crawl around. Tr. 101.

Ms. Uffens affirmed that petitioner complained about being dizzy a few times while out shopping, "which I thought was alarming." Pet. Ex. 24 at 2. At hearing, Ms. Uffens stated petitioner said she felt dizzy while shopping at Bath & Body Works on January 1st. Tr. 101-02. Ms. Uffens stated this was "a red flag," Tr. 94, and she told petitioner she needed to get that checked out. Tr. 107. According to Ms. Uffens, petitioner "wasn't making a big deal out of it" and agreed she "would go get it checked out when she got home." Tr. 107. According to Ms. Uffens,

¹⁹ Five or six days into petitioner's trip would place onset on December 28 or 29.

"it wasn't life or death" and "[i]t's always more expensive to go get things checked out when you are not at home," she did not consider it an emergency situation, but she did make sure that petitioner was sitting when she held the baby. Tr. 95, 104. Ms. Uffens further recalled petitioner asking her to repeat herself but did not recall her complaining of ear pain or difficulty hearing. Tr. 109.

Despite the foregoing, Ms. Uffens did not speak with petitioner again until she was advised that "things were going very poorly" when petitioner was in the hospital. Tr. 109-11. Ms. Uffens recalled receiving a phone call about chili she made, confirming to the caller that she did not do any canning. She also provided the name of a pizza restaurant they went to. Tr. 109-10. Ms. Uffens stated petitioner was also on that phone call, and she could not understand everything she was saying. Tr. 110. Ms. Uffens confirmed that none of her siblings or children were sick during this visit, and no one got sick from anything that they ate at a restaurant or had food poisoning. Tr. 108.

F. Affidavit of Matt Uffens, Petitioner's Son-In-Law

Matt Uffens is petitioner's son in law; he submitted an affidavit before the hearing and a corrected affidavit after the hearing but did not testify. Pet. Ex. 25 at 1; Pet. Ex. A, ECF No. 57.

In his original affidavit, Mr. Uffens affirmed that petitioner suffered the effects of GBS, and "after the point of when she became infected that her balance became severely affected." Pet. Ex. 25 at 1.

According to Mr. Uffens' initial affidavit, petitioner visited in mid-December 2015 and they went to Discovery Park. Pet. Ex. 25 at 1. He recalled petitioner having to hold his arm and going "ever-so-slowly" to navigate some logs. *Id.* at 2. "Before acquiring Guillan (sic) Barre, Gail would have had no problem walking across this relatively easy patch of logs, but after the fact this became a difficult obstacle to overcome, even with assistance." *Id.* She then had to sit because she was feeling dizzy. *Id.*

Mr. Uffens added that petitioner's vision "seemed to be significantly lessening." Pet. Ex. 25 at 2. She "noticeably had a difficult time reading restaurant menus while we went out to eat." *Id.* Mr. Uffens affirmed that petitioner seemed to have less energy and needed to rest frequently at the end of the day. *Id.*

After the hearing, petitioner's counsel advised that Mr. Uffens confused a trip to Discovery Park with a trip to Chambers Bay. *See* Response, ECF No. 55. In a corrected affidavit, Mr. Uffens explained that he "confused the timing of Gail's separate trips to Seattle" from July 2016 with her December 2015 visit. Pet. Ex. A at 1. Upon seeing photographs with time stamps that his wife Kistine had provided, he "realized that [his] original affidavit did not match the December 2015 timeframe." *Id.* at 1-2.

In a corrected affidavit, Mr. Uffens affirmed walking the Chambers Bay Golf Course after Christmas during petitioner's December 2015 visit. Pet. Ex. A at 2. There was a walking trail that followed the circumference of the golf course and it took them "some time" to complete the trail, "specifically coming up the hill as you complete the walk." *Id*.

G. Affidavit and Testimony of Kyle Perkins, Petitioner's Son

Kyle Perkins lives in Sandy, Utah and is petitioner's son. Tr. 64; Pet. Ex. 26 at 1. In December 2015, he was in dental school. Tr. 75. He graduated from dental school in May 2018 and practices general dentistry. Tr. 64-65. Prior to December 2015, he saw petitioner three to six times per year, depending on the year. Tr. 69.

According to Mr. Perkins, prior to receiving the Tdap vaccination, petitioner was "generally a healthy person" who "enjoyed being outside, doing things." Tr. 65-66. They would go on hikes and ride bikes. Tr. 66. "[S]he wore glasses on and off" but did not have any ailments. Tr. 65-66. Mr. Perkins did not recall petitioner ever complaining of dizziness or problems with her balance prior to her trip to Seattle in December 2015. Tr. 66.

Mr. Perkins arrived in Seattle on December 22nd or 23rd but was not with his parents 24 hours a day during that trip. Tr. 75, 77. He recalled at that time that his brother Devin's children were about four and eight years old, and his sister Kistine's children were young. Tr. 77-78. Mr. Perkins stated that petitioner was very active with her grandchildren. Tr. 78.

Mr. Perkins affirmed his mother having "slower than normal motor movements, vision impairment, rapid fatigue, dizziness and taking extra measures to maintain her balance" during Christmas 2015. Pet. Ex. 26 at 1. When playing with her grandchildren, she would pause for brief moments before grabbing a doll, Lego, or dice as if "she had to think about what she was going to do next." *Id.* at 2. At hearing, Mr. Perkins testified that petitioner had difficulty with motor movements and became easily fatigued. Tr. 68. She still played with the children, but it was harder for her and she had to stop sooner. Tr. 78-79. She could not dance with her grandchildren as long as she normally would, and she had to pause when picking up LEGOs. Tr. 68. Mr. Perkins did not recall any occasions where petitioner babysat for the children; he had no memories of his mother holding Ms. Uffens' new baby. Tr. 81-82.

Mr. Perkins affirmed during that visit, "as we made our way around walkways, parks, and around the house, I noticed her grabbing onto railings and counters, taking unusual extra precautions to stabilize herself, and do it with unusual frequency...Both fine movements, such as picking up small objects and gross movements such as walking up stairs." Pet. Ex. 26 at 2. At hearing, he recalled petitioner grabbing the rail when going up stairs, which was not normal for her. Tr. 67, 70. He recalled walking somewhere by the ocean and a bridge and offering to go get the car because petitioner was having difficulty with her balance. Tr. 80. He stated they never had to modify activities for her due to a loss of balance or dizziness before. Tr. 81. He did not recall any major itinerary modifications or changes being made during the December 2015 visit, because of petitioner's health, but they may have come back early from a walk. Tr. 81.

Mr. Perkins stated that he noticed petitioner also had more vision issues than she had before; when reading to her grandchildren, "she would kind of stare at the words a little bit and like just kind of look at the pages for longer." Tr. 67; *see also* Pet. Ex. 26 at 2 (Mr. Perkins affirmed petitioner was "squinting and concentrating uncharacteristically hard to make out what the words were" when reading to her grandchildren). He did not recall any other examples of petitioner

having vision issues and did not recall any occasions where petitioner drove while in Seattle. Tr. 67-68, 81. He did not recall petitioner complaining of ear pain. Tr. 70.

Mr. Perkins affirmed in the two weeks he spent with his mother in December 2015, she was "far from her normal self." Pet. Ex. 26 at 2. At hearing however, he testified he thought his mother having difficulties was odd, but he never spoke with her, his father, or his siblings about it. Tr. 79-80. He may have asked her if she was okay. Tr. 69-71.

Mr. Perkins stated, after the Seattle trip, he was on the phone with petitioner while she was driving his little sister to Wichita and she stated she had to pull over because she was not feeling well. Tr. 71. The next time he spoke with either of his parents was when his father called to say that petitioner would be in the hospital "a little while longer." Tr. 71.

Mr. Perkins went to visit petitioner while she was in Porter Hospital. Tr. 71. He did not recall any specific conversations with his mother about when her symptoms first started. Tr. 72.

Mr. Perkins testified that the doctors in Denver mentioned different vaccines when trying to figure out what had caused petitioner's problems. Tr. 85. He then admitted that he was not present for this conversation, but, "Well, because my dad, my father was there, and he was discussing – you know, the doctors would inform him, okay, we are going to send, I think they – I don't remember exactly what it was, but some – some immunotherapy thing that they had to order in from California or something." Tr. 85-86. When asked when he became aware that petitioner had received a Tdap vaccine, he responded, "Honestly, the type of vaccine, for the most part, I didn't know what type of vaccine this was caused from. I knew that my mom got flu shots, and it wasn't until very recently that I knew that she got a vaccine, but he did run a Google search to see what could be associated with vaccines, but he did run a Google search for GBS to learn about the prognosis and the recovery time. Tr. 88-89. He did not recall reading about flu vaccine causing GBS. Tr. 89.

III. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claims by a preponderance of the evidence. § 13(a)(1). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues, such as the timing of onset of petitioner's alleged injury, begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec 'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in an accurate manner, so that they are aware of enough

relevant facts to make appropriate treatment decisions. Sanchez v. Sec'y of Health & Human Servs., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), mot. for review denied, 142 Fed. Cl. 247 (2019), vacated on other grounds, 809 F. App'x 843 (Fed. Cir. 2020); Cucuras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F. 2d. 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred"). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." Id. A patient's motivation for providing an accurate recount of symptoms is more immediate, as opposed to testimony offered after the events in question, which is considered inherently less reliable. Reusser v. Sec'y of Health & Human Servs., 28 Fed. Cl. 516, 523 (1993); see Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir. 1992) (citing United States v. U.S. Gypsum Co., 333 U.S. 364, 396 (1948)). Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." Cucuras, 993 F.2d at 1528. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." Id.

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as in cases where records are deemed to be incomplete or inaccurate. *See Campbell ex rel. Campbell v. Sec'y of Health & Human 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."). The Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be given. *Andreu v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is used to overcome the presumption of accuracy given to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (quoting *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)); *see, e.g., Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs.*, No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). Moreover, despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. *Vallenzuela v. Sec'y of Health & Human Servs.*, No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs.*, No. 90-175V, 1994 WL 67704, at *3 (Fed. Cl. Spec.

Mstr. Feb 18, 1994) (explaining that § 13(b)(2) "must be construed so as to give effect to § 13(b)(1) which directs the special master or court to consider the medical record...but does not require the special master or court to be bound by them"). In short, "the record as a whole" must be considered. § 13(a).

IV. Discussion and Findings of Fact

The only issue to be determined at this time is the onset of symptoms associated with petitioner's ultimate diagnosis of Miller-Fisher variant GBS on or about January 8, 2016.

The medical records document various dates of onset for ear pain and sore throat, ranging from December 23, 2015 to January 2, 2016. *See* Pet. Ex. 1A at 493, 511; Pet. Ex. 2 at 1290, 1298; Pet. Ex. 4 at 1587, 1590. However, the medical records consistently document petitioner's reporting the onset of her dizziness and vision disturbance after January 4, 2016, which over the next three days escalated to include ataxia, retro-orbital pain, diffuse body tingling, and increased numbness of her entire body, particularly her face and jaw, causing difficulty eating and speaking. Pet. Ex. 2 at 1414, 1290, 1298; Pet. Ex. 1A at 493, 511.

Petitioner claims her dizziness, loss of balance, double vision, progressive weakness, and difficulty with speech began on December 15, 2015, or mid-December. Pet. Ex. 8 at 1. Petitioner and her witnesses provided affidavits and testimony addressing the week between December 23, 2015 and January 2, 2016 when petitioner visited Seattle. However, none explained how they recalled any of the details of this specific trip other than discussing activities for which there were credit card receipts and a few time stamped photographs. All provided essentially the same details about the same trips. It is notable that petitioner visited her family in Seattle again in July 2016, a little over five months after suffering GBS and the potential sequelae of her illness during which they apparently participated in family activities.

While the witnesses were candid and undoubtedly believed their testimony to be true, as evidenced by Mr. Uffens' confusion, the petitioner and her family seem to have conflated the July 2016 trip petitioner made to Seattle, five months after suffering from GBS with her visit in December 2015. Overall, the testimony did not rise to the level of persuasiveness necessary to overcome the presumption of accuracy afforded to contemporaneous medical records for the reasons set forth below.

Petitioner testified that she had ear pain during her flight to Seattle, which was normal for her, but she also testified to having intermittent ear pain and a sinus infection while in Seattle. Tr. 16-17, 40-41. Petitioner stated that she probably took Tylenol for the ear pain but denied taking any medication for her sinus infection because she does not like taking medicine. Tr. 41-42. She admitted, however, to regular use of over the counter allergy medicine. Tr. 42. Petitioner's medical records reflect that not only did she routinely take antibiotics for sinus infections, she specifically demanded antibiotics, being familiar with what was required to treat a sinus infection when she had one. *See* Pet. Ex. 4 at 1586, 1592-94. Further, petitioner reported to multiple physicians in January 2016 that her symptoms started with a sore throat and progressed to ear pain about a week prior to her presentation for medical care. *See* Pet. Ex. 1A at 493, 510; Pet. Ex. 2 at 1298; Pet. Ex. 4 at 1587.

Furthermore, there is little to no evidence in the record to corroborate the statements from petitioner and her witnesses that she suffered from dizziness, imbalance and vision problems beginning in mid-December and during her visit to Seattle between December 23, 2015 and January 2, 2016.

Petitioner testified that her dizziness, vision problems, and difficulty with balance and walking began in mid-December. However, Ms. Uffens testified that her mother was fine for the first five or six days of the trip, which would place the onset of petitioner's dizziness and vision and balance problems, if in fact they existed at that time, as December 29 or 30, 2015. Tr. 96. But that onset would be inconsistent with the testimony of petitioner, Mr. Kyle Perkins, and Ms. Uffens that petitioner had difficulty walking while at Chambers Bay on December 26. Tr. 12-13, 93, 80-81; Pet. Ex. 30 at 3 (Photo taken at Chambers Bay dated December 26). Notably, all of the testimony described petitioner as walking slowly or being fatigued; no one described petitioner as being off-balance; walking like she was drunk, having to sit due to dizziness, or being unable to see where she was walking. Mr. Kyle Perkins testified that the family did not have to change their plans to accommodate petitioner's "limitations." Tr. 81. Neither petitioner nor her family expressed any concern at that time for petitioner's health to her or to each other, and no one thought it was necessary to take petitioner to urgent care or an ER. Tr. 32-33, 38-39, 72, 79-80, 105-07. The testimony about the trip to Chambers Bay is further complicated by the corrected affidavit submitted by Mr. Uffens in which he admitted to confusing the trip to Chambers Bay in December 2015 with a trip to Discovery Park in July 2016, after petitioner's diagnosis of Miller-Fisher variant GBS. See Pet. Ex. A at 1-2. Petitioner also confused these two trips when she testified that she went on the water slides, even though she did not feel like it, because she wanted to participate with her grandchildren. Tr. 13. This raises the concern that the other witnesses also conflated the two trips and incorrectly placed their recollections of petitioner's debility in December 2015 rather than July 2016 after her illness.

Petitioner's reporting of the events between her return from Seattle on January 2nd and her presentation to the ER on January 6th was also inconsistent with her claimed onset of dizziness, vision problems, difficulty walking and balance issues in mid-December.

Petitioner, her husband, and her daughter returned home to Garden City on January 2, 2016. Records filed in this case show petitioner went to Target shopping on January 3, 2016. *See* Pet. Ex. 29 at 1. On January 4, petitioner drove herself, without issue, to Siena Medical Clinic, at which time she reported only ear pain and sinus problems with no mention of dizziness, vision problems, or difficulty with balance or walking. Tr. 46; Pet. Ex. 4 at 1586-87. The record reflects that she was neurologically intact, moved all extremities well and did not have joint heat, redness, swelling or gross deformity. She was diagnosed with a double ear infection and prescribed a Z-pack. Tr. 17-18; Pet. Ex. 4 at 1586. Her explanation for failing to report any dizziness, vision problems, or balance problems was because she was seen by a nurse practitioner who she did not think was qualified to address those complaints, yet she admitted she did not try to see a physician while she was there. Tr. 42-43.

On January 5, petitioner then drove three hours to Wichita for a violin with her 15-yearold daughter in the car. Tr. 18, 46-47. She conceded to having no difficulties driving the three hours to Wichita but recalled feeling ill once she arrived. Tr. 18-19. She testified that she had dizziness and double vision, and her daughter, who was in driver's education, had to drive them home from Wichita. Tr. 18-19, 47. It strains reason that petitioner would choose to drive three hours to Wichita with her child in the car if she had been suffering from dizziness, vision problems, and difficulty with walking and balance for over three weeks. It stands to reason, that as she stated, she did not feel well upon arrival in Wichita and this is when these symptoms began.

An onset of dizziness, double vision, difficulty walking and balance problems beginning in January 2016 is further validated by the history given by petitioner at St. Catherine's, when she reported developing a sore throat and ear pain while in Seattle that had worsened over several days and a three-day history of neurologic changes, including dizziness, double vision, and inability to drive a car. *See* Pet. Ex. 2 at 1290, 1298. Upon presentation to St. Catherine's, petitioner reported "[s]ymptoms began approximately one week ago with a sore throat while she was traveling in Seattle. Approximately 5 or 6 days ago she began to experience bilateral ear pain...[which] has worsened over the past several days." *Id*. She saw her primary doctor who diagnosed her with otitis media and prescribed azithromycin. *Id*. She started the antibiotics but reported "tonight" she had symptoms of dizziness, ataxia, worsening ear pain, subjective fevers, double vision, retro-orbital pain, and diffuse tingling throughout her body. *Id*. She denied focal weakness or numbness. *Id*. at 1299-1300; Pet. Ex. 3 at 1554-55.

At hearing, petitioner recalled being asked how long she had been having symptoms but could not recall what she told the ER doctor. Tr. 48, 53. Although she initially stated that the threeday history of neurologic changes was inaccurate, she later admitted that she told the doctors that her present symptoms had been severe for three days. Tr. 18-19, 48-49.

On February 27, 2016, petitioner presented to the ER with left ear pain that "started [T]uesday." Pet. Ex. 3 at 1231. She reported in early January that she had a double ear infection and approximately two days after being diagnosed with a double ear infection "ended up with" a variant of GBS. *Id*.

The medical records repeatedly noted that petitioner was alert and a great historian. *See*, *e.g.*, Pet. Ex. 1B at 1153 (Nursing note stating that petitioner was "very alert and exhibits very precise memory of past few weeks events"); Pet. Ex. 2 at 1414 ("Patient is alert and oriented[,] no confusion noted"). When asked about this at hearing, petitioner agreed, "Yeah, I had my mind with me." Tr. 60. Given petitioner's agreement that she was alert and capable of reporting an accurate history to her doctors, I am inclined to afford more weight to the contemporaneous medical records than the accounts rendered four years later by petitioner and her witnesses.

Based on the foregoing, I find the following series of events supportable by a preponderance of evidence:

1. Toward the end of a visit to Seattle over Christmas and New Year's 2015, around December 28-30th, *see* Tr. 96 (Ms. Uffens's statement that petitioner seemed fine until five or six days into the Seattle trip), petitioner developed ear pain and a sinus infection, which significantly worsened on January 2, 2016 when she flew home. *See* Tr. 55 (Petitioner's statement that her symptoms significantly worsened on January 2, 2016); Pet. Ex. 1A at

510 (Petitioner's report that she was in her usual state of health until January 2, 2016, when she flew home from Seattle); Pet. Ex. 4 at 1587 (Petitioner's report that she recently flew back from Seattle and her ear and sinus problems became worse).

- 2. On January 4, 2016, petitioner presented to Siena with ear and throat pain, was diagnosed with a double ear infection and prescribed a Z-pack; she did not report dizziness, double vision, or ataxia at this time. Pet. Ex. 4 at 1587.
- 3. On January 5, 2016, petitioner drove three hours from Garden City to Wichita and, upon her arrival in Wichita, developed dizziness, double vision, and ataxia and was unable to drive home. Her 15-year-old daughter drove home. Tr. 18-19, 48-49.
- 4. On January 6, 2016, petitioner presented to the ER at St. Catherine's, reporting a sore throat and ear pain treated by her PCP on January 4, but had now developed dizziness, ataxia, fever, double vision, retro-orbital pain, and diffuse tingling throughout her body. Pet. Ex. 2 at 1298. She was admitted for bilateral mastoiditis and otitis media labyrinthitis.
- 5. While in the hospital, she developed increased numbress of her entire body and was transferred to Porter, where she was diagnosed with Miller-Fisher variant GBS. Pet. Ex. 2 at 1298-1300, 1316, 1414; Pet. Ex. 1A at 493, 508.

V. Conclusion

Upon detailed review of the record in its entirety, I find that petitioner's symptoms of dizziness, imbalance, double vision, and ataxia, associated with her diagnosis of Miller-Fisher variant GBS, began after January 4, 2016, as consistently and cogently reported by petitioner at the time of her presentation for medical care, throughout her hospitalization in January 2016, and to her medical providers thereafter.

To continue pursuing her claim, petitioner must file an expert report which relies on the facts as found in this Ruling. Should petitioner's expert base his opinion on facts not substantiated by this Ruling, the expert's report will be disregarded. *See Burns by Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993).

Accordingly, the following is ORDERED:

By <u>Monday, February 22, 2021</u>, petitioner shall file either an expert report that is based on the onset as found herein, or a status report indicating how she intends to proceed. Petitioner shall provide a copy of this Onset Ruling to each of her expert witnesses, and her expert(s) shall rely on the timing of onset as I have found it in this Ruling. If petitioner is unable to secure reports from her expert(s) based on the timing of onset as I have found it, she shall file either a motion to dismiss, a joint stipulation for dismissal, or a motion for a ruling on the record, all of which will result in the dismissal of her claim.

IT IS SO ORDERED.

<u>s/Mindy Michaels Roth</u> Mindy Michaels Roth Special Master