In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 29, 2025

KRISTEN HOLMES,	*	
	*	
Petitioner,	*	No. 17-1306V
	*	
v.	*	Special Master Young
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Robert Joel Krakow, Law Offices of Robert J. Krakow, P.C., New York, NY, for Petitioner.
Dorian Hurley, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On September 22, 2017, Kristen Holmes ("Petitioner") filed a petition in the National Vaccine Injury Compensation Program (the Program"),[2] alleging that as a result of receiving a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine on September 24, 2014, she suffered "cramp-fasciculation syndrome [("CFS")] and other vaccine caused conditions and symptoms, including . . . tremor, pain in her scalp and other areas[,] and persistent fatigue." Pet. at 1–2, ECF No. 1.

After carefully analyzing and weighing all the evidence and testimony presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has failed to provide

[1] Because this Decision 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 Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted);

preponderant evidence that the Tdap vaccine she received on September 24, 2014, caused her to suffer from CFS or any other condition. Accordingly, Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed her petition on September 22, 2017. Pet. She filed medical records, medical literature, and a declaration on September 25 and 27, 2017. Pet'r's Exs. 1–28, ECF Nos. 5–7, 10–12. Additional medical records were filed on November 6, 2017, and December 12 and 18, 2017. Pet'r's Exs. 29–31, ECF Nos. 14, 17–18. Respondent filed his Rule 4(c) report, arguing against compensation, on July 9, 2018. Resp't's Rep., ECF No. 26. On July 23, 2019, Petitioner filed the package insert for the Tdap vaccine she received (Adacel). Pet'r's Ex. 32, ECF No. 37.

On September 16, 2019, Petitioner filed a declaration from one of Petitioner's treating physicians, Philip Blum, M.D., and accompanying medical literature. Pet'r's Exs. 33–35, ECF No. 40. On September 27, 2019, Petitioner filed an expert report from Arthur Brawer, M.D., P.A. Pet'r's Ex. 36, ECF No. 41. On December 2, 2019, Respondent filed a status report indicating he intended to proceed with a responsive expert report but first requested additional medical records and wanted clarity on Petitioner's theory of causation. ECF No. 46. Petitioner filed additional medical records on March 8, 2020, and May 17, 2020. Pet'r's Exs. 60–61, ECF Nos. 49, 53. I held a status conference on June 24, 2021 because Petitioner had still not filed all of the medical records that were requested. ECF No. 66. I stated that the purpose of these attempts to get Petitioner's medical records is to get clarity regarding her condition, particularly since Petitioner's treating neurologist, Dr. Blum, and expert, Dr. Brawer, had presented different theories of causation. Respondent further noted that Petitioner's symptoms could be attributed to a wide range of injuries. *Id.* at 1.

Petitioner filed a declaration regarding medical records on August 27, 2021, and filed the additional medical records as requested by Respondent in September and December 2021. Pet'r's Exs. 62–67, 81–87, ECF Nos. 67–75, 79–81, 83–90. On September 18, 2021, Petitioner filed a supplemental expert report from Dr. Brawer. Pet'r's Ex. 68, ECF No. 77. On June 16, 2022, Respondent filed expert reports from Alan Ducatman, M.D., M.Sc., You-Wen He, M.D., Ph.D., and Brian Callaghan, M.D., M.S. Resp't's Exs. A, C, E, ECF Nos. 96, 98, 100. Petitioner filed a supplemental report from Dr. Brawer on August 24, 2022. Pet'r's Ex. 90, ECF No. 104.

On December 6, 2022, Petitioner filed a motion for a ruling on the record as well as medical records, medical literature, and a declaration. Pet'r's Mot., ECF No. 109; Pet'r's Exs. 91–97, ECF Nos. 109, 111. Respondent filed a responsive brief on January 23, 2023. Resp't's Br., ECF No. 112. Petitioner filed her reply on February 28, 2023. Pet'r's Reply, ECF No. 117. Thereafter, the parties agreed to an entitlement hearing and on October 4, 2023, an entitlement hearing was scheduled for September 2024. ECF No. 118.

On January 10, 2024, Petitioner filed a motion for interim attorneys' fees and costs. ECF No. 119. On January 24, 2024, Respondent filed his response and petitioner filed her reply. ECF

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see also Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

Nos. 120–21. Petitioner was awarded interim attorneys' fees and costs on August 27, 202. ECF No. 133.

Petitioner filed additional medical records in August and September 2024. Pet'r's Exs. 99–100, ECF Nos. 129, 131, 139. An entitlement hearing was held on September 11 and 12, 2024. Min. Entry, docketed Sept. 12, 2024. After the transcript was released, the parties conferred and indicated post-hearing brief were not necessary. Informal Comm., docketed Nov. 13, 2024. This matter is now ripe for adjudication.

II. Factual History

A. Medical Records

1. Pre-vaccination Medical Records

Petitioner was born on January 3, 1981. Pet'r's Ex. 1 at 1, ECF No. 5-1. Petitioner's pre-vaccination history is significant for several intermittent illnesses, injuries, and conditions requiring medical attention. Petitioner gave birth to her first child on September 14, 2011. *See generally* Pet'r's Ex. 31 at 24–171, ECF No. 18. Approximately three months after returning from a trip to Australia, on January 26, 2012, Petitioner experienced abnormal tiredness, back and shoulder pain, and "sore patches of skin" that felt like sunburn. Pet'r's Ex. 12 at 14, 16, ECF No. 6-2. She scheduled an appointment with Memorial Hermann Medical Group ("MHMG"), but her symptoms had resolved by the time of her visit. *Id.*

Petitioner began seeing neurologist Dr. J. Gavin Norris a few months later. She went for an initial visit on April 18, 2012, complaining of "mild cognitive difficulty, fatigue polyarthralgia, and intermittent areas of dysesthesia in the last few months." Pet'r's Ex. 17 at 34, ECF No. 6-7. "The dysesthesia actually had happened in the past in small patches on her back, lasting a couple weeks before resolving. These [were] without erythema, but [felt] like sunburn." *Id.* The neurologic examination was normal and without fasciculations or adventitious movements. *Id.* Dr. Norris noted that "[w]hile none of the separate symptoms [were] to a marked degree, the constellation ha[d] a feel of autoimmunity." *Id.* Lab tests, including vitamin B-12 and routine inflammatory screening, were unremarkable. *Id.* 15, 32, 34.

Petitioner returned to Dr. Norris on May 1, 2012, and "share[d] some additional recent and some prior unreported symptoms," including ear fullness, tinnitus, jaw soreness, tingling on the skin, numb left little toe, distracted memory lapses, occasional heart palpitations, dry skin with cracked fingertips, cramping abdominally after bowel movement, cold feet, and heat intolerance at night, most of which were "intermittent, [could] come and go day to day." Pet'r's Ex. 17 at 32. Dr. Norris's impression was "[n]umerous nonspecific complaints, suggestive of a systemic etiology, possibly endocrine with the skin changes." *Id.* He also "consider[ed] demyelinating disease, though most of her symptoms [did] not seem to fit that typical presentation." *Id.* Dr. Norris ordered magnetic resonance imaging ("MRI") of Petitioner's brain, which showed moderate paranasal sinusitis but was otherwise unremarkable. *Id.* at 14, 32.

One year later, on April 12, 2013, Petitioner gave birth for the second time. *See generally* Pet'r's Ex. 31 at 172–350. On July 5, 2013, Petitioner presented to her primary care physician ("PCP"), Dr. Angela Chen, with erythema and swelling on her left elbow that was tender to the touch. Pet'r's Ex. 7 at 54, 56, ECF No. 5-7. Physical examination showed no involvement of the joint, and Petitioner was treated with a steroid cream. *Id.* at 56.

On September 18, 2013, approximately one year prior to the subject vaccination, Petitioner saw Dr. Chen for a three-day history of upper respiratory symptoms, bilateral ear pressure, sinus congestion, rhinorrhea, dry cough, muscle aches, sore throat, and fever. Pet'r's Ex. 7 at 43. Other complaints at that time included cracked skin on her right hand, pain in her right thumb, and hair loss. *Id.* Petitioner was prescribed steroid cream for right-hand eczema and nasal spray for rhinitis. *Id.* at 46–47.

Two days later, Petitioner returned to Dr. Chen for worsening cough and congestion. Pet'r's Ex. 7 at 37. Petitioner was worried about whooping cough as she had a small child under six months old. *Id.* She requested antibiotics and a nasal culture swab. *Id.* Dr. Chen prescribed azithromycin and amoxicillin. *Id.* at 37, 40. The diagnoses were deteriorated viral upper respiratory infection ("URI") and deteriorated allergic rhinitis. *Id.* at 39. Follow-up cultures revealed a common bacteria found in the nose, and a topical nasal antibacterial ointment was prescribed. *Id.* at 31.

From March to July 2014, Dr. Jacinta Ogechukwula Anyaoku from MHMG noted Petitioner had acute bronchitis, acute pharyngitis, acute sinusitis, an acute URI, and chronic rhinitis, which all resolved. Pet'r's Ex. 4 at 84, ECF No. 5-4.

On July 7, 2014, Petitioner saw family medicine specialist Mark Hand, D.O., at MHMG for a head injury sustained when she hit her head against a closet door two days earlier. Pet'r's Ex. 10 at 9, ECF No. 5-10. Petitioner also reported that she had a sore throat and associated headache for the past five days. *Id.* A rapid strep test was negative. *Id.* at 12. Dr. Hand prescribed nasal spray for her chronic allergic rhinitis and naproxen for acute pharyngitis. *Id.* Conservative measures were recommended for her head injury. *Id.*

On September 18, 2014, Petitioner saw the dermatologist to have angiomas removed from her neck and chest. Pet'r's Ex. 11 at 16, ECF No. 6-1.

2. Vaccination

On September 24, 2014, Petitioner presented to Dr. Chen for a two- to three-day history of a cut on one of her toes from a plastic swimming pool. Pet'r's Ex. 7 at 18. Petitioner reported it was not painful until recently and had turned red. *Id.* She was concerned it may be infected and was unsure when her last Tdap vaccine was. *Id.* She also complained of anxiety. *Id.* at 20. Dr. Chen ordered a Tdap booster, administered that day, and prescribed cephalexin for Petitioner's foot laceration. *Id.* at 21–22.

3. Post-Vaccination Medical Records

Nineteen days post vaccination, on October 13, 2014, Petitioner presented to ear, nose, and throat ("ENT") physician Dr. Benjamin W. Cilento. Pet'r's Ex. 8 at 5, ECF No. 5-8. Dr. Cilento noted that Petitioner "ha[d] been having headaches and drainage for a few months but this ha[d] coalesced to full and tender max sinuses." *Id.* He noted Petitioner was previously "placed on [antibiotics] cefdinir and Medrol[4] . . . but it ha[d] progres[s]ed. [A computed tomography ("CT") scan] show[ed] a sinus infection . . . involving the maxillary ethmoid and frontal sinuses." *Id.* at 5, 12–13. Petitioner also reported that she had "been having cramps and twitching in [her] right calf [everyday] and heart palpitations occasionally. These symptoms may be unrelated to the sinus issues though." *Id.* at 7. Following examination, Dr. Cilento's assessment was "acute sinusitis and deviated septum." *Id.* at 11. He prescribed prednisone, Bactrim, and a NeilMed Sinus Kit. *Id.* at 14.

That same day, an ultrasound was performed on Petitioner's right leg due to "[right] calf pain [for two] months." Pet'r's Ex. 22 at 1, ECF No. 7-2. The results were normal; there was no evidence of deep vein thrombosis ("DVT"). *Id.* Thereafter, Petitioner traveled to Australia.

On October 28, 2014, Petitioner presented to Wantirna Medical Center in Australia for complaints of a developing rash on her arms, legs, and torso, after taking Bactrim for a sinus infection. Pet'r's Ex. 82 at 5–6, ECF No. 81-1. The rash resolved when she stopped taking the Bactrim three days prior. *Id.* Petitioner reported symptoms from that morning of lower lip numbness and upper lip swelling that had resolved by her appointment time. *Id.* She also reported that she had stopped the prednisolone prescribed for her sinusitis after one day due to epigastric pains, palpations, and insomnia. *Id.* at 6. Examination revealed mild swelling of Petitioner's upper lip, mild macular rash on her arms and abdomen, and two small lymph nodes bilaterally on her posterior neck. *Id.* at 5–6. She was advised to stay off Bactrim and was prescribed Telfast, prednisolone, and Somac. *Id.* at 6.

On October 20, 2014, Petitioner presented to the Maroondah Hospital Emergency Department ("ED"). Pet'r's Ex. 60 at 1, ECF No. 49-1. Petitioner reported waking up that morning with lip swelling that had since retreated. *Id.* It was noted that she was on Bactrim for sinusitis for 12 days before stopping due to widespread rash. *Id.* At the time of presentation, the rash had largely receded although some remained on her buttocks and abdomen. *Id.* Petitioner reported seeing a general practitioner, who told her that her symptoms were a reaction to antibiotics and prescribed her prednisolone and fexofenadine. *Id.* In the ED, Petitioner was told to stop fexofenadine, continue prednisolone, and start loratadine. *Id*

Petitioner returned to the ED the following day with complaints of "pain in her entire upper body from the waist up, and generalized weakness." Pet'r's Ex. 60 at 2. She had no sensory changes. *Id.* She reported that she had not yet started to take loratadine and had not taken steroids

[4] Pharmacy records show that Petitioner filled prescriptions for cefdinir and methylprednisone by Dr. Sajja on October 9, 2014, but no records for a medical visit on October 9, 2014, or records from Dr. Sajja have been filed. *See* Pet'r's Ex. 61 at 15, ECF No. 53-1. In her December 17, 2021 declaration, Petitioner wrote: "To the best of my recollection, I do not think I took the [c]efdinir, or Medrol prescribed by Dr. Sajja on October 9, 2014, because I wanted a second opinion from a specialist." Pet'r's Ex. 87 at ¶ 11, ECF No. 91.

that day. *Id.* Her rash was the same as the day prior. *Id.* The history noted that "[s]ince taking slupha[] for sinusitis [Petitioner] ha[d] had [a] wide variety of symptoms including abdominal muscle pain, headaches, leg pain, and [the day prior,] the lip swelling and urticarial rash." *Id.* An examination revealed an urticarial, blanching rash over her abdomen and right buttock, some mild epigastric discomfort on palpation, tenderness in her shoulder girdle, and no scalp tenderness. *Id.*

On November 3, 2014, Petitioner returned to Wantirna Medical Center. Pet'r's Ex. 82 at 6. Petitioner's rash was mostly better but was still present and was reported to be worse in the mornings. *Id.* She was noted to have occasional muscular pains in her abdomen and legs. *Id.* The plan was to continue prednisolone for two more days and for bloodwork to be completed. *Id.* at 6–7. The initial results of bloodwork showed mild lymphocytosis but repeat bloodwork one week later was normal. *Id.* at 7.

By November 19, 2014, Petitioner had returned to the United States and saw Dr. Julie Toll at the Kelsey-Seybold Clinic due to intermittent, aching right-leg pain that started five days earlier while flying back from Australia. Pet'r's Ex. 28 at 6, ECF No. 12-1. The symptoms were "aggravated by movement and weight bearing." *Id.* Petitioner denied tingling and numbness. *Id.* The history noted that Petitioner "[h]ad [ultrasound] of same leg [one] month ago before the trip [to Australia] for cramping." *Id.* Dr. Toll ordered an ultrasound of the right lower extremity, which was done on November 21, 2014, and showed no evidence of deep vein thrombosis. *Id.* at 9–11; *see also* Pet'r's Ex. 22 at 3.

On December 10, 2014, Petitioner saw neurologist Dr. Norris for "twitching in legs and entire body." Pet'r's Ex. 17 at 30. History of present illness noted that Petitioner took cefdinir and steroids "for sinus symptoms several months ago, developed twitching in right calf with cramping, occasionally more diffuse cramping." *Id.* She had no calf cramping at the time of the visit and no back pain, but she sometimes felt hot. *Id.* Examination was unremarkable; no fasciculations were noted. *Id.* Dr. Norris's assessment included memory loss, disturbance of skin sensation, and pain in joint involving multiple sites. *Id.* His impression was "[f]asciculations without weakness, likely benign." *Id.* He suspected that the symptoms were "a reaction to fluoroquinolone and/or steroid." *Id.* At the bottom of his assessment and plan, Dr. Norris included a link to a website that discussed fasciculations and benign fasciculation syndrome ("BFS"), but he did not appear to have diagnosed Petitioner with BFS at this time. *Id.* at 31.

Petitioner followed up with Dr. Norris on January 6, 2015. Pet'r's Ex. 17 at 28. History noted Petitioner developed a "fine action tremor" since her last visit. *Id.* She still had fasciculations, mostly in the calves that were visible upon examination. *Id.* Essential tremor was added to the list of Dr. Norris' diagnoses. *Id.* A January 10, 2015 MRI of the lumbar spine showed some early disc degeneration at T12-L1 and L1-L2 and a small disc bulge at T12-L1. *Id.* at 10.

On January 13, 2015, Petitioner reported feeling like she was "tremulous internally," having two days of chills without fever, and mild GI discomfort. Pet'r's Ex. 17 at 26. Dr. Norris added "[a]bnormal involuntary movement" to the list of diagnoses. *Id.*

On January 27, 2015, Petitioner "continue[d] to report fasciculations" and reported that she "had a few instances of patchy skin sunburn-like dysthesia without erythema, which last[ed] a few

days, as she had after her first pregnancy. She developed this on her posterior scalp [the prior] week and still ha[d] it." Pet'r's Ex. 17 at 24. Dr. Norris noted that Petitioner asked about Isaac's syndrome, Parkinson's, amyotrophic lateral sclerosis ("ALS"), multiple sclerosis ("MS"), and myasthenia gravis. *Id.* He discussed with her a "possible inorganic cause as well, such as the pressure of having 4-5 kids" although she felt "certain that this [wa]s not of inorganic etiology." *Id.* The relevant diagnoses remained disturbance of skin sensation, pain in joint involving multiple sites, essential tremor, and abnormal involuntary movement, and the note: "[s]till have to consider some inorganic overlay." *Id.* at 24–25.

Petitioner presented to Dr. Chen on February 12, 2015, with complaints of muscle spasms of the legs, cheek tremors, scalp pain for two months, and wheezing. Pet'r's Ex. 7 at 8. Dr. Chen wrote:

> In September 2014, [Petitioner] had cut on foot and received tetanus shot and had [three] days of flu like illness and then felt better and then developed right lower leg muscle twitching then it changed to left calf muscle. [Petitioner] had acute sinusitis diagnosed by ENT and was given [] oral steroids and bactrim [three] week course. [Petitioner] went to Australia and developed an allergic reaction to sulfa in Bactrim and also did not respond well to oral steroids and developed severe hives on body and extremities/itchy/throat closed. [Petitioner] was hospitalized for [one] week[5] and was given antihistamine and oral steroids (which she says worked even though before she said she felt poorly). Returned from Australia but had continued internal body tremors and intermittent random muscle twitching and extreme fatigue. Blood work in Australia showed low [potassium] that resolved. [Petitioner] [] had sweating and then shivering. [Petitioner] [] had higher blood pressure and wheezing. + Back pain. [Petitioner] went to see neurologist and had brain and spine MRI that only showed sinus congestion and then slight lower back disc bulge. Neuro [ruled out] ALS/Parkinson's. [Petitioner] advise[d] [that] neuro told her there is nothing further to do but [Petitioner] is anxious as she feels that she and her husband will be trying to have babies and she is concerned.
>
> MMR titers requested by [Petitioner].
>
> Varicella nonimmune: [Petitioner] already had titer that was negative and [Petitioner] states that she does not want the vaccine because they will have to wait longer for trying to have kids. [A]nxiety: reassurance provided as [Petitioner] feels that there must be a residual [e]ffect of the tetanus booster that has caused the muscle spasms. Advise her not possible. This is beyond almost [five] months.

Id. The physical examination was unremarkable. *Id.* at 11. One of the diagnoses was "unspecified disorder of immune mechanism." *Id.* at 13. Dr. Chen questioned whether Petitioner could have an autoimmune disorder and referred her to a rheumatologist. *Id.*

Petitioner presented to ENT physician Dr. Patricia Maeso for her sinus problems on February 17, 2015. Pet'r's Ex. 19 at 6. Dr. Maeso reviewed Petitioner's October 2014 CT report,

[5] There are no records of a one-week hospitalization filed in the record.

and her impression was that Petitioner had "some inflammatory disease," but advised Petitioner to bring in the images for further review. *Id.* at 6, 9.

On March 10, 2015, Petitioner presented to Dr. Odafe at MHMG for a lump on the left side of her neck that she noticed about one week prior. Pet'r's Ex. 4 at 5. Petitioner told Dr. Odafe that she recently found out she was pregnant. *Id.* Petitioner "wanted [Dr. Odafe] to be aware that she [was] having reactions to the Tdap vaccine," which included muscle twitching in her legs, scalp pain, and fatigue. *Id.* The physical examination of her neck revealed a mildly enlarged left occipital node and two left anterior cervical nodes but all smaller than pea sized. *Id.* at 7. The diagnosis was cervical lymphadenopathy, possibly related to Petitioner's recent sinus issues. *Id.* at 8.

Petitioner saw rheumatologist Dr. John Gomez on March 26, 2015. Pet'r's Ex. 9 at 5. She presented for muscle cramps/pain in the lower extremities and occasionally the upper extremities, which she believed started about two weeks after the Tdap vaccine. *Id.* There was associated scalp tenderness and fatigue, but it was noted that both of these symptoms had since improved. *Id.* Examination was unremarkable. *Id.* Dr. Gomez diagnosed Petitioner with "[c]ramp of limb" and "[u]nspecified myalgia and myositis." *Id.* at 6. To Dr. Gomez, it was "[n]ot clear" if Petitioner's lower extremity cramping was related to the Tdap vaccine. *Id.* Dr. Gomez found "[n]o clear evidence of a connective tissue disease, myopathy[,] or myositis," and stated that other possible diagnoses included "developing [f]ibromyalgia" or "[r]estless leg syndrome." *Id.* Because Petitioner was pregnant, the plan was to avoid further medication besides Tylenol, and to follow up in three months.[6] *Id.*

Petitioner returned to Dr. Maseo for her sinus problems on June 12, 2015. Pet'r's Ex. 19 at 14. She reported that her symptoms had worsened and that she felt ear congestion, scalp pain, and an undesirable taste in the back of her throat. *Id.* She also reported temporomandibular joint ("TMJ") issues which had not yet been addressed. *Id.* Dr. Maseo believed that Petitioner's scalp pain and some of her ear pressure issues might be due to TMJ issues. *Id.* at 16. Management options for her chronic sinus problems were limited due to her pregnancy. *Id.*

On August 18, 2015, Petitioner returned to Dr. Gomez where she reported she was still having muscle twitches, mostly in her calves at night and while at rest, but that her fatigue and myalgia had improved. Pet'r's Ex. 9 at 8. Examination was normal with no signs of synovitis or neurologic deficits, and she had normal strength and range of motion. *Id.* Dr. Gomez noted that there was no clear etiology for Petitioner's episodes of muscle twitching and cramps. *Id.* He again documented that it was "[n]ot clear if symptoms [were] related to Tdap" and questioned whether "[r]estless legs might be" a possible diagnosis. *Id.* The plan was to continue to observe. *Id.*

Petitioner delivered her third child on November 8, 2015. *See generally* Pet'r's Ex. 30 at 84–103. On January 10, 2016, Petitioner had a brain MRI, which showed "[m]oderate chronic sinus inflammatory disease involving ethmoid maxillary sinuses," but was otherwise

[6] An addendum written by Dr. Gomez on August 12, 2015, stated that Petitioner communicated with the office to clarify that she had the Tdap vaccine, not the dT vaccine, and that in addition to muscle cramps and pain, she was experiencing muscle twitches in her legs and around her body, as well as the sensation of an internal tremor. Pet'r's Ex. 9 at 6–7. Dr. Gomez maintained that it was still "not clear if [these] symptoms were related or not to the administration of the vaccine." *Id.* at 7.

unremarkable. Pet'r's Ex. 19 at 18. Petitioner continued to seek care for her chronic sinus problems throughout 2016 and 2017. *See generally* Pet'r's Ex. 18; Pet'r's Ex. 19; Pet'r's Ex. 82.

On June 13, 2016, Petitioner saw Dr. Odafe for a few days of right lower back pain, seven months of right thumb and wrist pain, and three months of extreme fatigue. Pet'r's Ex. 4 at 33. Petitioner requested referrals to an ENT specialist for her chronic sinusitis, to a neurologist for her "chronic leg twitching and muscle cramping since receiving a Tdap in Sept 2014," and to a cardiologist for heart palpitations. *Id.* She reported she previously saw another neurologist who did not give her any answers. *Id.* Dr. Odafe noted that the etiology of Petitioner's muscle twitching was unclear and referred her to neurology. *Id.* at 34.

The following month, on July 12, 2016, Petitioner presented to neurologist Dr. Philip Blum for muscle twitching, cramps, face tingling, and pain in lower legs and back for two years. Pet'r's Ex. 6 at 4. The history that Petitioner reported to Dr. Blum stated, in relevant part:

> Two years ago [Petitioner] had a [Tdap] vaccine and a few days later . . . developed cramping then muscle twitching in her legs and occasionally elsewhere in her body but always in the legs. Over the next few weeks[,] she developed an internal body tremor, headaches, areas of sore sunburned skin, dystonia in the left cheek and left face tingling. . . . She has known sinusitis. She had a neurology evaluation and had testing. After, he informed her that the symptoms were likely benign though he could see the twitches. There was no [electromyography ("EMG")]. [Bloodwork] was normal. She had a spine and brain MRI and these were normal. She was worried about MS or AL[S] or [Parkinson's] two years ago. She did not know she was [allergic to] sulfa [] at the time.

Id. Examination was normal with no twitches observed. *Id.* at 4–5. Dr. Blum's assessment was "[b]enign fasciculation-cramp syndrome" and "[v]accination complication." *Id.* at 5. He wrote, "The symptoms of cramping and fasciculations with normal exam[ination] and extensive workup including EMG[7] and MRIs is [consistent with] BFS. The symptoms began [two] days after TDAP vaccination. [He thought] this [was] likely to have been the immediate cause of the syndrome." *Id.* Dr. Blum further stated that the condition is benign and treatable, but Petitioner did "not require nor desire treatment at this time." *Id.* He noted that Petitioner's fasciculations would improve within six weeks of reintegrating exercise into her lifestyle. *Id.* There are no additional medical records from treatment with Dr. Blum.

Benign fasciculation syndrome is noted as Petitioner's reported history in subsequent medical records. *See, e.g.*, Pet'r's Ex. 4 at 72 (May 9, 2017), 110 (June 6, 2017); Pet'r's Ex. 67 at 14 (February 18, 2018). On a few occasions in 2019, the review of neurological systems was positive for Petitioner reporting "tremors" during visits to Southwest Surgical Associates for issues related to breast pain. Pet'r's Ex. 84 at 160–61 (January 22, 2019), 120–21 (February 13, 2019); 104–05 (September 18, 2019). No tremors were observed by the providers during these visits. During an August 29, 2020 visit to gastroenterologist Dr. Radha Tamerisa for swallowing discomfort, Petitioner reported that she "had a vaccine for [T]dap—had a reaction with []

[7] An EMG was not performed. *See* Pet'r's Ex. 6 at 4; Pet'r's Ex. 62 at 5; Pet'r's Ex. 87 at 5.

twitching—[BFS]." Pet'r's Ex. 64 at 8. There are no additional records that document care for ongoing symptoms or BFS after July 12, 2016.

B. Declarations

1. Petitioner

Petitioner submitted four declarations and testified at the hearing on September 11, 2024. Pet'r's Ex. 27, ECF No. 11; Pet'r's Ex 62, ECF No. 67;[8] Pet'r's Ex. 87, ECF No. 91;[9] Pet'r's Ex. 91, ECF No. 111; Tr. 3.

In September 2014, Petitioner cut her toe on the edge of a plastic swimming pool in her backyard. Pet'r's Ex. 27 at ¶ 4. While she cleaned the cut well, it appeared infected about one week later, so she sought care from her PCP Dr. Chen on September 24, 2014. *Id.* Dr. Chen recommended getting the Tdap vaccine to prevent tetanus for her toe injury. *Id.* at ¶ 5. Petitioner testified that Dr. Chen did not know if her toe was actually infected. Tr. 13. While Petitioner was apprehensive about getting the vaccine, she ultimately agreed to receive it. Pet'r's Ex. at ¶ 5–7. She received the Tdap vaccine on September 24, 2014, at approximately 2:00 pm. *Id.* at ¶ 7. Petitioner testified she also received an antibiotic for her toe injury. Tr. 14. At the time of this visit, Petitioner did not have any other health conditions. *Id.*

Within about 15 to 20 minutes of vaccination, Petitioner recalled feeling "unwell." Pet'r's Ex. 27 at ¶ 8; Tr. 14. Her "throat started to hurt and not long after that, [she] started to feel extremely tired. [She] then started experiencing other flu-like symptoms like muscle aches, a headache, and a backache." *Id.* "These symptoms lasted for about three days." Pet'r's Ex. 27 at ¶ 9.

"A few days after that," about seven-to-ten days post vaccination, Petitioner "started experiencing muscle twitching and painful cramping in [her] right calf muscle. [Her] calf kept cramping every time [she] sat down or laid down to go to sleep. It was extremely painful." Pet'r's Ex. 27 at ¶ 9; *see also* Tr. 15. Petitioner asserted she had never experienced cramps or twitching like that before. Pet'r's Ex. 27 at ¶ 9; Tr. 15, 17. "Around the same time, [Petitioner] developed severe fatigue and bad headaches. [She] was about to go on a trip to Australia, so [she] was concerned about the muscle twitching/cramping" given the long flight ahead.[10] Pet'r's Ex. 27 at ¶ 9. Accordingly, she went to get an ultrasound in October 2014 to rule out DVT. *Id.*; Tr. 21–22. The results were negative for DVT. Pet'r's Ex. 27 at ¶ 9.

[8] This declaration outlines the completeness and availability of previously requested medical records and indicates the antibiotics she was or was not taking at the time of her vaccination. Pet'r's Ex. 62.

[9] This declaration outlines the completeness and availability of previously requested medical records and indicates the antibiotics she was or was not taking at the time of her vaccination. Pet'r's Ex. 87.

[10] Also prior to her trip, Petitioner testified she saw Dr. Cilento for her sinus problems. Tr. 23. He prescribed her a three-week course of Bactrim and prednisone. Tr. 24. While she was in Australia, she received medical attention due to an allergic reaction (hives and swelling) to the Bactrim. Tr. 25–26. She testified these symptoms cleared up prior to retuning to the United States. Tr. 27–28.

"Just after this," Petitioner started getting "twitching and cramping in [her] left calf muscle as well and then the twitching started to spread around [her] body, jumping from one body part to another, 24 hours a day." Pet'r's Ex. 27 at ¶ 10; Tr. 23. She wrote that she had twitching in her "left cheek muscle, eyes, eye lids, arms, buttocks and legs," and it was constant in both her legs, mainly her calves. Pet'r's Ex. 27 at ¶ 10. She reiterated the twitching in her calves was constant, explaining there was "no break at all." *Id.* at ¶ 11. Petitioner had frequent cramping and became very tired. *Id.* At this time, her back also started aching and feeling stiff. *Id.* She then started to experience "a tight left cheek muscle that felt like it would tense up and not relax for long periods of time." *Id.* She also started having "severe headaches, including some migraines, which led to temporary vision problems." *Id.* Petitioner "started experiencing tingling on the left side of [her] face and had constant fatigue. [She] also started sweating out of nowhere at times throughout the day and during the night." *Id.* Petitioner subsequently "developed severe scalp pain" which she described as an "internal tremor," explaining it felt "like [her] whole body [was] buzzing at all times." She also experienced itchiness on the palms of her hands and feet. *Id.*

Petitioner recalled the numerous doctors she visited. Pet'r's Ex. 27 at ¶ 12. In July 2016, she saw Dr. Blum, who diagnosed her with BFS. *Id.* at ¶ 13; *see also* Tr. 42–43. She asserted that Dr. Blum also "stated [her BFS] was most likely caused by the Tdap vaccine." *Id.*

Petitioner recounted how prior to the subject vaccination, she was healthy. Pet'r's Ex. 27 at ¶ 16. She had recovered from any short-term illnesses she had and did not have any chronic health conditions. *Id.*

Throughout her declarations and testimony, Petitioner maintained that she did not have cramping, twitching, or fasciculations prior to the vaccine at issue. *See, e.g.*, Pet'r's Ex. 27 at ¶ 9; Pet'r's Ex. 91 at ¶ 3; Tr. 15, 17, 59–60. Petitioner's fourth declaration specifically addressed the assertion by Respondent's expert, Dr. Ducatman, that Petitioner had fasciculations prior to the subject vaccination. *See* Pet'r's Ex. 91; Resp't's Ex. A, ECF No. 96. Petitioner explained that when she saw Dr. Norris on April 18, 2012, she completed the intake forms and medical history questionnaire in blue ink. Pet'r's Ex. 17 at ¶¶ 4–9, 93 at 1-5. She knows this because one of the intake forms requested the age of her children. *Id.* at ¶ 35–38; Tr. 38. Petitioner wrote, in blue ink, that she had one child, age seven months. Pet'r's Ex. 17 at ¶¶ 8, 93 at ¶ 4. Petitioner's first child was born September 14, 2011. Pet'r's Ex. 31 at ¶ 24. On or around April 18, 2012, that child would have been approximately seven months old. Petitioner stated that she wrote "1" child and "seven months" in the same blue ink that she used to date the form "4/18/12". Pet'r's Ex. 93 at ¶¶ 1, 4. During that visit, she complained of "mild cognitive difficulty, fatigue, polyarthralgia, and intermittent areas of dysthesia in the last few months." Pet'r's Ex. 17 at 34. Petitioner asserted that the symptoms she noted at that time were short lived and believed to be hormonal, so she did not return to Dr. Norris for them. Pet'r's Ex. 91 at ¶ 40

When she returned to Dr. Norris on December 10, 2014, she updated her medical history by adding to the same intake form that she used in 2012. Tr. 29. To distinguish old symptoms from new symptoms, Petitioner was asked to write her new symptoms in a red pen. *Id.* Petitioner explained that using red ink, she crossed out "1" and wrote "2" to indicate that she had two children at that time, aged "3 and 18 months." Pet'r's Ex. 93 at 1, 4. Petitioner explained that in December 2014, her child born in September of 2011 would have been three, and her second child, birthdate

April 12, 2013, would have been approximately 18 months. *Id.* In short, she was given her medical history form initially completed in 2012, at her 2014 visit, and differentiated her 2014 symptoms by using a different color ink. Pet'r's Ex. 91 at ¶ 39. Petitioner asserted that the complaints of fasciculations on the form were written in 2014 (red ink), not 2012 (blue ink). *Id.* at ¶¶ 22–24. The symptoms she experienced after vaccination were "completely different from the symptoms [she] experienced before the vaccination." *Id.* at ¶ 41.

2. Dr. Philip Blum, M.D.

Dr. Blum submitted one declaration dated September 16, 2019. Pet'r's Ex. 33, ECF No. 40-1. He did not testify at the hearing. Dr. Blum began by describing his credentials. He graduated from Baylor College of Medicine and completed neurology training at Georgetown University and Baylor College of Medicine. *Id.* at ¶ 1. His residency focused on EMG and nerve conduction studies and his fellowship focused on neuroimaging of the central nervous system. *Id.* His medical practice "often involves the consultation and treatment of uncommon neurological disorders within [his] specialty interest of immunology and neuromuscular disease, including [MS], peripheral neuropathy, [chronic inflammatory demyelinating polyneuropathy ("CIDP")] and other inflammatory nerve diseases such as myositis, myasthenia gravis and entrapment neuropathy such as carpal tunnel syndrome." *Id.* Petitioner did not file Dr. Blum's CV and did not proffer him as an expert.

Dr. Blum asserted that he met Petitioner on July 17, 2016,[11] and she is his patient, whom he diagnosed with BFS. Pet'r's Ex. 33 at ¶ 2. He explained the diagnosis of "BFS relies on the exclusion of more dangerous causes of muscle twitching, which was accomplished prior to [Petitioner's] consultation with [him]." *Id.* at ¶ 3. BFS is a benign, common disorder of fasciculations, cramps, subjective weakness, and other sensory symptoms. Pet'r's Ex. 34 at 1, ECF No. 126-6.[12] According to Filippakis et al., which studied the relationship between BFS and anxiety, it can be diagnosed based on clinical presentation and/or the absence of EMG activity. *Id.* The authors did not include an assessment for CFS, either by EMG or serum studies for voltage-gated potassium channel antibodies. *Id.* at 2–3. They explained that "[a]lthough many patients reported cramps, they did not have any other features of peripheral nerve hyperexcitability [("PNH")], such as myokymia or neuromyotonia, clinically or electrodiagnostically." *Id.* at 3. Persons suffering from BFS "do not die from it or suffer debility other than the symptoms are unusual enough that they tend to distract, annoy, and frighten those who have it, and the symptoms are difficult to ignore. BFS syndrome lasts for years." Pet'r's Ex. 33 at ¶ 3 (citing Pet'r's Ex. 34). Dr. Blum asserted that the "syndrome is known to frequently begin after viral syndromes whether that syndrome is due to a vaccination or a viral invasion of the body. There are no large studies of BFS since the syndrome overlaps many other diseases and does not maim or kill people." *Id.* at ¶ 4.

According to Dr. Blum,

[11] Medical records indicate Petitioner had one visit with Dr. Blum.

[12] Alexandra Filippakis et al., *A Prospective Study of Benign Fasciculation Syndrome and Anxiety*, 58 MUSCLE & NERVE 852 (2018).

> The reason viruses and vaccinations would theoretically be capable of causing BFS is the idea of antigenic spread—a common cause of autoimmune disease. Vaccines are viral particles or whole killed virus compounded with adjuvant intended to stir up an immune response. If the vaccination is placed in a muscle, the immune system will arrive on site and cells designed to do so, will attack the virus particles and ingest them. Protein particles can coat the surface of normal structures they land near such as muscle and the immune system—in the antigenic spread model—will fail to recognize the muscle with viral protein coating and may attack and kill or damage the muscle in a variety of ways. This process can be sustained.

Pet'r's Ex. 33 at ¶ 5. He added that the Tdap vaccine is manufactured using neomycin sulfate and that sulfates are "known by themselves to be capable of causing nerve diseases including neuritis." *Id.* at ¶ 6.

Dr. Blum opined that "given [Petitioner] was well with no symptoms of the disease until she underwent vaccination and then expressed the symptoms within days of the vaccination, based on a reasonable degree of medical probability, the syndrome was caused by the vaccination." Pet'r's Ex. 33 at ¶ 7.

III. Expert Reports

A. Expert Review

1. Petitioner's Expert, Arthur E. Brawer, M.D.

Dr. Brawer submitted four expert reports and testified at the hearing on September 11, 2024.[13] Pet'r's Ex. 36, ECF No. 41-1; Pet'r's Ex. 68, ECF No. 77-1; Pet'r's Ex. 88, ECF No. 104-1; Pet'r's Ex. 89, ECF No. 104-2; Pet'r's Ex. 90, ECF No. 104-3; Tr. 3.

Dr. Brawer is a board-certified rheumatologist. Pet'r's Ex. 80 at 1–2. He received his M.D. from Boston University School of Medicine. Tr. 64. He completed internal medicine training and an arthritis fellowship at Boston City Hospital. Tr. 64–65. He is currently an Associate Clinical Professor at Drexel University School Medicine. Tr. 65. He has maintained an active clinical practice in rheumatology for almost 50 years and has seen over 25,000 patients. Tr. 65–67. He has diagnosed patients with BFS. Tr. 68–69. Dr. Brawer has authored or co-authored multiple publications, mainly in rheumatology. Tr. 65; Pet'r's Ex. 80 at 2–8.

2. Respondent's Expert, Brian C. Callaghan, M.D.

Dr. Callaghan submitted one expert report and testified at the hearing on September 11, 2024.[14] Resp't's Ex. E, ECF No. 100-1; Tr. 3.

[13] Dr. Brawer was proffered as an expert in rheumatology. Tr. 69. Dr. Brawer did not return for the second day of the hearing. Petitioner's counsel did not know why and was unable to reach him.

[14] Dr. Callaghan was proffered as an expert in neurology, neuromuscular medicine, and electrodiagnostic medicine. Tr. 197.

Dr. Callaghan is a board-certified neurologist. Resp't's Ex. F at 1. He received his M.D. from the University of Pennsylvania, followed by a neurology residency. Tr. 193. Thereafter, he completed a fellowship at the University of Michigan. *Id.* Currently, Dr. Callaghan is a Professor of Neurology at the University of Michigan and a clinician at the Ann Arbor Veterans Affairs Hospital. Tr. 194. About 20% of his time is dedicated to patient care, which is primarily comprised of patients with neuromuscular disorder. Tr. 194–95. Dr. Callaghan has published articles that mostly pertain to peripheral neuropathy. Tr. 195–96; Resp't's Ex. F at 8–15.

3. Respondent's Expert, Alan Ducatman, M.D.

Dr. Ducatman submitted one expert report and testified at the hearing on September 12, 2024.[15] Resp't's Ex. A, ECF No. 96-1; Tr. 273.

Dr. Ducatman is a board-certified internist. Resp't's Ex. B at 3. He received M.D. from Wayne State University, where he also completed a residency. Tr. 278. He completed training in internal medicine and occupational medicine at the Mayo Clinic. Id. He is currently a Professor Emeritus at West Virginia University School of Public Health and does consulting in toxic exposure. Tr. 278–81. His prior work included patient care; however, as of 2018, Dr. Ducatman no longer sees patients. Tr. 279. While he was an active clinician, he saw patients with cramps and fasciculations. Tr. 283–84. Dr. Ducatman has authored or co-authored numerous publications. Tr. 284; Resp't's Ex. B at 9–22.

4. Respondent's Expert, You-Wen He, M.D., Ph.D.

Dr. He submitted one expert report and testified at the hearing on September 12, 2024.[16] Resp't's Ex. C, ECF No. 98-1; Tr. 273.

Dr. He is an immunologist. Tr. 364; Resp't's Ex. D at 1. Dr. He received his M.D. from The Fourth Military Medical University in China and received his Ph.D. in immunology at the University of Miami School of Medicine. Tr. 362; Resp't's Ex. D at 1. Dr. He is currently a Professor of Integrative Immunobiology at Duke University. Tr. 363. This role includes directing research, teaching, and serving as a reviewer and editor for journals. *Id.* Dr. He has published numerous articles. *Id.*; Resp't's Ex. D at 9–18.

B. Expert Reports and Testimony

1. **Petitioner's Expert, Dr. Brawer**[17]

a. Diagnosis

[15] Dr. Ducatman was proffered as an expert in internal medicine and toxic exposure. Tr. 287.
[16] Dr. He was proffered as an expert in immunology. Tr. 364.
[17] Respondent's experts found Dr. Brawer's opinions confusing and hard to follow. *See* Tr. 205–06, 255 (Dr. Callaghan); Tr. 294 (Dr. Ducatman); Tr. 135 (Dr. He). I agree with Respondent's experts. While Dr. Brawer's testimony jumped around by topic and was not outlined in his expert reports, in effort to streamline his opinions, I discuss them in an order which best reflects his intended arguments. I do not go through Dr. Brawer's redundant or irrelevant material in depth.

Dr. Brawer opined that Petitioner "developed a vaccine-induced autoimmune peripheral neuropathy characterized by dysfunction of voltage-gated potassium channels." Tr. 71, 127, 157. He initially testified that he did not see any discrepancy between this diagnosis term and Dr. Blum's BFS diagnosis. Tr. 71. Dr. Brawer explained that the diagnosis of vaccine-induced peripheral nerve dysfunction is "categorized under the umbrella of a variety of overlapping neurological conditions, including PNH syndrome, neuromyotonia,[18] myokymia,[19] and [CFS]."[20] Pet'r's Ex. 36 at 1; *see also* Tr. 83, 127. Hart et al.[21] described PNH syndromes and noted it generally presents as "spontaneous and continuous muscle overactivity." Pet'r's Ex. 24 at 1, ECF No. 126-2. "The clinical features of the motor nerve dysfunction are diverse and include cramps, muscle twitching (fasciculations or myokymia), stiffness," and delayed muscle reaction after contraction. *Id.* Isaacs syndrome[22] and CFS are considered PNH syndromes. *Id.* at 2.

In his first expert report, Dr. Brawer cited medical literature on Isaacs syndrome, including Ahmed and Simmons.[23] Pet'r's Ex. 36 at 2 (citing Pet'r's Ex. 38, ECF No. 126-8). The Ahmed and Simmons article defined Isaacs syndrome as a PNH syndrome with a pathophysiology that affects voltage-gated potassium channels. Pet'r's Ex. 38 at 1–2. The authors suggested that Isaacs syndrome has an autoimmune pathogenesis, and electrodiagnosis plays a key role in the diagnosis. *Id.* at 1-2. The article identified "[t]wo other clinical entities that should be considered when evaluating a patient with possible Isaacs syndrome are [CFS] and rippling muscle syndrome. *Id.* at 3. Dr. Brawer testified that Isaac's syndrome is a channelopathy and an autoimmune condition but opined that Petitioner does not have Isaac's syndrome. Tr. 77, 128. Dr. Brawer also conceded that Petitioner does not have neuromyotonia. Tr. 147. He explained that myokymia can be seen within Isaac syndrome, where you "have a syndrome of cramps, myokymia, neuromyotonia, autonomic dysfunction, muscle hypertrophy, so a series of things." Tr. 202. He continued that you

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[18] Neuromyotonia is "myotonia caused by electrical activity of a peripheral nerve, characterized by stiffness, delayed relaxation, fasciculations, and myokymia." *Neuromyotonia*, DORLAND'S MED. DICTIONARY ONLINE. Myotonia is "dyskinetic movements due to disordered tonicity of muscle" "involving increased muscular irritability and contractility with decreased power of relaxation." *Myotonia*, DORLAND'S MED. DICTIONARY ONLINE, *Dystonia*, DORLAND'S MED. DICTIONARY ONLINE.

[19] Myokymia is "a benign condition marked by brief spontaneous tetanic contractions of motor units or groups of muscle fibers, usually adjacent groups of fibers contracting alternately." *Myokymia*, DORLAND'S MED. DICTIONARY ONLINE.

[20] CFS is "a relatively mild form of PNH characterized by fasciculations, cramps, and intermittent myokymia, without neuromyotonia; it is usually idiopathic but in some cases is autoimmune in origin." PNH is the "excessive irritability of peripheral nerves, with symptoms, such as cramps, stiffness, and neuromyotonia, in the muscles they innervate." *Peripheral Nerve Excitability*, DORLAND'S MED. DICTIONARY ONLINE.

[21] Ian K. Hart et al., *Phenotypic Variants of Autoimmune Peripheral Nerve Hyperexcitability*, 125 BRAIN 1887 (2002).

[22] Isaacs syndrome is "a rare autoimmune form of PNH that affects the potassium channels of motor nerve axons, resulting in abnormal nerve firing and consequent spontaneous muscle activity, characterized by progressive muscle stiffness, delayed muscle relaxation after contraction, cramping, myokymia, and hyperhidrosis." *Isaacs Syndrome*, DORLAND'S MED. DICTIONARY ONLINE.

[23] Aiesha Ahmed & Zachary Simmons, *Isaacs Syndrome: A Review*, 52 MUSCLE & NERVE 5 (2015). The article also distinguishes Isaacs syndrome from other PNH syndromes including CFS. Pet'r's Ex. 38 at 4 tbl.1.

can also see "clinical and/or electrodiagnostic myokymia and neuromyotonia in CFS that you do not see in BFS." Tr. 204. Dr. Brawer agreed during his testimony that Petitioner does not have any of the differential diagnoses listed in the Ahmed and Simmons article. Tr. 204.

Dr. Brawer clarified that CFS and BFS are not the same condition. Tr. 135–36. He was asked directly if he agreed with Dr. Blum that Petitioner has BFS. Tr. 130. He stated that he "may not have used that terminology, but [thinks] it's adequate to describe what's wrong," with Petitioner. Tr. 130.

He went further, asserting that BFS can overlap with a PNH syndrome. Tr. 133. As it relates to Petitioner, Dr. Brawer testified that tremors, involuntary quivering, and facial tingling can be seen in BFS. Tr. 131. But muscle cramps are not consistent with BFS and muscle and joint pains, while "can probably be seen," are not necessarily specific to BFS. *Id.* He opined Petitioner's condition "is a little more generalized" than BFS. Tr. 133. According to Dr. Brawer, BFS is a diagnosis of exclusion and that it is "some type of peripheral neuropathy." Tr. 131. "Basically, it's a problem with unexplained muscle tremors and twitching and fasciculations, for which there's not a totally clear pathologic entity." *Id.* He testified the characteristics and clinical features of BFS can also be seen in a channelopathy. Tr. 133.

Within the PNH syndromes, Dr. Brawer testified Petitioner specifically has a "problem with potassium gating." Tr. 136. "She has a problem with the classical features of potassium gating, and [] you can see that with either sodium, . . . potassium, [or] calcium." *Id.* "She has a problem where potassium ingress and egress in and out of nerve cell membranes is impaired." *Id.* He described her condition as a channelopathy that was "brought to life by chemical exposure." Tr. 136; *see also* Tr. 122 (testifying Petitioner has a "definitive neurological disorder" from an underlying channelopathy). CFS, Dr. Brawer acknowledged, does not involved voltage-gaged potassium channel antibodies. Tr. 129.

When asked what about Petitioner's cramps and fasciculations led him to believe Petitioner has a channelopathy, Dr. Brawer testified it was based on her clinical features. Tr. 137. He clarified that a channelopathy diagnosis requires genetic testing. *Id.* While that was not done here, he opined her clinical picture is consistent with a channelopathy. *Id.* Under further questioning, Dr. Brawer characterized Petitioner's disease as "a potassium-gated channelopathy," without a specific name. Tr. 160.

b. Causation

In his first expert report, Dr. Brawer primarily proposed molecular mimicry as the causal theory. Pet'r's Ex. 36 at 2–4. He explained "there exists a cross reactivity between routinely used vaccine materials and self-antigens in the body." *Id.* at 2. As such, "antigens of infectious agents can cross react with self-antigens present on a variety of body cells, including immunocompetent cells, thereby triggering systemic inflammatory and autoimmune reactions." *Id.* He noted that molecular mimicry is not the only mechanism for which vaccinations can trigger autoimmune diseases and listed, but did not describe, polyclonal B cell activation, bystander activation, the role of T cells, and adjuvants. *Id.* at 3–4.

In his second expert report, Dr. Brawer introduced his "perfect storm" theory and the concept of vaccine toxicity. Pet'r's Ex. 68 at 2. He wrote, "the medically and scientifically sound premise is that there are multiple sequential components to the vaccine toxicity experienced by [Petitioner], not all of which are necessarily clinically relevant on day one." *Id.*; *see also* Tr. 75 (stating his belief that there is not one explicit mechanism that will cause vaccine toxicity but rather a "whole host of interactions"). He postulated that there is an "initial acute chemical toxicity which subsequently becomes accompanied by multiple secondary amplification loops." Pet'r's Ex. 68 at 2. "Thus, multiple mechanisms of disease causation are not necessarily simultaneously present at the onset of vaccine[-]induced toxicity, but once such disorder is underway[,] all of these 'perfect storm' integrated variables can participate in the delayed production of multiple autoantibodies." *Id.*; *see also* Tr. 81 (testifying that "initiators of vaccine toxicity are not necessarily the same mechanisms that cause chronicity of the toxicity"); Tr. 109 (testifying molecular mimicry is not the initiator of Petitioner's condition but part of what perpetuates it). He noted however, that while molecular mimicry is part of his theory,[24] it is not necessary, and even "[i]f you took molecular mimicry out of the equation for [Petitioner], she still would have acquired the illness following vaccination." Tr. 149–50; *see also* Tr. 109, 148.

Dr. Brawer continued with his perfect storm theory in his hearing testimony. *See* Tr. 77, 124. He talked about the components of the perfect storm theory and why not everyone who gets a vaccine develops an autoimmune condition. Tr. 80, 124. He testified:

> [T]here has to be a convergence of a half a dozen items in order to see this type of toxicity. And the convergence includes not just the unlisted toxins and chemicals in the vaccine, it also has to do with how one metabolizes them. It also has to do with other genetic problems that are likely present, such as a channelopathy, which is unmasked by exposure. It has to do with molecular mimicry as part of it. It has to do also with what [he] call[s] T-cell dysfunction and mitochondrial dysfunction. And you put all of this together along with even the potential or inhibition of enzymes that control neurotransmitters, and you've got a perfect storm.

Tr. 124.

First, is a channelopathy, which affects the mitochondria, T-cells, regulatory T-cells, "and so forth and so on." Tr. 84. Second, a person has to have a problem metabolizing the chemicals in the liver "so they hang around longer." *Id.* "[T]here has to be a problem genetically with the cytochrome P450 system such that it prolongs the life of the chemicals that were administered in the vaccine." *Id.*"). The next element to his perfect storm theory is the presence of chemicals. Tr. 84. He opined the primary chemicals at play are silicones and silica,[25] which he acknowledged are

[24] On cross-examination, Dr. Brawer admitted that he cannot definitively say whether molecular mimicry was in play, but believed it was more likely than not at play here. Tr. 150. He did not identify similarity between antigens in the Tdap vaccine and self-antigens in human. Tr. 152. But he testified "there are probably amino acid sequences in the vaccine . . . that mimic some of the amino acid sequences in the gatekeeper protein in the channel of the . . . peripheral nerves." Tr. 175.

[25] Dr. Brawer explained the molecules/elements in silicon and silica do not occur/exist in any living organism so when administered parenterally into the body, it is a "fundamentally difficult problem for the

not listed on the vaccine label. *Id.* He reasoned neither silicones nor silica are required by the FDA to be listed on consumer products.[26] Tr. 169. Despite the lack of labeling on vaccinations, according to Dr. Brawer, many vaccines contain silicones and silicas, including Tdap. Tr. 88, 99–100, 104.

To explain how he knows silicones and silica are in vaccines, he testified that "almost every vaccine" has polysorbate 80 ("PS80") in it. Tr. 88. But to add PS80 to a vaccine, "it has to be cleansed of the residual sorbitol molecules that appear once the [PS80] is made." Tr. 141; Tr. 188 (testifying that "any vaccine that has [PS80] in it is going to have a "potpourri of different concentrations of sorbitol" in it so "you have to put the silicones in in order to neutralize that"). He testified that "when you make PS80, you're making roughly close to 300 different molecules of different molecular weight. It's not a single compound. It's a soup mixture of different compounds, all of which are referred to as [PS80]." Tr. 141. To cleanse it, Dr. Brawer said, "you dump silicones into the soup mixture." Tr. 89; *see also* Tr. 141. In other words, proof that silicones and silica are present in vaccines is simply "part of the engineering process to make [PS80] in the first place" and "knowing the biochemistry[27] and the chemical reactions that are necessary to produce [PS80]." Tr. 140–41.

According to Dr. Brawer, Exhibit 70 (authored by Dr. Brawer) supports the process of how PS80 is made and the different molecular sizes. Tr. 142; *see* Pet'r's Ex. 70, ECF No. 127-2.[28] The article begins by stating that 21 vaccines[29] contain at least one of the following: PS80, immunostimulatory compound ("ISCOM"), and sodium dihydrogen phosphate dihydrate ("SDPD"). Pet'r's Ex. 70 at 1. It then provides that the synthesis of PS80 "leaves residual sorbitol as a residue . . . which produces cloudiness in the solution. Visual clarity is rendered by the addition of [silicones] and [silica], whose presence also exists in both ISCOM and SDPD." *Id.* The article references Nilsson et al.[30] for the proposition that "350 different polysorbate compounds of varying length can be produced during its routine synthesis." *Id.* "This heterogeneity and lack of precise chemistry implies that varying concentrations of sorbitol may linger at the end of each PS-80 production process. Thus, any standard estimate of how much sorbitol needs to be removed may not be repetitively reliable." *Id.* Dr. Brawer wrote that that this analysis poses the question of what toxicity can occur if variable residual concentrations of sorbitol are parenterally administered with other vaccine ingredients. *Id.* He continued in the article that combination of silicones, silica, and sorbitol can expand the toxicity creating vaccine-induced disorders including autoimmune

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body to deal with." Tr. 85. He testified it "behaves like metal at times" but did not describe what that behavior is. Tr. 167.

[26] Dr. Brawer testified that he thinks silicones and silicas are either ignored or hidden by the FDA because they are toxic. Tr. 169.

[27] When asked about his educational, clinical, or research experience in biochemistry, he testified he took the required biochemistry course in medical school and "did research on it when [he] started to investigate the silicone breast implant toxicity." Tr. 168; see also Tr. 189.

[28] Arthur E. Brawer, *The Continuing Saga of Hidden Vaccine Toxicity*, 4 J. MED. CLINICAL RSCH. & REVS. 1 (2020). This is an article published by Dr. Brawer himself and references other articles also published by himself. Tr. 143; Pet'r's Ex. 70 at 2. The references authored by Dr. Brawer that he cites in Exhibit 70 are irrelevant to PS80 synthesization. Tr. 143.

[29] The article did not state which 21 vaccines it refers to.

[30] Petitioner did not file this article as an exhibit.

diseases. *Id.* The article concluded that further research is needed "to assess the interrelationships between vaccine additives and inherent disease susceptibility." *Id.* at 2.

Dr. Brawer then testified that Exhibit 40 (authored by Dr. Brawer) infers that any vaccine that has PS80 in it, has silicones in it due to the process of synthesizing PS80. Tr. 186; *see* Pet'r's Ex. 40, ECF No 126-10.[31] Exhibit 40 is a case report about a 21-year-old female that developed generalized fatigue, memory lapse, chronic headaches, widespread generalized pain in multiple joints and muscles, tingling and numbness in her extremities, anxiety, and non-restorative sleep after receiving the HPV Gardasil vaccinations. Pet'r's Ex. 40 at 1–2. This was defined as a "multisystem illness." *Id.* at 2. In the article, Dr. Brawer argued the cause of the patient's illness was the non-antigenic ingredients in the HPV vaccine. *Id.* He wrote that the HPV vaccine contains PS80. *Id.* Because the process of synthesizing PS80 leaves residual sorbitol in the solution, silicones and silica are added to the compound to render the vaccine clear. *Id.*; *see also* Tr. 186. The article provided that silica has a "proven history of human toxicity." Pet'r's Ex. 40 at 2. He concluded that post-HPV vaccine illness is caused by "multiple toxic disturbances of the body's biochemistry induced by emulsifiers, surfactants, and immune-stimulatory complexes." *Id.* at 3.

On cross-examination, Dr. Brawer testified that he was not aware of any other published literature, besides the ones he wrote, that caution the public against the dangers of silicone or silica in vaccines due to the risk of toxicity. Tr. 169.

According to Dr. Brawer, PS80 is in the Tdap vaccination.[32] Tr. 140. Dr. Brawer posited that silicones and silica are present in the Tdap vaccine "by inference because of the way the PS80 is made." Tr. 140. He opined the process is done to "any of the newer vaccines that have the immunostimulatory compounds in them." Tr. 186-87.[33] While he does not have any knowledge of anyone directly testing a Tdap vaccine for the presence of silicones, it is probable to be in there based on the process. Tr. 187.

Dr. Brawer acknowledged that there is no literature that specifically associates the Tdap vaccine with twitching. Tr. 105. His reasoning is that this is rare and most of these cases happen bedside, but doctors (clinical neurologists) do not conduct additional research or publish on it because they are "too busy." Tr. 105–06. Nonetheless, he argued that Cabrera-Maqueda et al.[34] and Cerami et al.[35] are directly supportive or analogous of his theory that vaccines can cause BFS. Tr. 104–05; Pet'r's Ex. 42, ECF No. 126-12; Pet'r's Ex. 43, ECF No. 126-13.

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[31] Arthur E. Brawer, *Hidden Toxicity of Human Papillomavirus Vaccine Ingredients*, 5 J. RHEUMATIC DISEASES & TREATMENT (2019).

[32] PS80 is not listed in the Adacel (the Tdap vaccine Petitioner received) package insert. Pet'r's Ex. 32 at 3. PS80 is also not listed as an ingredient for the Adacel vaccine on the CDC website whereas it is listed in the Boostrix (another Tdap vaccine) vaccine. https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/about-vaccine.html.

[33] While Dr. Brawer testified that includes the Tdap vaccine, he admitted the Tdap vaccine that Petitioner received did not have ISCOMs in it. Tr. 187.

[34] Jose M. Cabrera-Maqueda et al., *Optic Neuritis in Pregnancy After Tdap Vaccination: Report of Two Cases*, 160 CLINICAL NEUROLOGY & NEUROSURGERY 116 (2017).

[35] Chiara Cerami et al., *Autoimmune Neuromyotonia Following Human Papilloma Virus Vaccination*, MUSCLE & NERVE 466 (2013).

Cabrera-Maqueda et al. discusses two case reports of optic neuritis in pregnant patients after receiving Tdap vaccinations. Pet'r's Ex. 42. The authors noted that there is no definitive link for the relationship between vaccination and optic neuritis. *Id.* at 2. Cerami et al. is a case report of a patient who developed autoimmune neuromyotonia following an HPV vaccination. Pet'r's Ex. 43. The authors wrote that the patient's "clinical features along with instrumental and laboratory finding are consistent with PNH, due to an acquired autoimmune potassium channelopathy." *Id.* at 2. Dr. Brawer testified that it has been established that the HPV vaccine also has silicones and sulfates in it. Tr. 104. "[T]here's no question that the chemical in the vaccines you receive are capable of causing protein dysfunction, and therefore they're capable of bringing a channelopathy to life that otherwise might be completely innocuous." *Id.*

In response to Dr. Blum's theory, Dr. Brawer testified that he has no knowledge of neomycin being in the subject vaccine. Tr. 155. *But see* Tr. 115–16 (testifying that the difference between Dr. Blum's explanation and theory of what happened versus his is "one of terminology, not methodology").

Dr. Brawer testified that there "are many, many mechanisms that need to be present simultaneously in order to produce a reaction like [Petitioner] got."[36] Tr. 88. He summarized, there has to be a susceptible host, problems with the chemicals, problems with metabolizing chemicals, molecular mimicry, interference with regulatory T cells, problems with mitochondria and quantum tunneling, and problems with DNA transcription. Tr. 87–88. Dr. Brawer testified the Tdap vaccine contains the toxic chemicals described in his theory. Tr. 99. Thus, he opined that "if it wasn't for the vaccination, [Petitioner] wouldn't be suffering from this potassium-gated problem." Tr. 112. "She wouldn't be suffering from the peripheral neuropathy." *Id.*; *see also* Tr. 123.

As to the logical sequence of cause and effect showing that the Tdap vaccine was the cause of Petitioner's autoimmune neuropathy, Dr. Brawer first opined that prior to the September 24, 2014 vaccination, Petitioner did not have a systemic neurological condition. Pet'r's Ex. 36 at 2, 4; *see also* Tr. 119. While he believed Petitioner did not have any symptoms of chronic illness prior to September 24, 2014, he believed that Petitioner "definitely had a channelopathy that was benign until environmental exposure brought it to life." Tr. 92. He added, "there's probably no doubt that she probably also has a problem with the liver cytochrome P450 system." Tr. 93. He explained someone gets a channelopathy with potassium-gated channel dysfunction, like Petitioner, due to genetics. Tr. 90. Thus, there is a genetic component or predisposition to the condition. *See* Tr. 90, 94; *see also* Tr. 91 (testifying that "your constitutional makeup determines how you react to toxicity"). But Dr. Brawer acknowledged that no genetic testing was done in this case. Tr. 151.

Second, he opined Petitioner's neurological condition "cannot be attributed to any other well defined clinical entity or infection that could have triggered this condition in her." Pet'r's Ex. 36 at 4. To explain Petitioner's quivering sensation, Dr. Brawer testified that if the channelopathy involves part of the sympathetic or autonomic nervous system, then one may feel quivering inside. Tr. 109.

[36] Dr. Brawer testified that "part of the problem here as well, as part of the perfect storm theory,] [is] [w]hether it actually happened to Mrs. Holmes, I don't know for certain." Tr. 97.

Third, Dr. Brawer posited that Petitioner's chronic PNH syndrome manifested within seven to ten days after the Tdap vaccination and there exists an appropriate temporal relationship.[37] Pet'r's Ex. 36 at 4. He testified the initial stages of vaccine toxicity occur within one to seven days after vaccination. Tr. 98. Then "all the other domino effects that occur with regulatory T-cell dysfunction, mitochondrial dysfunction, and so forth, you then have a transition to autoantibody production, which perpetuates it and makes it chronic." Tr. 99. While Dr. Brawer opined molecular mimicry was not the initiator of Petitioner's condition, and therefore not what made it manifest within seven days, he opined it could be part of what perpetuates it. Tr. 94, 109–11.

Dr. Brawer was asked what in Petitioner's presentation led him to believe her condition was autoimmune. Tr. 163. In response, he testified that it is his "opinion, based on probability, that the temporal relationship exists between the vaccination and her channelopathy and the potassium-gated problem. *Id.* "Clearly, there was some reaction going on between the time the vaccine was initiated and the seven days later when the neuropathy symptoms started." Tr. 165. Dr. Brawer noted that Petitioner had symptoms of achiness and headache "in the few days" following her vaccine. *Id.* Dr. Brawer continued that Petitioner's vaccination caused an innate immune reaction that eventually developed into autoimmune disease because of the presence of toxic levels of silicone/silica in vaccines. Tr. 169.

2. Respondent's Expert, Dr. Callaghan

a. Diagnosis

Dr. Callaghan testified that Dr. Brawer's diagnosis was confusing as he talked about both BFS and PNH/an autoimmune channelopathy. Tr. 205–06, 255. He disagreed with Dr. Brawer that both diagnoses, BFS and autoimmune peripheral nerve dysfunction of voltage gated potassium channels (which he referred to Isaacs syndrome), are possible. Resp't's Ex. E at 6.

In his expert report, Dr. Callaghan explained BFS is a condition of unknown cause consisting of isolated cramps and fasciculations without other symptoms. Resp't's Ex. E at 6. During the hearing, Dr. Callaghan testified BFS is a labeled condition "to reassure patients that [it] is not something serious," that it is not ALS, but there is twitching. Tr. 205, 267. He summarized, BFS is simply when patients have fasciculations for unknown reasons; "[i]t's kind of like headaches. It affects over 90 percent of people." Tr. 201. "When fasciculations are seen in isolation, they're usually just a normal consequence, something that most people experience." Tr.199; *see also* Tr. 205 (testifying BFS is "incredibly common"). BFS "just means you have fasciculations that we're not concerned about." Tr. 203; *see also* Tr. 205. Dr. Callaghan testified that BFS is not a concerning condition as there is no treatment for it. Tr. 223, 244, 264. He further explained BFS is not an autoimmune condition and accordingly not an autoimmune peripheral dysfunction of multi-gated potassium channels. Tr. 202. In contrast, Isaacs syndrome involves cramps, myokymia, neuromyotonia, autonomic dysfunction, and muscle hypertrophy. Tr. 202; *see also* Tr. 252–53 (testifying about potassium channelopathy). It requires evidence of antibodies to voltage gated potassium channels for a diagnosis. Pet'r's Ex. E at 6; Tr. 226. Dr. Callaghan testified

[37] When initially asked if a temporal association is enough to show causation, Dr. Brawer answered 'no.' Tr. 138. But when later asked if a temporal relationship is causative, he answered 'yes.' Tr. 163.

his standard practice is to test patients for CASPR and LGI-1 antibodies, if Isaacs syndrome is suspected.[38] Tr. 200–01.

In his expert report, Dr. Callaghan opined that Petitioner's "diagnosis and underlying cause are unclear." Resp't's Ex. E at 6 ("[C]ramps and fasciculations are common symptoms that often have no clear underlying cause."). But in the hearing, Dr. Callaghan agreed with Dr. Blum's diagnosis of BFS.[39] Tr. 203, 207, 222–23. He disagreed with Dr. Brawer and opined Petitioner does not have a PNH syndrome, including Isaacs syndrome or CFS. Tr. 204 (citing Pet'r's Ex. 38), 206. Accordingly, he did not believe the diagnoses of Dr. Blum and Dr. Brawer are consistent with one another. Tr. 206. Dr. Callaghan testified there was no evidence that Petitioner had a peripheral neuropathy, a PNH syndrome, or an autoimmune peripheral nerve dysfunction of voltage-gated of potassium channels. Tr. 206–07. "What she had was cramps and fasciculations, and then a constellation of a lot other symptoms as well." *Id.* He noted the "ever-evolving group" of other symptoms were "internal tremors, chills without fever, gastrointestinal discomfort, sudden burn-like dysesthesias, left cheek tremors, scalp pain, wheezing, extreme fatigue, sweating, shivering, elevated blood pressure, anxiety, swelling in her neck, left face tingling, word-finding difficulties, being overwhelmed by organizational details, and being extremely stressed." Tr. 207. Dr. Callaghan opined her symptoms are connected to each other and that anxiety is the likely explanation of such. Tr. 229, 240.

Dr. Callaghan testified he does not think it is possible for a peripheral neuropathy to manifest as a channelopathy. Tr. 260–61. "Peripheral neuropathy is injury to the peripheral nerve, and you get examination findings of that, sensory nerves or motor nerves, but when you're talking about something like this that's involving channels, that's not the same thing as a peripheral neuropathy. We think of those in separate categories." Tr. 261.

b. Causation

Dr. Callaghan opined that even if CFS disorder or Isaacs syndrome was the appropriate diagnosis, "there is no convincing evidence to suggest a causal association between Tdap vaccination and either of these conditions." Resp't's Ex. E at 7. First, he criticized the medical literature filed by Dr. Brawer and noted that the only article pertaining to the Tdap vaccine described "molecular mimicry and polyclonal activation of beta 2 glycoprotein in the immune response of mice after exposure to the tetanus toxin." *Id.* (citing Pet'r's Ex. 54). Also, the only article pertaining to a "perfect storm" was about long COVID and authored by Dr. Brawer. *Id.* (citing Pet'r's Ex. 72, ECF No. 127-4).[40] He did not know how either of these are related to Petitioner's case. *Id.*

[38] Dr. Callaghan noted that if just potassium antibodies are tested, it will likely be a false positive since they appear naturally in the body. Tr. 261–62.

[39] While Dr. Callaghan agreed BFS is appropriate diagnosis, he opined it does not account for "the multitude of other symptoms" Petitioner has. Resp't's Ex. E at 6. This is addressed in Dr. Callaghan's causation section.

[40] Arthur E. Brawer, *The Perfect Storm Relationship Between Vaccination-Induced Disorders and Illness Manifested by Post-Covid-19 Long Haulers*, 1 J. SARS-COV-2 RSCH. 3 (2021).

According to Dr. Callaghan, there is no supporting evidence of a link between the Tdap vaccine and BFS or CFS. Tr. 222, 224. He noted there was one case report of neuromyotonia (with potassium channel antibodies, as such referring to it as Isaacs syndrome) following an HPV vaccine. Tr. 224 (citing Pet'r's Ex. 43). This case report did not involve the condition or the vaccine at issue in this case. Tr. 224–25.

Indeed, in this case, Dr. Callaghan opined there is no logical sequence of cause and effect between Petitioner's September 24, 2014 Tdap vaccine and her cramps. Tr. 225. Independent of her cramps and fasciculations, he testified Petitioner reported a similar "constellation of things" in April 2012 as she did after vaccination including fatigue, dysesthesias, headaches, and "patches on her back that felt like sunburn." Tr. 209. He noted that none of these symptoms are related to BFS. *Id.* After vaccination, Petitioner saw several physicians with "an evolving number of complaints." Tr. 211. While Dr. Callaghan averred Petitioner reported similar symptoms to Dr. Norris post vaccination as she did in 2012, he noted three new symptoms were reported in January 2015 that differed from her December 2014 visit, including internal tremors, chills without fever, and mild GI discomfort. Tr. 216. He also noted that while Petitioner reported "sunburn-like dysesthesias," a 2012 symptom," the sensation was now in her posterior scalp, a new location. Tr. 217. Dr. Callaghan opined all of these symptoms are "kind of an evolving set of symptoms, none of which really kind of go together in a way to make a specific diagnosis." Tr. 216.

During the hearing, Dr. Callaghan said cramps are nonspecific, often idiopathic, and likely related to her anxiety, BFS, or both. Tr. 225. But he stated there is "no reason to invoke the vaccination, which has never been linked to any of those conditions." *Id.* Moreover, Dr. Callaghan believed that Petitioner's calf cramps predated her vaccination.[41] *See* Tr. 212–13, 226, 233–35. He based this opinion on the ultrasound that noted Petitioner had calf pain for two months, placing onset around mid-August. Tr. 212–13 (citing Pet'r's Ex. 22 at 3). While the ultrasound report only wrote calf pain as the reason, Dr. Callaghan equated calf pain with calf cramps because it was discussed in the same visit. Tr. 233–34 (referring to the October 13, 2014 visit where Petitioner described calf cramping and twitching and the ultrasound report which noted calf pain for two months).

He testified that Petitioner was not diagnosed with or treated for an autoimmune condition. Tr 222. Specifically, no antibody or EMG testing was done to confirm or rule out potassium channel antibody syndromes, which are "incredibly rare" and cannot be diagnosed otherwise. Tr. 226. Dr. Callaghan noted that although Petitioner "saw multiple neurologists, neither of them ordered those tests because they were not worried because she had a normal neurologic exam." *Id.*; *see also* Tr. 253. Rather, Dr. Blum just reassured Petitioner of her BFS as there is no treatment. Tr. 223.

Dr. Callaghan also pointed out that Petitioner's treating physicians did not believe the vaccine was the cause of her symptoms. Tr. 219, 242. He noted Petitioner's PCP informed her it was not possible for the Tdap vaccine to be the cause, and her rheumatologist advised it was unclear if the vaccine was the cause and "didn't want to delve into that and then talked about fibromyalgia and restless leg syndrome as a possible diagnosis." Tr 219. Dr. Norris, Petitioner's

[41] Dr. Callagan acknowledged Petitioner did not have twitching prior September 24, 2014. Tr. 233, 254.

neurologist, indicated Petitioner's condition was of inorganic cause. Pet'r's Ex. 17 at 24. Dr. Callaghan interpreted this as evidence that Petitioner's condition had no clear underlying etiology and that it might be related to stress or anxiety. Tr. 217, 237.

Indeed, while Dr. Callaghan agreed with Petitioner's treating neurologists that she has BFS, he also opined "there's a larger context here of lots of symptoms, [] similar to what you would see in patients that have severe anxiety." Tr. 223. He noted she had this before vaccination, and that anxiety is the most important history here. Tr. 208, 223. He then pointed out several instances evidencing her anxiety. *See* Tr. 223, 243 (describing how Petitioner was worried about a brain tumor, MS, ALS, and Parkinson's based on her symptoms); 244 (Dr. Callaghan testifying that patients are usually reassured after ruling out ALS and having a normal neurologic examination and if they are not, it is usually a severe underlying anxiety); 245–46 (testifying that anxiety is listed in her medical records amongst her comorbidities and that he does not have any doubt that her physicians think she has anxiety) 221 (noting how Petitioner is still worried about her condition 10 years later despite reassurance by several physicians).

3. Respondent's Expert, Dr. Ducatman

In his expert report, Dr. Ducatman initially concluded that Petitioner's symptoms existed prior to the vaccination in 2012. Resp't's Ex. A at 5, 10–11. Upon learning that Petitioner was instructed to use the same form at Dr. Norris's office in 2012 and 2014, with different color pens for each year, he accepted the explanation.[42] *See* Tr. 306, 308–09, 316. However, he testified that his opinion did not rely on one medical record, and the temporality of the cramps is still unclear. Tr. 306–07 (relying on the ultrasound indicating symptoms were present for two months, placing them before the vaccination), 310–11 (testifying it is unclear when the cramps began but "it's not that important because whether or not they began beforehand, [his] opinion would not change" as his opinion does not rely on temporality). *But see* Tr. 324 (agreeing on cross-examination that with the corrections, there is no direct evidence in the medical records of cramps prior to September 24, 2014). Dr. Ducatman testified that his opinion relies on the absence of any evidence that Petitioner has a voltage-gated neuropathy and that there is no evidence to support a relationship between such neuropathy and vaccination. Tr. 311–12. He stated it was "pretty clear that the ultrasound was for cramps and not for some more general concept of pain." Tr. 307. Dr. Ducatman referred to Petitioner's affidavit, "Petitioner actually says that in her affidavit, that it was for cramps, which makes sense." Tr. 307. He then explained how sometimes in his own practice, he would write 'pain' instead of 'cramps' on an ultrasound for insurance reimbursement purposes. *Id.* He admitted he does not know if that is what happened here. *Id.*; *see also* Tr. 323, 324 (agreeing on cross-examination that there is no direct evidence in the medical records of cramps prior to September 24, 2014).

Dr. Ducatman opined that Dr. Blum's assertion that neomycin caused Petitioner's condition is not supported by the record.[43] Resp't's Ex. A at 5, 9; *see also* Tr. 290–91. He noted that neomycin is not an ingredient contained in the Adacel Tdap vaccine according to the package insert. Resp't's Ex. A at 9 (citing Pet'r's Ex. 32), Tr. 290, 292, 357. Neomycin is contained in

[42] Based on the revised understanding of these records, Dr. Ducatman did not see evidence of fasciculations per se in the earlier records. Tr. 317, 352.

[43] Dr. Ducatman testified that he has expertise in neomycin as a toxin. Tr. 283.

other vaccines but even if it was in the vaccine Petitioner received, he opined it would not cause her condition. Resp't's Ex. A at 9. He reasoned this because of the small dosage of neomycin in vaccines, less than what we are continuously exposed to in modern society. *Id.* Moreover, Dr. Ducatman performed a literature search and did not find any relation between neomycin and BFS, CFS, or autoimmune peripheral neuropathy of voltage-gated potassium channels. *Id.*; Tr. 291. Additionally, as to Dr. Blum's other concern that sulfated neomycin is more toxic, Dr. Ducatman averred this belief may be a misunderstanding from Dr. Blum as possibly confusing sulfates with other sulfur compounds such as sulfites since sulfates are "an unavoidable part of our daily diet and necessary for our cellular physiology." Resp't's Ex. A at 9; *see also* Tr. 292–93 (Dr. Ducatman testifying that Dr. Blum was conflating sulfates with either sulfites or sulfides), 355. He testified "[t]here's no evidence of any toxic sulfide that [he] saw in the vaccine from any source." Tr. 355.

When asked about PS80, Dr. Ducatman testified that "microgram quantities, residual polysorbate" is in the Tdap vaccine.[44] Tr. 294; *see also* Tr. 337. He stated, "it's reported in reliable literature that somewhere between 20 and 80 micrograms of residual [PS80] can still be present in a vaccine that's given to people if the vaccine uses that, for example, as an emulsifier, which would be one of the uses." Tr. 294. He did not cite to any supporting literature.

He testified that PS80 does not contain any silicone or silica compounds. Tr. 296. "It's the contaminants that Dr. Brawer thinks are residual in this microgram quantity that's in there . . . they're not [PS80], they're contaminants of [PS80]. So, this is some fraction of the residual micrograms that he thinks are also present." Tr. 296. Dr. Ducatman was not aware of silicones or silica being in the Tdap vaccine and was not aware of a causal relationship between silicones or silica and BFS or peripheral nerve dysfunction of voltage-gated potassium channels. Tr. 298, 300. Dr. Ducatman testified that the only place he had seen or heard of silicones being in vaccines and causing a peripheral neuropathy by initial direct toxic exposure was in Dr. Brawer's testimony the day before. Tr. 302–03. He noted that Dr. Brawer's theory "assumes the presence of agents which we don't know are in the vaccine." Tr. 358–59. He testified that humans are normally exposed to PS80 daily in food (specifically ice cream) and cosmetics, and that exposure to PS80 is generally regarded as safe and there is "not much concern about chronic toxicity."[45] Tr. 295, 337–38. Notwithstanding the fact that he testified PS80 is in the Tdap vaccine, he was unaware of any causal relationship between PS80 and BFS or peripheral nerve dysfunction of voltage-gated potassium channels. Tr. 296, 298. Dr. Ducatman testified that the residual dosage of PS80 present would not cause peripheral neuropathy. Tr. 340.

He also did not find literature on silicone or silica causing peripheral neuropathy or gated channel problems. Tr. 297; *see also* Tr. 343. He discussed the "ancient case reports" on silicone breast implant leaks that caused an inflammatory response but explained that is different than here because it was a nerve compression neuropathy and the exposure to silicone was in ounces, not micrograms. Tr. 297.

[44] Dr. Ducatman testified that because PS80 is listed in vaccine ingredients that it is safe. Tr. 341.

[45] Dr. Ducatman admitting that a sufficient does of anything, including PS80 can cause an adverse effect. Tr. 338, 339 ("[Y]ou might get a site reaction, [to PS80], if you put enough into a vaccine."). But in microgram doses, Dr. Ducatman did not believe it is "impressive as a concept of toxicology." Tr. 339.

Dr. Ducatman testified that "[t]here is no evidence to support it," but "[t]here is evidence against" the proposition that Petitioner's September 24, 2014 Tdap vaccine caused her cramps and fasciculations. Tr. 305. He continued, "[t]here is no evidence that this vaccine or anything in it causes any neuropathy in [Petitioner]." Tr. 310. In fact, he noted Petitioner was never diagnosed with a neuropathy, voltage-gated or otherwise. *Id.* Like Dr. Callaghan, Dr. Ducatman also characterized Petitioner's anxiety as a risk factor for BFS. *See* Tr. 349–50. He also noted that infections are often predecessors to BFS. Tr. 348.

4. Respondent's Expert, Dr. He

Dr. He offered an expert opinion rebutting Petitioner's reliance on molecular mimicry as a biological mechanism, and discussed the Institute of Medicine ("IOM") standards for molecular mimicry and how they are not met here.[46] *See* Tr. 371–75, 381, 398, 402. In summation, the three criteria are (1) a genetically susceptible host, (2) homology between an antigen and self-proteins, and (3) cross reactivity with relevant host tissue. Tr. 371–75, 398. Dr. He testified that there was no evidence of this criteria here. *Id.*

Dr. He explained the difference between a viral infection and vaccination. Tr. 382, 384–85. According to Dr. He, the "major difference is the strength in activation of the immune system caused by viral infection versus vaccination." Tr. 382. "A viral infection will . . . act on the immune system much, much stronger than a vaccination." *Id.* He added that multiple infections create an even stronger activation of the immune system. *Id.* Dr. He noted that Petitioner had two infections at the time of vaccination—a sinus infection and a toe infection.[47] Tr. 384. He opined these are important for determining causation because "they are much stronger immunostimulants." Tr. 384–85. In contrast to Dr. Blum's opinions, Dr. He testified that Petitioner did not receive a vaccine with viral particles in it or a whole killed virus vaccine with adjuvants. Tr. 395. He testified that Dr. Blum's description of the autoimmune system was "completely not understandable in immunological terms." Tr. 386.

Dr. He explained the timeline of immune responses generally. He testified that most autoimmune diseases require an adaptive immune response to develop. Tr. 369. In the first three days, it will primarily be an innate immune response. *Id.* And from day five to ten, will be the adaptive immune response. *Id.* Accordingly, seven to 10 days after a Tdap vaccine for example, would be sufficient to induce an adaptive immune response. *Id.* Dr. He commented, however, that when a vaccination induces an adaptive immune response, it is not by molecular mimicry itself. Tr. 370.

Dr. He testified that his knowledge of the Tdap vaccine ingredients was based on the package insert. Tr. 368. Based on the package insert, Dr. He opined the only ingredient capable of

[46] Dr. He acknowledged that Dr. Brawer backed off his initial theory that relied heavily in molecular mimicry. Tr. 398. Therefore, I will not discuss all of Dr. He's critiques of molecular mimicry.

[47] Dr. He believed there was an active infection of Petitioner's toe because it was red and painful and because a Tdap vaccine was given as preventative treatment. Tr. 388–92. Also testified that "the record is very clear" that Petitioner had a sinus infection. Tr. 395. Based on this, he thinks it is more likely that an infection, even as early as August 2014, caused an autoimmune response in early October 2014. Tr. 395–95, 396–97.

creating an immediate innate immunological response is aluminum as an adjuvant. *Id.* However, aluminum was not part of Dr. Brawer's theory. *Id.* Dr. He was unaware of an ingredient in the Tdap vaccine besides the aluminum compound capable of creating an immediate innate immunological response. Tr. 369; *see also* Tr. 378. Dr. He testified that he had not heard of silicones or silica causing autoimmune disorders outside of Dr. Brawer's testimony. Tr. 366.

Dr. He found no evidence that Tdap vaccines can cause neuropathy characterized by voltage-gated potassium channels. Tr. 380. Likewise, he found no evidence that the toxic components Dr. Brawer raised have any connection with BFS or any other autoimmune disease. Tr. 403, 406.

IV. Applicable Legal Standards

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at § 14, as modified by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* § 11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, she must prove that her injury was caused-in-fact by a Table vaccine.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. § 13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(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. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *Id.* "[C]lose calls regarding causation are resolved in favor of injured claimants." *Id.* at 1280. Further, evidence used to satisfy one prong of the test may overlap to satisfy another prong. *Capizzano*, 440 F.3d at 1326.

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. den'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548

(Fed. Cir. 1994). Such theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. 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). Scientific and "objective confirmation" of the medical theory with additional medical documentation is unnecessary. *Althen*, 418 F.3d at 1278–81; *see also Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Indeed, the Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) (citing *Moberly*, 592 F.3d at 1322 and *LaLonde*, 746 F.3d at 1339). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357,1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* requires that courts determine the reliability of an expert opinion before it may be considered as evidence. 509 U.S. 579 (1993). However, in the Vaccine Program, the *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."); *see also Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the

> factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors are "meant to be helpful, not definitive." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999). The factors do not "constitute 'a definitive checklist or test'" and may be applied differently depending on the facts of a particular case. *Id.* at 150 (quoting *Daubert*, 509 U.S. at 593).

"In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Daubert*, 509 U.S. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 7664475, at *24 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (stating that the Vaccine Act "require[s] a chain of reliable propositions supporting [a] petitioner's theory").

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Capizzano*, 440 F.3d at 1326. This is because "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.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, there is no "presumption that medical records are accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record." *Id.*

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (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 & Hum. Servs.*, 110 Fed. Cl. 184, 203 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

To satisfy the third *Althen* prong, a petitioner must 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 & Hum. 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 & Hum. 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.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must also show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

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 & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen*, 35 F.3d at 547. In such a case, the government must not merely prove the existence of an alternative cause, but that such an alternative actually caused the injury. *Knudsen*, 35 F.3d at 549. Consequently, when and if the petitioner establishes a prima facie case, 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. *See de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008); *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the 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.'" § 13(a)(2); *see also Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349 (Fed. Cir. 2010) (stating that an idiopathic diagnosis cannot be a "factor unrelated," as it is idiopathic).

V. Discussion

A. Diagnosis

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the *Althen* analysis. *See Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1358, 1364-65 (Fed. Cir. 2012); *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011); *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (finding that in a case where the injury itself is in dispute, it is appropriate for the special master to "first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test so that the special master could subsequently determine causation relative to the injury."). Here, diagnosis is at issue, and so it is appropriate to address first. The petition alleges Petitioner suffered from CFS, tremor, scalp pain, and persistent fatigue. Whereas the experts focused on the diagnoses of BFS and potassium-gated channelopathy. I will address each of these.

To begin, Dr. Brawer's opinions regarding Petitioner's condition were continuously evolving. Over the course of his written submissions and testimony, Dr. Brawer asserted that:

(1) Petitioner developed an autoimmune, peripheral, neuropathy, characterized by dysfunction of voltage-gated potassium channels.
(2) Petitioner developed a peripheral nerve dysfunction categorized under the umbrella of a variety of overlapping neurological conditions, including PNH syndrome, neuromyotonia, myokymia, and CFS.
(3) BFS is adequate to describe Petitioner condition, which is a little more generalized.
(4) Petitioner suffers from a potassium-gated channelopathy without a specific name.
(5) Characteristics and clinical features of BFS can be seen in a channelopathy.

Dr. Brawer simultaneously asserted:

(1) Petitioner does not have Issac's Syndrome: an autoimmune, PNH syndrome that affects potassium channels.
(2) Petitioner does not have any condition that is, per his submitted literature, a clinical syndrome characterized by PNH.
(3) Petitioner does not have neuromyotonia.
(4) Petitioner does not have CFS.
(5) BFS is not an autoimmune peripheral nerve dysfunction of multi-gated potassium channels.

Taken together, his opinions are disjointed, varying from inconsistent to mutually exclusive. Adding to the confusion, Dr. Brawer's constant equivocations made it difficult to clarify his opinions.

Q. Okay. To be clear, do you think the diagnosis is [BFS]?
A. No. No, I didn't diagnose her with that. I think it's a little more generalized than that.
Q. *Okay. So, do you disagree with Dr. Blum then?*
A. No, I don't disagree with him … So, you know, it depends. As I said, it's a question of nomenclature and a question of terminology, not necessarily a question of methodology.
Q. But [BFS] is different than [CFS]; correct?
A. Yes, according to people who publish on it. That doesn't mean you can't see overlap.
Q. What is your opinion, Dr. Brawer?
A. My opinion is that you can see the overlapping symptoms of either disorder in either disorder.
Q. But they're not the same disorder; right?
A. Well, there's a lot of things that aren't the same disorder…
Q. So, is [BFS] --
A. So, you're splitting – you're splitting hairs, okay? You're splitting hairs here. All right. I chose not to do that.

Tr. 133–34.

Due to the style of Dr. Brawer's delivery, it is difficult to analyze his proposed diagnosis and supporting arguments. Moreover, Dr. Brawer did not give a tangible standard for diagnosis.

Q. And, okay. So, which condition exactly within PNH syndromes do you think she has?
A. She has a problem with potassium gating.
Q. Okay. So, that's the diabetic diagnosis.
A. She has a channelopathy that was brought to life by chemical exposure.
Q. You said earlier that channelopathies are a genetic -- have a genetic involvement; correct?
A. That's genetically based, that's correct.
Q. Has Ms. Holmes been tested for genetic channelopathy?
A. No.
Q. What evidence do you have that she has a channelopathy?
A. She has a problem with the classical features of potassium gating,… Okay.… she would have had it at a very young age, before even teenager. So, it can only happen,… with chemical exposure that brings the channelopathy to life.
Q. Cramps can be idiopathic; right?
A. Yes.
Q. And fasciculations can be idiopathic; right?
A. Yes.
Q. And there are a number of different conditions that involve cramps and fasciculations; right?
A. Yes.
Q. What specifically about Ms. Holmes' cramps and fasciculations leads you to the conclusion that she has a channelopathy?
A. Well, if she hasn't been tested genetically for it, then making this statement is based on her clinical features, okay? So, if you want to diagnose a channelopathy, you really need to do the genetic testing for it. Okay, I don't believe she's had that done. All right. But her clinical picture is consistent with that.

Tr. 136–37.

Without a of logical discussion of Petitioner's symptoms and a cogent explanation of her diagnosis by Dr. Brawer, I am unable to meaningfully use his opinions to evaluate the evidence in this case. The filed medical literature is more helpful, and Respondent's experts are more persuasive in this endeavor.

Dr. Brawer opined Petitioner's diagnosis is "a vaccine-induced autoimmune peripheral neuropathy characterized by dysfunction of voltage-gated potassium channels." Tr. 71, 127, 157. He testified that he did not see any discrepancy between the diagnosis description that he used, and that which Dr. Blum used, BFS. But a comparison of the two conditions reveals distinctions, and the evidence does not reflect that the two diagnoses are interchangeable.[48]

Dr. Brawer described Petitioner's condition as a specific potassium-gated problem within the broad category of PNH syndromes or a "potassium-gated channelopathy" with no specific name. Tr. 160. The Ahmed and Simmons article described the role of voltage-gated potassium channels in the pathophysiology of Isaacs syndrome, in a near exact reiteration of Dr. Brawer's asserted diagnosis in this case. The Hart et al. article discussed patients with myokymia, another subtype of voltage-gated, potassium channel PNH, and evaluated whether there were distinguishing features in patients that had evidence of autoimmunity or EMG discharge. The authors distinguished myokymia from other PNH syndromes by the presence of serum antibodies. The article did not further describe the condition. Petitioner did not receive an EMG and was not tested for the antibodies relevant to myokymia or any voltage-gated potassium channel nerve hyperexcitability. Dr. Brawer also did not provide preponderant evidence differentiating the potassium-gated channelopathy Petitioner allegedly has with the PNH syndromes described in the medical literature. Furthermore, the medical records lack any EMG, abnormal neurologic examination, or antibody testing in support of such a diagnosis. Dr. Brawer did not provide preponderant evidence that Petitioner has any voltage-gated potassium channel dysfunction. Indeed, Dr. Brawer conceded that Petitioner does not have Isaacs syndrome. He further conceded that Petitioner does not meet the electrodiagnostic criteria or have any of the other PNH subtypes discussed in the article, including CFS. Notably, BFS was not discussed in the article. Dr. Callaghan interpreted Dr. Brawer's proposed diagnosis as Isaacs syndrome and opined that Petitioner does not have Isaacs syndrome.

Dr. Callaghan did not believe that Petitioner has any autoimmune peripheral nerve dysfunction, and there is not preponderant evidence that Petitioner has any autoimmune condition. Petitioner's treating physicians diagnosed her with BFS and did not consider the diagnostics tests usually accompanied with an autoimmune diagnosis, specifically a peripheral neuropathy, including antibody testing or an EMG. Furthermore, PNH syndromes are thought to be autoimmune and BFS, according to Dr. Callaghan, is not. Dr. Callaghan agreed with the BFS diagnosis, even though he opined BFS does not encompass all Petitioner's symptoms. Dr. Brawer stated BFS is a diagnosis of exclusion while Dr. Callaghan described BFS as a labeled condition

[48] Petitioner did not file medical literature specific to the diagnostic criteria of these conditions. Notwithstanding, using the literature that was provided, a distinction is clear between the two conditions.

for when people have fasciculations for unknown reasons that are not concerning. Dr. Callaghan's definition is more consistent with the notes of Petitioner's providers and her treatment history.

On December 10, 2014, Dr. Norris assessed Petitioner with "[f]asciculations without weakness, likely benign," and included a link to a website that discussed BFS. Pet'r's Ex. 17 at 30. On July 12, 2016, Dr. Blum diagnosed Petitioner with BFS. While his assessment noted Petitioner's "symptoms of cramping and fasciculations with normal exam and extensive workup including EMG and MRIs [was consistent with] BFS," there is no record that an EMG was performed. Pet'r's Ex. 6 at 5. Petitioner's neurological examinations were normal with the exception of visible fasciculations on one examination.

Notably, the injuries alleged in the petition are CFS, tremors, scalp pain, and fatigue. I do not find preponderant evidence that Petitioner suffered from CFS. As discussed above, CFS and BFS are not the same. Petitioner's filed literature distinguishes the two: "BFS is a benign-neuromuscular disorder that is distinct from CFS, which is an immune-mediated disorder of the pathologic neuromuscular excitation." Pet'r's Ex. 34 at 3. While Dr. Blum initially used the term "benign fasciculation-cramp syndrome," he later referred to Petitioner's condition as BFS, and confirmed this diagnosis in his declaration. *See* Pet'r's Ex. 6 at 5; Pet'r's Ex. 33 at ¶ 2. Dr. Blum met with Petitioner one time. None of Petitioner's other providers diagnosed her with CFS or even listed it as a differential diagnosis. None of the experts, including Dr. Brawer, believed her diagnosis was CFS. In fact, Dr. Brawer agreed BFS and CFS are different and opined Petitioner does not have CFS. Accordingly, there is not preponderant evidence that Petitioner's suffered from CFS, especially given the BFS diagnosis by her treaters.

Almost four months post vaccination,[49] on January 6, 2015, Petitioner complained of a tremor, which had developed since her December 10, 2014 visit, with Dr. Norris. Pet'r's Ex. 17 at 28. The medical record from this visit reveals that Dr. Norris did not consider tremors the same as fasciculations as he noted that Petitioner "[h]ad developed a fine action tremor since last visit. Still has fasciculations, mostly in the calves, and these are visible today." *Id.* The experts also seemed to refer to tremors and fasciculations as different entities. Dr. Brawer described BFS as a "problem with unexplained muscle tremors *and* twitching *and* fasciculations." Tr. 131 (emphasis added). Dr. Callaghan testified to Petitioner's alleged tremors separately from her fasciculations. Further, Dr. Callaghan included tremors in Petitioner's constellation of other symptoms separate from her BFS. *Dorland's* also distinguishes between the two symptoms.[50] Petitioner has not presented any evidence that tremors are attributable to CFS, BFS, or a potassium-gated channelopathy.

[49] A medical record from February 12, 2015, indicated Petitioner had "continued internal body tremors" upon returning from Australia (October 2014). Pet'r's Ex. 7 at 8. A July 12, 2016 medical record also noted that Petitioner developed an internal body tremor within a few weeks of her September 2014 vaccination. Pet'r's Ex. 6 at 4. However, that is not recorded in any of the earlier-in-time medical records. In one of Petitioner's declaration, she reported internal tremors and severe scalp pain after vaccination. Pet'r's Ex. 27 at ¶ 11.

[50] A tremor is "an involuntary trembling or quivering." *Tremor*, DORLAND'S MED. DICTIONARY ONLINE. A fasciculation is "a small local contraction of muscles, visible through the skin, representing a spontaneous discharge of a number of fibers innervated by a single motor nerve filament." *Fasciculation*, DORLAND'S MED. DICTIONARY ONLINE.

Similarly, complaints of scalp pain and fatigue were both documented in Petitioner's medical record. However, there is not preponderant evidence that either symptom was attributable by a medical provider to CFS, BFS, a potassium-gated channelopathy, or otherwise caused by her vaccination. Dr. Maseo believed that Petitioner's scalp pain might be related to her TMJ condition. *See* Pet'r's Ex. 19 at 16. Petitioner's medical records do not indicate that her treaters diagnosed her with any specific condition based on her reports of fatigue, and Petitioner has a history of fatigue, dating back as early as 2012. *See* Pet'r's Ex. 17 at 34. Tremors, scalp pain, and fatigue were all complaints in the medical record; however I find preponderant evidence that as described, they were regarded by treaters as generalized symptoms and not a stand-alone diagnosis for the purpose of a vaccine injury claim. *See Broekelschen*, 618 F.3d at 1349 (A "vaccine-related injury" must be "more than just a symptom or manifestation of an unknown injury[;]" "[m]edical recognition of the injury claimed is critical."); § 13(b)(1) (The opinions of treating physicians are not "binding on the special master or court.").

Dr. Brawer's arguments for a "vaccine-induced autoimmune peripheral neuropathy characterized by dysfunction of voltage-gated potassium channels," any PNH syndrome, or any peripheral neuropathy, are unpersuasive to overcome the opinion of Petitioner's treaters, the medical literature, and Dr. Callaghan's opinions. Petitioner has not presented preponderant evidence that she suffers from PNH. Additionally, Petitioner has not presented preponderant evidence that her nonspecific symptoms: tremors, scalp pain, and fatigue qualify as a vaccine-related injury. After consideration of the medical record and the expert analysis, I find preponderant evidence to support the diagnosis of BFS.

B. *Althen* Prong One

The Federal Circuit has held that "if the special master finds, as a preliminary matter, that petitioner has failed to substantiate the alleged injury, the special master need not apply the *Althen* test for causality." *Stillwell v. Sec'y of Health & Hum. Servs.*, 118 Fed. Cl. 47 (2014), *aff'd*, 607 F. App'x 997 (Fed. Cir. 2015) (citing *Broekelschen*, 618 F.3d 1339; *Lombardi*, 656 F.3d at 1352–53). Because Dr. Brawer's theory is for a "vaccine-induced autoimmune peripheral neuropathy characterized by dysfunction of voltage-gated potassium channels," and I did not find preponderant evidence supporting that diagnosis, an analysis of his proposed theory is moot. Additionally, because Dr. Brawer does not provide a biological mechanism specific to Petitioner's tremors, scalp pain, or fatigue, in addition to including these symptoms into her PNH, there is not preponderant evidence of a causation theory for consideration.

Importantly, Petitioner did not propose any mechanistic theory for BFS, despite Dr. Norris's note and Dr. Blum's diagnosis. Drs. Brawer and Callaghan agreed that BFS and CFS are not the same condition, and Dr. Brawer did not articulate any reason why his asserted causation theory would be applicable to a BFS diagnosis. Dr. Brawer's causation theory proposes channel dysfunction, but BFS is not a channelopathy.

Similar to Dr. Brawer's opinions regarding Petitioner's diagnosis, the explanations of his causation theory were imprecise. For example, in his initial expert report, Dr. Brawer described molecular mimicry as "the medical theory casually connecting a vaccine to injury." Pet'r's Ex. 36 at 2. He listed "a variety of medical disorders triggered by a variety of bacterial and viral vaccine

materials," but he did not include BFS, CFS, or PNF in that list. *Id.* at 3. He also listed several other potential theories, but did not define them. In his second report, Dr. Brawer noted that his (and Dr. Blum's) "understanding of disease processes are continuously altered by the evolution of research discoveries." Pet'r's Ex. 68 at 1. He identified the perfect storm theory and explained that "that there are multiple sequential components to the vaccine toxicity experienced by Petitioner, not all of which are necessary clinically relevant on day one, [including molecular mimicry]." *Id.* at 2. He did not identify the specific components relevant to Petitioner's case or apply them, except to say that the "theories underlying her illness involve the complex chronological interactions of multiple mechanisms of disease causation, all of which are elaborated in the nine [attached] peer reviewed publications." *Id.* During the hearing, Dr. Brawer expanded on the perfect storm theory and first introduced the specific concepts of PS80 and silicones/silica. At the core of Dr. Brawer's perfect storm theory for how vaccines can cause a potassium-gated channelopathy is vaccine toxicity. He asserted the presence of toxic chemicals, silicones and silica, can cause injury. According to Dr. Brawer, silicones and silica "behave[] like metal" when administered into the body but did not describe what that behavior is. Tr. 167. He acknowledged neither of these substances are listed on the vaccine label but argued they are present in the vaccine by way of PS80. According to Dr. Brawer, PS80 is in "almost every vaccine," and proof that silicones and silica are present in vaccines is simply "part of the engineering process to make [PS80] in the first place" and "knowing the biochemistry and the chemical reactions that are necessary to produce [PS80]." Tr. 140–41. Dr. Brawer does not have specific training in biochemistry, and Petitioner provided no subject matter literature or other evidence in support of his assertions. Although I did consider all of evidence filed, it would be inefficient to recount every article and argument due to the sheer volume of material that is not applicable or relevant to the facts and arguments made in this case.

Dr. Brawer testified that Exhibits 40 and 70 support his position that PS80 is in vaccines and the synthesization of PS80 involves silicones and silica. Both articles were written solely by Dr. Brawer and neither provide additional support beyond what Dr. Brawer testified to. When I asked Dr. Brawer how he knows silicones/silica are in the Tdap vaccine he replied: "I know that." Tr. 170. Moreover, Respondent's experts could not find support for Dr. Brawer's theory. *See, e.g.*, Tr. 366–67 (Dr. He testifying he had not previously heard of Dr. Brawer's theory or that silicones/silica cause autoimmune disorders).

Dr. Brawer's theory relies on the presence of PS80 in the Tdap vaccine but there is nothing in the record that indicates PS80 is in the Tdap vaccine. It is not listed as an ingredient in the package insert. Further, Petitioner's counsel confirmed that Dr. Brawer had no direct evidence of the contents of the Tdap vaccine to answer whether or not silicones or silica are present. Tr. 183. There was no evidence presented that anyone has tested the Tdap vaccine for the presence of either. Tr. 184. Interestingly, Dr. Ducatman testified that "microgram quantities" of residual PS80 has been reported to be in vaccines, but he did not indicate where this has been reported. Tr. 294. Dr. He, who testified his knowledge of the Tdap vaccine ingredients was based on the package insert, did not identify PS80 as an ingredient. PS80 is also not listed as an ingredient for the Adacel Tdap vaccine on the CDC website. *See* https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/about-vaccine.html. It is, however, listed as an ingredient for the Boostrix Tdap vaccine, suggesting that it would be likewise listed as an ingredient for the Adacel variety if it was an ingredient. *Id.* It is undisputed that Petitioner received Adacel.

While Dr. Brawer indicated that molecular mimicry was a singular, unnecessary component of his theory, he did not provide evidence that the Tdap vaccine can cause a cross-reaction that results in peripheral neuropathy of voltage-gated potassium channels. Tr. 154. He also did not identify any case reports of peripheral neuropathy of voltage-gated potassium channels following the Tdap vaccination. Tr. 154. Additionally, Petitioner did not produce any literature specifically associating the Tdap vaccine with twitching, the hallmark symptom of BFS, and Dr. Brawer admitted there is none.

While Petitioner did not proffer Dr. Blum as an expert, I find his proposed theory of causation also deficient. Dr. Blum's theory of antigenic spread occurs due to the use of neomycin sulfate in the manufacture of the Tdap vaccine. He opined that sulfates are causal agents for nerve disease. Pet'r's Ex. at 6. Dr. Blum did not submit any written follow-up or published medical literature to support his assertions. He did not testify and was not subject to cross-examination. Dr. Brawer testified that he had no knowledge of neomycin being in the Adacel Tdap vaccine. Dr. Ducatman also did not find neomycin to be in the Tdap vaccine and opined that even if it was, it would not cause Petitioner's condition. Dr. Ducatman did not find any relation between neomycin and BFS, CFS, or potassium-gated channelopathy. Given Dr. Ducatman's work as a toxicology consultant and expertise in neomycin toxicity, I find his opinions more persuasive than Dr. Blum's.

After consideration of the evidence, I do not find that Petitioner has presented preponderant evidence of a sound and reliable explanation that the Tdap vaccine can cause BFS, potassium-gated channelopathy, CFS or any other related condition, or other alleged symptoms, including tremors, scalp pain, and persistent fatigue. She has failed to meet her burden pursuant to *Althen* prong one.

C. *Althen* Prong Two

Because Petitioner has failed to meet her burden as to *Althen* prong one, she cannot meet her burden as to *Althen* prong two and provide a logical sequence of cause and effect between the Petitioner's Tdap vaccine and CFS, tremors, scalp pain, fatigue, or a potassium-gated channelopathy.

Dr. Brawer stated Petitioner "definitely had a channelopathy that was benign until environmental exposure brought it to life." Tr. 92. He added, "there's probably no doubt that she probably also has a problem with the liver cytochrome P450 system." Tr. 93. He explained someone gets a channelopathy with potassium-gated channel dysfunction, like Petitioner, due to genetics. Thus, there is a genetic component or predisposition to the condition. But Dr. Brawer acknowledged that no genetic testing was done, nor was Petitioner subject to an EMG or tested for voltage-gate potassium channel antibodies. Furthermore, Petitioner did not provide preponderant evidence that she has an autoimmune condition generally.

Dr. Blum was Petitioner's only treating physician that attributed her condition to her Tdap vaccine. As stated above, Dr. Blum's theory of causation is not supported by preponderant evidence. In contrast, Petitioner's PCP noted it was "not possible" that her vaccine caused her

condition. Pet'r's Ex. 7 at 8. Her rheumatologist said causation was unclear, and Dr. Norris said her BFS was of "inorganic cause." Pet'r's Ex. 17 at 24.

Respondent's experts identified infection and anxiety as a predecessor and risk factor to BFS, respectively. Dr. He opined that infections are stronger immunostimulants and noted that Petitioner had two infections at the time of vaccination. However, he did not opine that the infections were more likely than not the cause of Petitioner's condition nor do I find preponderant evidence of that. Dr. Callaghan and Dr. Ducatman highlighted evidence of Petitioner's anxiety in the medical record. Moreover, Petitioner submitted an article regarding the relationship between BFS and anxiety. Dr. Callaghan believed, at a minimum, Petitioner's other symptoms are related to her anxiety. Because this issue is not at bar, I do not make a finding regarding a possible connection between Petitioner's anxiety and her other generalized symptoms. However, evidence of alternative causal factors is relevant to making a more likely than not determination pursuant to *Althen* prong two. *See de Bazan*, 539 F.3d at 1352; *Pafford*, 2004 WL 1717359, at *8; *Flores v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 157, *aff'd*, 586 F. App'x 588 (Fed. Cir. 2014). Overall, I find preponderant evidence of a logical sequence of Tdap-caused injury lacking in this case, and thus, Petitioner has failed to meet her burden for the second *Althen* prong.

D. *Althen* Prong Three

Althen prong three is also somewhat dependent on a reliable causation theory. Petitioner's inability to meet her burden demonstrating how the Tdap vaccine can cause Petitioner's condition(s), effectively precludes her from being able to show that her symptoms were temporally appropriate according to said theory. Petitioner did not provide preponderant evidence that she suffered from CFS (as alleged in the petition) or channelopathy (as asserted by Dr. Brawer), nor did she offer a sound and reliable theory of vaccine causation for either. Therefore, she cannot demonstrate that her condition(s) arose in a medically acceptable timeframe consistent with vaccine causation.

As to Petitioner's more generic symptoms, she first complained of scalp pain to a medical provider on January 27, 2015. Pet'r's Ex. 17 at 24. She described it as "patchy skin sunburn-like dysthesia" which she also experienced in 2011 after her first pregnancy. Pet'r's Ex. 17 at 24. There is no diagnosis in the medical records that references scalp pain or suggests that Petitioner's treaters associated this symptom with her vaccination. Moreover, Petitioner herself likened the sensation to something she experienced prior to her vaccination, albeit in a different location of the body. Petitioner has not presented evidence that scalp pain is attributed to any condition relevant to this case. Petitioner's complaints of tremors also began in January of 2015. There is nothing in the medical records that suggests Petitioner's treaters associated this symptom with her vaccination. Petitioner's accounts of scalp pain and tremors occurred four months following her vaccination, and she has not presented preponderant evidence that four months is an appropriate time period consistent with vaccine causation for either of these symptoms.

Finally, as to Petitioner's allegation of fatigue, I find this symptom onset to be untimely. Petitioner's complaints of fatigue predate her vaccination. *See* Pet'r's Ex. 17 at 34 (complaining of fatigue polyarthralgia for a few months at an April 18, 2012 visit with Dr. Norris). Therefore, that symptom cannot be caused by her vaccination. *See Locane*, 685 F.3d at 1381 ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the

illness."). Petitioner does not allege a significant aggravation claim for her fatigue. Further, Petitioner has not provided preponderant evidence that fatigue is a defining symptom of any relevant condition. Accordingly, I find Petitioner has not met her burden with respect to *Althen* prong three.

VI. Conclusion

After a careful review of the record, Petitioner has failed to prove by preponderant evidence that she suffered from any injury caused-in-fact by her September 24, 2014 Tdap vaccination. Accordingly, I **DENY** Petitioner's claim and **DISMISS** her petition.[51]

IT IS SO ORDERED.

s/Herbrina D. S. Young
Herbrina D. S. Young
Special Master

[51] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.