

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

Filed: January 9, 2026

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HORTENCIA TORRES,
Petitioner,
v.
SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent.
* * * * *

No. 21-1356V
Special Master Young

Sean Greenwood, The Greenwood Law Firm, Houston, TX for Petitioners.
Megan Murphy, United States Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT

On May 14, 2021, Hortencia Torres ("Petitioner") filed a petition in the National Vaccine Injury Compensation Program ("the Program"). The petition alleged that Petitioner received a tetanus, diphtheria, and acellular pertussis ("Tdap") vaccine on May 22, 2018, and as a result suffered from trigeminal neuralgia ("TN"). Pet. at Preamble, ECF No. 1; Am. Pet. at Preamble, ECF No. 24.

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 TN is "severe, episodic pain in the area supplied by the trigeminal nerve, often precipitated by stimulation of well-defined trigger points." Trigeminal Neuralgia, DORLAND'S ONLINE MED. DICTIONARY, https://www.dorlandsonline.com/dorland/definition?id=92499 (hereinafter, "DORLAND'S").

A careful analysis and weighing of all the evidence and testimony presented in this case in accordance with the applicable legal standards,⁴ reveals that Petitioner has failed to provide preponderant evidence that the Tdap vaccine she received on May 22, 2018, was the cause-in-fact of her TN. Accordingly, Petitioner is not entitled to an award of compensation.

I. Procedural History

Petitioner filed her petition on May 14, 2021. Pet. Petitioner filed medical records via compact disc that was received January 19, 2022, and additional medical records on March 7, 2022. Pet'r's Exs. 4–15; Pet'r's Exs. 16–17, ECF No. 14. Petitioner filed an amended petition on January 13, 2023. Am. Pet. Respondent filed his Rule 4(c) report, recommending that compensation be denied, on February 16, 2023. Resp't's Rept., ECF No. 25.

On June 15, 2023, Petitioner filed an expert report from Joseph S. Jeret, M.D. Pet'r's Ex. 18, ECF No. 27. Petitioner filed additional medical records on August 16, 2023, August 28, 2023, October 9, 2023, October 10, 2023, October 23, 2023, and November 6, 2023. Pet'r's Ex. 45, ECF No. 30; Pet'r's Ex. 46; Pet'r's Exs. 47–50, ECF No. 33; Pet'r's Ex. 51, ECF No. 35, Pet'r's Exs. 52–53; Pet'r's Exs. 54–55. On October 10, 2023, Petitioner filed a motion for interim attorneys' fees and Respondent filed a response on October 18, 2023. ECF Nos. 36–37. I issued a decision awarding interim attorneys' fees on December 19, 2023. ECF No. 43. On January 29, 2024, Respondent filed an expert report from Dara G. Jamieson, M.D. Resp't's Ex. A, ECF No. 47. Petitioner filed a supplemental report from Dr. Jeret on February 6, 2024. Pet'r's Ex. 56, ECF No. 48. Respondent filed a supplemental report from Dr. Jamieson on April 12, 2024. Resp't's Ex. C, ECF No. 49.

On April 23, 2024, the parties confirmed via email that expert reporting was complete and requested a briefing schedule for a ruling on the record. Informal Comm., docketed Apr. 23, 2024. Petitioner filed a motion for a ruling on the record on June 13, 2024. Pet'r's Mot., ECF No. 51. Respondent filed a response on August 5, 2024, and Petitioner filed a reply on August 11, 2024. Resp't's Resp., ECF No. 52; Pet'r's Reply, ECF No. 53. This matter is now ripe for consideration.

II. Factual History

A. Relevant Medical Records

Petitioner's pre-vaccination medical history was significant for ADHD and irritable bowel syndrome ("IBS"). *See* Pet'r's Ex. 7 at 1. Her history was also notable for headaches. Specifically, on April 27, 2018, Petitioner sought treatment from her primary care provider ("PCP") for "nasal congestion and a headache for the last week and a half," with some fatigue but no cough or

⁴ 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); *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.").

sneezing. Pet'r's Ex. 4 at 215. She was diagnosed with allergic rhinitis and sinusitis, and prescribed an antibiotic, an antihistamine, and a nasal spray. *Id.* at 216. Because Petitioner was expecting a new grandchild, she received the subject Tdap vaccine on May 22, 2018, at 58 years old. *Id.* at 210.

Twenty-six days later, on June 17, 2018, at 6:00 pm, Petitioner presented to the emergency department ("ED") at Inova Fairfax Hospital ("Inova") for a left frontal headache that progressed in severity since onset the day before (June 16, 2018). Pet'r's Ex. 5 at 6–8, 10. Her "headache onset occurred more than 24 hours prior to arrival and reached [its] peak intensity over the course of the day." *Id.* at 10. Petitioner described her headache as "throbbing in nature and associated with tenderness to the forehead." *Id.* at 7. At triage, Petitioner also complained of a tingling sensation in her hands, but she later denied any tingling. *Id.* at 6, 8, 28. The headache was not associated with any photophobia,⁵ nausea, vomiting, or vision changes. *Id.* at 7. She also reported a blood shot eye since the day before, described by the ED resident as an "invasive conjunctival hemorrhage in the left lateral sclera." *Id.* at 8. Petitioner admitted to having previous headaches associated with sinus pressure, but currently did not have sinus pressure or symptoms of infection. *Id.* Physical examination indicated Petitioner was not in distress. *Id.* Neurologic examination was normal. *Id.* at 9. Her "[p]upils [were] equal, react[ed] to light. Extra ocular muscles [were] intact without nystagmus. There [was] no facial droop. Cranial nerves II through XII [were] intact. Strength [was five] out of [five] in all [] extremities." *Id.* A head computed tomography ("CT") scan was unrevealing. *Id.* at 18–19, 68. The ED resident ordered an intravenous injection of sodium chloride, ketorolac (Toradol), and metoclopramide (Reglan). *Id.* at 66. The injection was administered at or around 7:15 pm. *Id.* at 23, 66. At or before 9:20 pm, Petitioner, with the IV catheter still in her arm,⁶ left the ED before being seen by the attending physician or being formally discharged. *Id.* at 7, 17–18, 66, 79. The resident's working diagnosis was a tension headache. *See id.* at 12, 23, 74

The next day, on June 18, 2018, Petitioner was transported to the ED at Virginia Hospital Center ("VHC") via ambulance for "persistent sharp headache." Pet'r's Ex. 7 at 1; *see also* Pet'r's Ex. 6 at 30. The emergency medical services ("EMS") report indicated Petitioner had a headache for two days and that the "pain would reduce and become intermittent but never completely go away." Pet'r's Ex. 6 at 30. She reported to EMS personnel that her pain was a 10/10. *Id.* In the ED, Petitioner reported "persistent sharp headache" for two days with accompanying diarrhea and a subconjunctival hemorrhage to her left eye. Pet'r's Ex. 7 at 1. She reported that she was seen at the Inova ED the day prior and after receiving the IV medications, "she experienced a 40% reduction in pain." *Id.* She stated she left the Inova ED last night at 9:00 pm but awoke at 1:00 am "experiencing severe pain." *Id.* At home, she took Vimovo, a proton pump inhibitor used for arthritis, without relief. *Id.* Examination in the ED revealed no neurological deficits. *Id.* at 3. A "migraine cocktail," consisting of Toradol, sodium chloride, Reglan Benadryl, and dexamethasone (Decadron) was ordered and "completely resolved" Petitioner's headache. *Id.* at 5; Pet'r's Ex. 6 at 14. No diagnosis was made; Petitioner was prescribed Fioricet for headaches as needed and discharged with a neurology referral. Pet'r's Ex. 7 at 5; Pet'r's Ex. 6 at 17.

⁵ Photophobia is the "abnormal visual intolerance of light." *Photophobia*, DORLAND'S.

⁶ The police later made contact with Petitioner at her home and the IV was removed. Pet'r's Ex. 5 at 7.

On June 21, 2018, Petitioner presented to neurologist Aman Savani, with a chief complaint of headaches. Pet'r's Ex. 8 at 2. It was noted that Petitioner had no prior history of recurrent or debilitating headaches. *Id.* Petitioner reported that on June 5, 2018, she was told by her work colleagues that her left eye “appeared injected,” and she noticed some pain. *Id.* Since then, she experienced “multiple recurrent, disabling, frontal headaches . . . centered between [her] eyes and [were] associated with nasal congestion and left-sided conjunctival injection.” *Id.* Non-steroidal anti-inflammatory drugs (“NSAIDs”) provided her with temporary relief, but she still felt a “sensation of a mild headache which often spike[d] in intensity unpredictably.” *Id.* Petitioner related the onset of her symptoms to starting a new fasting diet but maintained she drank plenty of fluids and had fasted in the past without any symptoms. *Id.* She denied any visual changes. *Id.* Petitioner's examination was normal. *Id.* at 4. Dr. Savani's impression was headache, and he noted that Petitioner

ha[d] been experiencing episodic new onset headaches which may be associated with one of the trigeminal autonomic cephalgia [(“TAC”)] [] given that she [] noted redness in the eye and nasal congestion. They do not conform to migraine criteria and cluster headaches seem less likely given the relative unpredictable time of onset. It is unclear why she is now experiencing headaches given the absence of any clear past headache history.

Id. Dr. Savani ordered a contrast-enhanced brain magnetic resonance imaging (“MRI”) “in search of inflammatory or structural abnormalities that would be associated with her symptoms,” and prescribed her a five-day trial of indomethacin, 50 mg, taken three times per day. *Id.*

Petitioner returned to the VHC ED on June 24, 2018, for “pain in forehead and behind eyes” with associated nausea for one week. Pet'r's Ex. 7 at 6. She reported she was taking Fioricet, Naproxen, and ibuprofen which were not helping. *Id.* The ED physician, Christopher Lawler, D.O., noted that on examination, Petitioner was “extremely uncomfortable with her head buried in the pillow rocking back and forth.” *Id.* at 11; *see also id.* at 8 (examination noting Petitioner appeared “[m]oderately uncomfortable”). Neurologic examination was nonfocal and Dr. Lawler found it “not diagnostic.” *Id.* at 8–9, 12. Dr. Lawler noted there were “no red flags on this headache.” *Id.* at 11. Petitioner received saline, promethazine (Phenergan), Decadron, Benadryl, and magnesium “with almost complete relief of her headache.” *Id.* The diagnosis was “nonintractable episodic headache.” *Id.* at 12. Petitioner was discharged with a prescription for Phenergan and was instructed to continue the indomethacin for two to three more days. *Id.* at 11. Petitioner was instructed to not take ibuprofen with indomethacin and that if the indomethacin was not working after three days, she could take ibuprofen. *Id.* at 11–12.

On June 26, 2018, Petitioner underwent an MRI of her brain. Pet'r's Ex. 17 at 39–40. After her MRI that same day, Petitioner returned to the VHC ED at approximately 4:30 pm for a two-week history of headache, with the pain worsening after her MRI. Pet'r's Ex. 7 at 15. She also had lightheadedness but denied sensitivity to light or sound. *Id.* Petitioner reported that the “throbbing headache was frontal previously but now radiate[d] to the back of her head, neck, and into her facial bones.” *Id.* She stated she took 800 mg of ibuprofen that day at 3:00 pm with minimal relief. *Id.* Nursing notes indicated Petitioner requested a migraine cocktail consisting of Benadryl,

Phenergan, and morphine,⁷ although she refused the medications until she spoke with Dr. Russell Goldstein. *Id.* at 20. After speaking with Dr. Goldstein, she received the medications at around 6:00 pm but refused the morphine. *Id.* at 20–21. She was tearful and wanted to know what was wrong with her and wanted her MRI read today. *Id.* at 21. The nurse explained that outpatient MRI results “are generally not read stat.” *Id.* Petitioner stated, “If I get a bleed, I’m going to sue you.” *Id.* The nurse asked if Petitioner felt she needed a CT scan, but Petitioner stated she had a normal head CT scan on June 16th and that her headache remained unchanged since that time. *Id.* Petitioner reported her headache was “causing her significant life distress due to sleep disruption [and] difficulty [at] work.” *Id.* Petitioner requested to be discharged as soon as possible. *Id.* She stated that the hospital staff had “not been very compassionate; if I was related to a doctor, I know I would be getting better care and a second MRI today that would be read immediately; I know [you] are under insurance complaints, so that’s why the care isn’t as good.” *Id.* Petitioner denied improvement of her headache since having the Benadryl and Phenergan 15 minutes earlier. *Id.* At 6:41 pm, Petitioner called the nurse to her bedside stating she wanted to leave as the medications were not working. *Id.* The nurse made Dr. Goldstein aware and told Petitioner he would come speak with her shortly. *Id.* By 6:50 pm, Petitioner again called the nurse to her bedside and was “upset” that Dr. Goldstein had not come to see her yet. *Id.* at 22. Dr. Goldstein spoke with Petitioner bedside at 6:59 pm. *Id.* A note at 7:09 pm from Dr. Goldstein indicated Petitioner reported “mild to moderate improvement after medications” and requested to be discharged. *Id.* at 18. She stated her headache had “overall been waxing and waning over the past couple of weeks” but became worse after her MRI that day. *Id.* Dr. Goldstein offered to do a repeat CT scan, but Petitioner was worried about the radiation and declined. *Id.* No diagnosis was made. *Id.* at 19. Petitioner was discharged with instructions to follow up with her neurologist and return if her symptoms worsened. *Id.*

On June 27, 2018, Petitioner saw Annise Claude, physician assistant (“PA”), at Dr. Savani’s office for follow-up and to discuss her MRI results. Pet’r’s Ex. 8 at 8. Petitioner’s MRI revealed nonspecific findings, as well as prominent abnormal signal changes in both frontal sinuses, and in the left maxillary and ethmoid sinuses, “most likely due to acute sinusitis.”⁸ Pet’r’s Ex. 17 at 39–40; *see also* Pet’r’s Ex. 8 at 8. Petitioner reported to PA Claude that she continued to have “daily headache[s] mostly midfrontal thought she [did] experience some pain more so toward her left frontal area.” Pet’r’s Ex. 8 at 8. She described the pain as sharp and did not radiate. *Id.* She denied associated nausea. *Id.* Petitioner stated she tried indomethacin but that it gave her no relief. *Id.* Notes indicated she started a prednisone taper yesterday and noticed “significant improvement in her symptoms” but also noted that she took a dose of Fioricet yesterday prior to starting the steroids. *Id.* Review of symptoms was positive for dizziness/lightheadedness and tingling/numbness. *Id.* at 9. Neurologic examination was normal. *Id.* at 10. PA Claude’s impression was “[p]ossible [TN].” *Id.* at 11. She wrote, Petitioner had

⁷ Petitioner told the nurse she was allergic to opiates and required both Benadryl and Phenergan to prevent a reaction. Pet’r’s Ex. 7 at 20.

⁸ Specifically, the brain MRI included abnormalities in the paranasal sinuses most likely due to acute sinusitis, and nonspecific findings related to the prominent Virchow-Robin spaces in both of Petitioner’s cerebral hemispheres, with a few areas of increased signal intensity on FLAIR in the white matter in close proximity to the prominent Virchow-Robin spaces. Pet’r’s Ex. 17 at 39–40. The largest measured 10 mm in diameter and was located in the subcortical white matter of the right frontal lobe. *Id.* at 40. Clinical correlation was recommended. *Id.* at 39.

new onset of headaches since the beginning of this month. She [] had no response to indomethacin which makes [TAC] less likely. I have personally reviewed with her the imaging and results of her MRI brain which does show some acute left maxillary sinusitis but her degree of pain seems to be out of proportion to this. . . . She has no previous history of headaches including migraines. Question if her symptoms are related to an atypical form of [TN]. We discussed potential for treatments with carbamazepine or gabapentin and she would like to proceed with gabapentin trial.

Id. PA Claude prescribed her 100 mg of gabapentin and instructed to up the dose to 300 mg if tolerated. *Id.*

Petitioner returned to Dr. Savani's office on July 27, 2018, where she again saw PA Claude. Pet'r's Ex. 8 at 12. Petitioner reported that since her last visit, she was taking gabapentin intermittently for severe pain and it helped alleviate her symptoms. *Id.* She felt the gabapentin was causing her to have blurred vision. *Id.* She now described her headaches as including "left-sided scalp paresthesias" and radiating into her upper teeth, which the PA felt was concerning for "potential [TN]." *Id.* at 12, 14. Petitioner described the pain as "a sharp cutting pain." *Id.* at 12. Petitioner also expressed her own concern that her symptoms were triggered by her recent Tdap immunization. *Id.* The diagnosis remained "[p]ossible [TN]." *Id.* at 14. She was instructed to take gabapentin more consistently for its preventative benefit and follow up in three months. *Id.* at 14–15.

On October 26, 2018, Petitioner followed up with PA Claude. Pet'r's Ex. 8 at 16. Petitioner continued to have pain on the "left side of her head which radiate[d] into her upper as well as lower face and jaw." *Id.* Over the past few weeks, she reported having a headache nearly every day. *Id.* She also reported "an episode of transient left facial weakness with left upper extremity numbness and tingling that occurred last month." *Id.* She was currently using CBD oil with THC as well as gabapentin which she found helpful. *Id.* During this visit she became tearful and admitted to suicidal ideation. *Id.* The relevant impressions were transient ischemic attack ("TIA") and headache. *Id.* at 19. PA Claude wrote that Petitioner

had an episode of headache with associated left facial weakness with speech changes and left upper extremity paresthesias last month which may have been a TIA versus a complicated migraine. Given this event [PA Claude] again recommended and urged her to complete MRI of the brain, transcranial Doppler, carotid duplex ultrasound as well as discuss having an echocardiogram.

Id. She added that Petitioner's "headache etiology [] remained difficult to fully diagnose as some features may be consistent with migraine[,] however[,] she ha[d] no history of headache/migraines in the past. Her initial facial pains complaint may represent [TN]. She did not respond to indomethacin making TACS less likely." *Id.* Petitioner declined an offer of physical therapy for her associated neck pain but expressed interest in exploring occipital nerve blocks. *Id.*

On November 14, 2018, Petitioner returned to neurology to discuss the results of her latest testing, including a brain MRI completed on November 2, 2018, and transcranial and carotid dopplers completed on November 5, 2018, all of which were normal. Pet'r's Ex. 8 at 22–26. The abnormalities present on the prior MRI were stable and remained non-enhancing, and Petitioner's sinus abnormalities were no longer present. *Id.* at 27, 29–30; Pet'r's Ex. 17 at 40–41. Petitioner remained on 900 mg daily of gabapentin. Pet'r's Ex. 8 at 27. Under the headache assessment, it was noted that it “remain[ed] unclear if these pains represent [TN] or migraine variant.” *Id.* at 29. Treatment options were discussed and Petitioner “wishe[d] to pursue treatment options for [TN] at this time. She agree[d] to a trial of carbamazepine which she will up titrate to 400 mg daily.” *Id.*

On December 14, 2018, Petitioner presented to internist Dr. Tareq Abedin as a new patient. Pet'r's Ex. 10 at 4. She reported frequent left sided headaches located in the periorbital, frontal, temporal, and parietal regions, associated with numbness of her hands (but in the mornings only). *Id.* She reported her headaches were severe, but described the pain as dull, and reported headaches lasting for hours at a time, five times per week. *Id.* She discontinued gabapentin and was treating primarily with carbamazepine. *Id.* Dr. Abedin diagnosed Petitioner with frequent headaches and TN.⁹ *Id.*

Petitioner presented to a new neurologist, Dr. Matthew Churchill on January 3, 2019. Pet'r's Ex. 17 at 24. On her intake paperwork, Petitioner reported “[i]ntense headaches on the frontal area” that began “May 22 – June.” *Id.* at 31. Petitioner advised Dr. Churchill her symptoms began “abruptly at the beginning of June while she was getting ready to film a YouTube video.” *Id.* at 24. “As the symptoms began about 10 days after vaccination, there was a question of this being a reaction to the vaccine, acute disseminated encephalomyelitis [(“ADEM”)] presumably being considered given the white matter lesions on the brain.” *Id.* It was noted that Petitioner continued to have a headache almost every day since onset. *Id.*

The headache [was] primarily a stabbing, shooting pain in the left parietal region. Initially, the headache was more frontal and centered between the eyes as if it was “her third eye.” She [did] not have any sharp pain over the eye or cheek, but she [did] believe that sometimes she ha[d] a strange dysesthesia when she touche[d] her left cheek and occasionally there [was] some numbness.

Id. Petitioner recently stopped taking carbamazepine and was taking CBD/THC oil. *Id.* According to Dr. Churchill, Petitioner's brain MRI “was somewhat suspicious for demyelination” but noted the findings “could certainly be nonspecific.” *Id.* at 24, 27. On examination, Petitioner's cranial nerves were normal, and Dr. Churchill noted equivocally reduced fine motor movements in the left leg, symmetric hyperreflexia at the biceps, triceps, patellae, and ankles, and several beats of clonus bilaterally. *Id.* at 26. Dr. Churchill's assessment was neuralgia.¹⁰ *Id.* He recommended an MRI of the cervical spine to exclude demyelination or a lesion in the left upper spinal cord that could cause occipital or trigeminal nerve symptoms. *Id.* at 27. The MRI was completed on January 8, 2019, and showed mild degenerative changes without spinal cord lesions. *Id.* at 29–30.

⁹ At a second encounter with Dr. Abedin on February 28, 2019, TN was removed from the diagnosis, leaving frequent headaches as the only diagnosis. Pet'r's Ex. 10 at 2–3.

¹⁰ Neuralgia is “pain extending along the course of one or more nerves.” *Neuralgia*, DORLAND'S.

On January 10, 2019, Petitioner returned to Dr. Churchill. Pet'r's Ex. 17 at 20. She reported constant nausea and stomach upset, that her eyes were bloodshot with her headaches if they were severe, and that the left side of her face was sensitive to cold air. *Id.* at 21. Her neurological examination was unchanged, and Dr. Churchill noted that "there [was] still the possibility that the initial lesion was a reactive autoimmune trigeminal neuropathy resulting from the vaccine and resulting in either a clinically isolated syndrome versus [multiple sclerosis ("MS").]" *Id.* at 23. His assessment was "[c]hronic common migraine without aura," "CNS demyelinating disorders," "[t]rigeminal nerve injury," and neuralgia. *Id.* at 22. He further commented that her symptoms were most consistent with chronic migraine, and "possible trigeminal neuropathy," along with components of chronic tension headaches. *Id.* at 23. He prescribed clonazepam for insomnia, and a Medrol dosepak. *Id.*

Petitioner returned to Dr. Churchill on January 31, 2019, and reported that her headaches were "a bit better" with treatment, including steroids and medical marijuana she obtained from California. Pet'r's Ex. 17 at 17. She reported "soreness in the left occipital parietal area and a feeling of soreness or poking in the left eye that was mild," and her symptoms almost always worsened throughout the day and with stress but improved with rest. *Id.* Dr. Churchill noted her current headache symptoms were "most consistent with chronic migraine resulting from tension but perhaps set off by trigeminal and occipital neuralgia." *Id.* at 18. He noted that because he never examined her when her symptoms started, it was "difficult to tell" if her present chronic tension migraines were set off by an earlier trigeminal or occipital neuralgia. *Id.* Dr. Churchill prescribed Maxalt, and considered occipital nerve blocks, Botox, amitriptyline, and calcitonin gene-related peptide inhibitors ("CGRP injectables") as possible future treatment if Petitioner's symptoms persisted. *Id.* at 19.

On February 28, 2019, Petitioner returned to Dr. Churchill and reported her headaches were "worse again." Pet'r's Ex. 17 at 13. Her migraines now "switch[ed] sides" and were recently right sided. *Id.* She did not respond positively to Maxalt but felt she responded well to the steroid pack. *Id.* She also responded well to medical marijuana but felt she was developing a tolerance. *Id.* She was now taking 1800 mg of gabapentin twice per day. *Id.* Dr. Churchill's assessments remained "[c]ommon migraine without aura with intractable migraine with status migrainosus," "[c]hronic common migraine without aura," "CNS demyelinating disorders," "[t]rigeminal nerve injury," and neuralgia. *Id.* at 14. He administered a headache protocol infusion of Kytril, Depacon, Toradol, and magnesium. *Id.* at 14–15. He felt her current symptoms were "most consistent with chronic migraine and tension headaches" and that they did not respond to Fioricet or Lorazepam but did seem to respond to steroids. *Id.* at 15.

On March 27, 2019, Petitioner returned to Dr. Churchill and reported that she was "doing much better" following her most recent treatment (the headache protocol infusion and Medrol dosepak) which eliminated her headaches, with only two total headaches in the last month. Pet'r's Ex. 17 at 9. She also noticed her headaches were aggravated by looking at a screen. *Id.* Dr. Churchill noted her recent headaches were "very manageable" and able to be treated with CBD oil and THC vaping. *Id.* at 10–11. Dr. Churchill maintained that Petitioner's current symptoms were "most consistent with chronic migraine and tension headaches" *Id.* at 10. Petitioner reported seeing a dentist for a nightguard, and Dr. Churchill and believed temporomandibular joint ("TMJ") pain was contributing to her symptoms. *Id.* at 11. He recommended she return as needed for headache

protocol infusions, gave her a prescription for another Medrol dosepak for future use, and advised her to follow up in one year or less for a follow-up brain MRI. *Id.*

Between March 28, 2019, and February 23, 2021, Petitioner did not seek any medical treatment specifically related to her headaches.

On February 24, 2021, Petitioner returned to Dr. Savani's office, where she saw PA Claude, for follow-up and reevaluation of care for her headaches. Pet'r's Ex. 8 at 31. History indicated Petitioner was previously followed for "headaches thought to be related to possibly one of the [TACs] or [TN]." *Id.* Petitioner was not currently taking any medications and reported that "with dietary adjustments and fasting[,] her headaches [were] better controlled." *Id.* However, she reported that "over the last [three] months, she [] had several episodes of intense headache occurring for several days in a row." *Id.* The headaches were left-sided with eye redness and pain. *Id.* She reported benefit with THC chocolates but recently found them less effective. *Id.* Petitioner reported "having what she [thought] was an [sphenopalatine ganglion ("SPG")] block for [three] times with pain management with resulting long lasting pain benefit but did not return for subsequent treatments." *Id.* Neurologic examination was normal. *Id.* at 33. The diagnoses were "[p]ossible [TN]" and "[h]e headache." *Id.* at 33–34. The treatment plan was for Petitioner to repeat a brain MRI, revisit pain management for a repeat SPG block, and a trial of lidocaine spray for breakthrough pain. *Id.* at 34. It was noted that she previously tried indomethacin, gabapentin, carbamazepine, and Lycra "without sustained benefit." *Id.*

Petitioner underwent a repeat brain MRI on March 3, 2021, which revealed no abnormalities of the trigeminal nerve or along any of its three divisions, and "[m]ild supratentorial white matter signal abnormalities which are nonspecific but statistically secondary to chronic microvascular sequela." Pet'r's Ex. 8 at 36.

On March 8, 2021, Petitioner saw pain management specialist Dr. Mehul Dasai. Pet'r's Ex. 4 at 149–52. Petitioner described her pain as a "daily throbbing and stabbing." *Id.* at 151. "No particular movements improve[d] the pain but she report[ed] brushing her hair can cause the pain to flare." *Id.* Dr. Dasai noted Petitioner's prior treatment with medication, three prior SPG blocks (with good response), and THC. *Id.* at 151–52. Dr. Dasai performed a left SPG nerve block, with a note to consider a trigeminal nerve block in the future. *Id.* at 152. Two days later, Petitioner reported to neurology that the lidocaine spray and SPG block were helpful for her pain. Pet'r's Ex. 8 at 37.

On April 12, 2021, Petitioner consulted with Dr. Todd Goodglick of the Washington Eye Physicians & Surgeons for an oculoplastic and neuroophthalmological review. Pet'r's Ex. 14 at 1–2. Petitioner told Dr. Goodglick she had pain when moving her eye which raised the question of whether she had inflammatory optic neuropathy. *Id.* at 1. Dr. Goodglick could not determine the cause of her eye pain and deferred to the previous TN diagnosis as the best possible explanation. *Id.*

Petitioner returned to Dr. Savani on May 4, 2021. Pet'r's Ex. 8 at 42. Petitioner reported intermittent pain, which was no longer daily, but frequently, up to five times per day when it occurred, and lasted between five and thirty minutes. *Id.* He reviewed her most recent imaging and

lab work, which were normal. *Id.* Dr. Savani diagnosed Petitioner with possible TN or possible TACs. *Id.* at 44. He prescribed Aptiom and advised Petitioner to follow up in three months or sooner if necessary. *Id.* One week later, on May 10, 2021, Dr. Desai completed another SPG nerve block. Pet't's Ex. 4 at 144–47.

On August 2, 2021, Petitioner had a telemedicine appointment with Dr. Savani. Ex. 8 at 45. She had not started Aptiom. *Id.* She reported no headaches or facial pain in the past three months, after taking ashwaganda, melatonin, and magnesium supplements. *Id.* Dr. Savani noted “her symptoms ha[d] improved following a nerve block.” *Id.* at 47. Petitioner was directed to monitor her symptoms and return if necessary. *Id.*

B. Petitioner’s Affidavit

Petitioner submitted one affidavit dated March 7, 2022. Pet'r's Ex. 16. In her affidavit, Petitioner asserted she received the Tdap vaccine in her left arm on May 22, 2018. *Id.* at ¶ 2.

On June 17, 2018, Petitioner went to the ED because of “a severe headache and [] a tingling sensation in [her] hands.” Pet'r's Ex. 16 at ¶ 3. She recalled telling the doctor that her headache started on June 5, 2018. *Id.* The pain was “intensifying and reached peak pain levels over the course of the last 24 hours.” *Id.* She tried taking ibuprofen but had no relief. *Id.* while at the hospital, she also noticed she had “a burst blood vessel” in her left eye. *Id.* She was admitted and received a Ketorolac injection for the pain. *Id.* Her head CT was negative for any abnormalities. *Id.* Upon discharged, Petitioner asserted she “was told [she] was suffering from a tension headache.” *Id.*

The next day, around 3:00 am, Petitioner woke up with “sharp head pain.” Pet'r's Ex. 16 at ¶ 4. She did not have any pain relief with over-the-counter medications and later that day, “the pain became so unbearable” she went to the ED. *Id.* She told the doctor her headache “had been on going for the past two days” and the pain level was a 10/10. *Id.* She also recounted that the pain injections she received at the hospital the night before only reduced her pain by 40%. *Id.* She stated she had never experienced these symptoms before. *Id.* At the hospital, she received a migraine cocktail consisting of morphine, Benadryl, Phenergan, and a cortisone, but it did not relieve the pain. *Id.* The doctor told her “if [her] pain d[id] not respond to painkillers, it [was] most likely a nerve pain” and she would need to see a neurologist. *Id.*

Petitioner visited Dr. Savani on June 21, 2018, for a neurology consult concerning her headaches. Pet'r's Ex. 16 at ¶ 5. She told Dr. Savani that June 5, 2018, was around the time she started experiencing “these debilitating headaches.” *Id.* She also told him “how the use of NSAIDs would only temporarily relieve [her] pain because [she] would often still have a mild headache that would spike again shortly after.” *Id.* At this time, Petitioner thought her headaches were caused by a new diet, but she started to be skeptical of this because she was cautious to stay hydrated. *Id.* Dr. Savani was doubtful Petitioner’s headaches were migraines because she did not have a history of prior headaches. *Id.* Dr. Savani ordered an MRI and prescribed indomethacin. *Id.*

On June 23, 2018, Petitioner returned to the ED for “the same ongoing headache pain [she] had been experiencing for the past week.” Pet'r's Ex. 16 at ¶ 6. The medication prescribed by Dr. Savani did not help her pain. *Id.* “The pain [she] was experiencing at this point was so debilitating

that [she] did not know what else to do other than try to find some comfort by covering [her] head with pillows and rock [her]self back and forth.” *Id.* They gave her a combination of Phenergan, Decadron, Benadryl, and magnesium which gave her some relief. *Id.*

Petitioner had an MRI on June 26, 2018. Pet’r’s Ex. 16 at ¶ 7. Later that day she returned to the ED. *Id.* at ¶ 8. Sher reported to the doctor that she was experiencing “waxing and waning headache pain for the past [two] weeks.” *Id.* After her MRI that day, her “headache pain intensified, and the pain was now radiating to the back of [her] head and was no longer localized to the front of [her] head.” *Id.* She recalled reporting to a nurse that her headache pain was “so severe it [was] impeding her ability to work¹¹ and sleep thus causing [her] significant distress.” *Id.* She did not feel she was getting proper care there, so she “went home to deal with the pain.” *Id.*

The next day, on June 27, 2018, she followed up with Dr. Savani to discuss her MRI results. Pet’r’s Ex. 16 at ¶ 9. Dr. Savani told her the brain MRI “showed a few scattered but nonspecific white matter, and some air fluid levels in the left maxillary sinus.” *Id.* Petitioner also reported to Dr. Savani she was now experiencing “dizziness and lightheadedness, with some tingling/numbness.” *Id.* He ordered Petitioner to take gabapentin for possible TN and to follow up if there was no improvement. *Id.*

On July 27, 2018, she recalled returning to Dr. Savani for ongoing headache pain. Pet’r’s Ex. 16 at ¶ 10. She told Dr. Savani the gabapentin eased some of her symptoms, but that her pain level was still high. *Id.* The pain was “mostly centralized to the left side of [her] head” and she described it as “a sharp cutting pain.” *Id.* At this visit, Petitioner asserted she told Dr. Savani she was concerned that her headache symptoms were “tied to the administration of [her] Tdap vaccine.” *Id.*

On October 26, 2018, Petitioner followed up with Dr. Savani. Pet’r’s Ex. 16 at ¶ 11. At this point she had a headache “almost every single day for the last few weeks.” *Id.* She also reported “an episode of numbness and tingling sensation on the upper left side of [her] body.” *Id.*

Petitioner recalled getting an MRI, transcranial doppler, and duplex ultrasound done. *See* Pet’r’s Ex. 16 at ¶¶ 11–14. The results were normal and the previously found white matter lesions seen on MRI were stable. *Id.* at ¶ 14. Petitioner recalled Dr. Savani telling her again “he thinks it is possible [she] ha[s] [TN]” and she stated she wanted to move forward with treatment. *Id.* At this point her gabapentin was 900 mg twice per day. *Id.* Dr. Savani decided to take Petitioner off gabapentin because it was affecting her mental health. *Id.* She started carbamazepine instead. *Id.*

On December 14, 2018, Petitioner saw Dr. Abedin for her TN pain. Pet’r’s Ex. 16 at ¶ at 15. She reported she had headaches almost daily for the past six months, lasting hours at a time. *Id.* The pain was still localized to the left side of her face, and she was now experiencing numbness in her hands in the morning. *Id.*

At the Neurology Center of Fairfax on January 1, 2019, Petitioner reported she had suffered headaches since early June. Pet’r’s Ex. 16 at ¶ 16. On January 7, 2019, Petitioner told Dr. Churchill that she started to have headaches approximately 10 days after the Tdap vaccine. *Id.* at ¶ 17. She

¹¹ Petitioner is an attorney. Pet’r’s Ex. 16 at ¶ 33.

recounted that she remembered exactly when the headaches started because she was getting ready to film a video for work and had “some pain over [her] left eye.” *Id.* She also remembered “the video producer pointing out that [her] eye was bloodshot.” *Id.* She told Dr. Churchill she started experiencing “a strange numbing/tingling feeling on the left side of [her] face.” *Id.*

Petitioner continued that on March 6, 2019, she told Dr. Churchill that “just a few days ago,” she suffered “one of the worst headaches [she] had in months,” and how her current medications were not working. Pet’r’s Ex. 16 at ¶ 21. Petitioner recalled that was the first time she reported the pain was on the right side of her face, not just the left side. *Id.*

On July 13, 2019, Petitioner reported new symptoms to Dr. Churchill including “constant nausea and stomach pain when [she did] not have a headache.” Pet’r’s Ex. 16 at ¶ 23. She also stated her eyes were “bloodshot” every time she had a headache, and the left side of her face was “sensitive to cold air.” *Id.* Petitioner averred that she recalled Dr. Churchill telling her he believed “the initial lesions that were found in [her] first MRI could have been a reactive autoimmune [TN] resulting from the Tdap vaccine and resulted in a clinically isolated syndrome.” *Id.* In September 2019, Petitioner stopped taking carbamazepine due to side effects such as skin abrasions and blisters. *Id.* at ¶ 24.

Petitioner saw Dr. Savani on February 24, 2021, for reevaluation. Pet’r’s Ex. 16 at ¶ 25. Petitioner reported her headaches had “become uncontrollable over the past three months, and they [] lasted over several days with associated eye redness and pain.” *Id.* She also told him about the different medications she had tried but that they did not have long-term benefits. *Id.* The only medication that seemed to suppress her symptoms was an SPG block. *Id.* The first few days after SPG treatment she had no headaches, although she averred SPG treatments were so painful. *Id.* at ¶¶ 28, 31, 33.

On April 12, 2021, Petitioner saw Dr. Goodglick for an oculoplastic and neuroophthalmological consultation. Pet’r’s Ex. 16 at ¶ 29. Petitioner reported she was “experiencing eye discomfort when [she] move[d her] eye and [] was worried it may be an inflammatory optic neuropathy.” *Id.* She stated Dr. Goodglick “could not pinpoint the cause of [her] left eye pain and concluded that [her] previous [TN] diagnosis [was] the best possible explanation.” *Id.*

Petitioner asserted that prior to the subject Tdap vaccine, she did not have any of the symptoms described above. Pet’r’s Ex. 16 at ¶ 34.

III. Experts

A. Expert Qualifications

1. Petitioner’s Expert, Joseph S. Jeret, M.D.

Dr. Jeret is board certified in psychiatry and neurology. Pet’r’s Ex. 18 at 1. He received his M.D. from SUNY Health Science Center at Brooklyn, where he subsequently completed a neurology residency and a clinical neurophysiology fellowship. *Id.*; Pet’r’s Ex. 19 at 1. He is

currently employed by Optum Health as an active physician in the department of neurology. Pet'r's Ex. 18 at 1. He is also on staff at South Nassau Community Hospital and Mercy Medical Center, as well as maintains a neurology practice. *Id.* Over his career, he has cared for approximately 30,000 patients, interpreted thousands of MRI scans, and performed thousands of EMG/NCS studies. *Id.* at 2. He routinely cares for patients with neurological diseases and has specifically diagnosed patients with TN. *Id.* Dr. Jeret has numerous publications in the field of neurology. *Id.* at 1; Pet'r's Ex. 19 at 3–8.

2. Respondent's Expert, Dara G. Jamieson, M.D.

Dr. Jamieson is board certified in neurology and vascular neurology. Resp't's Ex. A at 1. She received her M.D. from the University of Pennsylvania and subsequently completed a neurology residency and cerebrovascular fellowship at the Hospital of the University of Pennsylvania. *Id.*; Resp't's Ex. B at 1. She was a practicing neurologist for 32 years before transitioning to a teaching appointment. Resp't's Ex. A at 1. While she was practicing, she “treated many patients each year with [TN] and with multiple headache types, including [TACs].” *Id.* at 2. Dr. Jamieson is currently a Clinical Associate Professor of Neurology at Weill Cornell Medicine. *Id.* at 1. In this role, she teaches medical students in neurology courses and clinical inpatient clerkships as well as gives lectures to residents and fellows. *Id.* Dr. Jamieson has numerous publications and is in editorship positions for neurology journals. *Id.* at 1–2; Resp't's Ex. B at 10–15.

B. Expert Opinions

1. Petitioner's Expert, Dr. Jeret's First Report

Dr. Jeret opined Petitioner developed TN approximately two weeks after receiving the Tdap vaccination. Pet'r's Ex. 18 at 12. He proposed molecular mimicry and an inflammatory immune-mediated response as causal theories. *Id.* at 13. He wrote, “[t]he diagnosis of TN is established. Its occurrence after the vaccine is established. The mechanism of the development of TN still requires explanation.” *Id.* 10.

a. Diagnosis

Dr. Jeret opined the correct diagnosis here is TN. Pet'r's Ex. 18 at 10. He cited to the National Institutes of Health's (“NIH”)¹² website to describe TN. *Id.* at 9–10 (citing Pet'r's Ex. 44). The NIH wrote that TN is “a type of chronic pain disorder that involves sudden, severe facial pain. . . . TN is a type of neuropathic pain, typically caused by a nerve injury or nerve lesion.” Pet'r's Ex. 44 at 1. Symptoms include:

- Sudden, intense pain, typically on one side of the face
- Pain attacks that can last for a few seconds to about two minutes
- Numbness or a tingling sensation

¹² *Trigeminal Neuralgia*, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, <https://www.ninds.nih.gov/health-information/disorders/trigeminal-neuralgia> (last reviewed Apr. 7, 2023).

- A burning, throbbing, shock-like, or aching sensation
- Attacks of pain that occur regularly for days to weeks or longer, sometimes several times a day

Id.

TN “affects the trigeminal nerve, or fifth cranial nerve, which provides feeling and nerve signaling to many parts of the head and face.” Pet’r’s Ex. 44 at 1. “The trigeminal nerves are a pair of cranial nerves that connect your brain and brain stem to different parts of the brain, head, torso, and neck. Each of the 12 nerves splits to serve the two sides of your body and brain. Each nerve also has three branches that conduct sensations from the upper, middle, and lower portions of your face.” *Id.* (1) “The ophthalmic, or upper, branch supplies sensation to most of the scalp, forehead, and front of your head,” (2) “[t]he maxillary, or middle, branch stimulates your cheek, upper jaw, top lip, teeth and gums, and to the side of the nose,” and (3) “[t]he mandibular, or lower, branch supplies nerves to your lower jaw, teeth and gums, and bottom lip.” *Id.*

Dr. Jeret observed the NIH website “echoes the diagnostic criteria” for TN in the third edition of the International Classification of Headache Disorders (“ICHD-3”).¹³ Pet’r’s Ex. 18 at 9 (citing Pet’r’s Ex. 43). The ICHD-3 diagnostic criteria for TN are:

Recurrent paroxysms of unilateral facial pain in the distribution(s) of one or more divisions of the trigeminal nerve, with no radiation beyond¹, and fulfilling criteria B and C

A. Pain has all of the following characteristics:

1. lasting from a fraction of a second to 2 minutes²
2. severe intensity³
3. electric shock-like, shooting, stabbing or sharp in quality

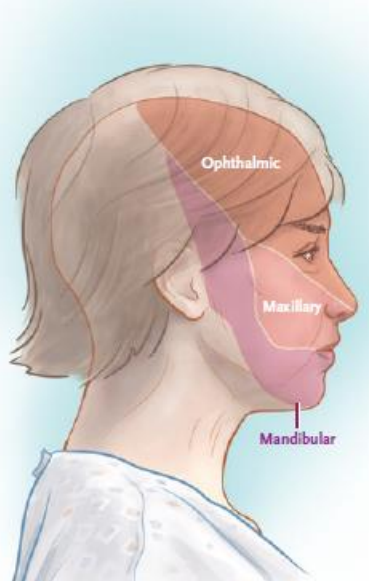
B. Precipitated by innocuous stimuli within the affected trigeminal distribution⁴

C. Not better accounted for by another ICHD-3 diagnosis.

Pet’r’s Ex. 43 at 3. Cruccu et al.¹⁴ shows the three distributions of the trigeminal nerve:

¹³ (last reviewed May 7, 2023).

¹⁴ Giorgio Cruccu et al., *Trigeminal Neuralgia*, 383 NEW ENG. J. MED. 754 (2020).



Pet'r's Ex. 26 at 2 fig. 1.

Applying ICHD-3 criteria here, Dr. Jeret opined that Petitioner has TN for several reasons. First, Petitioner described her pain to Dr. Goodglick as “‘shocking or electric’ painful episodes several times per day.” Pet'r's Ex. 18 at 8 (quoting Pet'r's Ex. 14 at 2). Second, Petitioner complained that brushing her hair caused her pain to flare. *Id.* at 9 (citing Pet'r's Ex. 4 at 152). Dr. Jeret implied this was consistent with the ICHD-3 criterion that the pain can be “[p]recipitated by innocuous stimuli within the affected trigeminal distribution.” *Id.* (quoting Pet'r's Ex. 43 at 3). Third, Dr. Jeret listed the visits where he believed Petitioner was diagnosed with TN by several providers including Dr. Savani (on June 21, 2018, and May 14, 2021), PA Claude (on June 27, 2018, and July 27, 2018), Dr. Abedin (on December 14, 2018), Dr. Churchill (on January 10, 2019), and Dr. Goodglick (on April 12, 2021).¹⁵ *Id.* at 10 (citing Pet'r's Ex. 8 at 4, 11, 14, 44; Pet'r's Ex. 10 at 4; Pet'r's Ex. 14 at 1; Pet'r's Ex. 17 at 23). Dr. Jeret opined the ICHD-3 would specifically classify Petitioner's TN as 13.1.1.2.3, “[TN] attributed to other cause.” *Id.* at 9–10.

Dr. Jeret also stated that TN is typically treated with certain seizure medications including Tegretol, Trileptal, gabapentin, and Lyrica, and that all four of these medications were used for Petitioner at different times throughout her care. Pet'r's Ex. 18 at 9 (citing Pet'r's Ex. 26). He concluded, the “record shows that TN developed after Tdap vaccination and was treated with the typical remedies for TN. Other possible diagnostic considerations [were] excluded.” *Id.* at 13.

b. Causation

Dr. Jeret wrote, “[m]olecular mimicry is cited in the literature. Immune-mediated inflammatory response is cited in the literature One or both of these phenomena caused [Ppetitioner's] TN.” Pet'r's Ex. 18 at 13.

¹⁵ These are discussed in more depth below in section B.4.

Dr. Jeret described molecular mimicry. Pet'r's Ex. 18 at 12. "Vaccines stimulate the body's immune system to create antibodies. Occasionally, the immune system 'gets the wrong message' and will attack an unintended target by creating an autoimmune response against peripheral nerve myelin." *Id.* He explained this is "called molecular mimicry due to similarity of the body's own peptides to the foreign peptides in the vaccine." *Id.* "The same immune error can target nerves in a different way and result in [Guillain-Barré syndrome ("GBS").]"¹⁶ *Id.* He opined this is the basis for GBS after flu vaccine and Tdap vaccine. *Id.* Dr. Jeret then cited several pieces of literature on post-vaccination GBS as well as post-vaccination Bell's palsy, vasculitic neuropathy, and vasculitis. *Id.* at 11–12; *see, e.g.*, Pet'r's Ex. 20;¹⁷ Pet'r's Ex. 21;¹⁸ Pet'r's Ex. 22;¹⁹ Pet'r's Ex. 23;²⁰ Pet'r's Ex. 30;²¹ Pet'r's Ex. 33;²² Pet'r's Ex. 39;²³ Pet'r's Ex. 43.²⁴

Specific to TN, Dr. Jeret stated that TN has been described in the literature after the COVID-19 vaccine. Pet'r's Ex. 18 at 11 (citing Pet'r's Ex. 31;²⁵ Pet'r's Ex. 32).²⁶ "Molecular mimicry and immune-mediated inflammatory response are hypothesized to explain the development of TN after the COVID-19 vaccine." *Id.*

Kaya & Kaya reported a case of TN three days after receiving a COVID-19 vaccine. Pet'r's Ex. 31 at 1. The patient was admitted to the hospital with three days of facial and jaw pain, fatigue, and toothache. *Id.* Three days prior to admission, she received the first dose of a COVID-19 vaccine. *Id.* The patients "features of the pain were unilateral, acute onset, and severe. It was of short duration and localized to the right of the face." *Id.* The patient also "noticed it was triggering with brushing her teeth and putting on makeup." *Id.* A nonsteroid anti-inflammatory drug was

¹⁶ GBS is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated." *Guillain-Barré Syndrome*, DORLAND'S.

¹⁷ Hussam Ammar, *Guillain-Barré Syndrome After Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine: A Case Report*, 5 AMMAR J. MED. CASE REPS. 502 (2011).

¹⁸ Rohit Bakshi & Michael C. Graves, *Guillain-Barré Syndrome After Combined Tetanus-Diphtheria Toxoid Vaccination*, 147 J. NEUROLOGICAL SCIENCES 201 (1997).

¹⁹ Carola Bardage et al., *Neurological and Autoimmune Disorders After Vaccination Against Pandemic Influenza A (H1N1) with a Monovalent Adjuvanted Vaccine: Population Based Cohort Study in Stockholm, Sweden*, 343 BMJ CASE REP. d5956 (2011).

²⁰ Blandine Bertin et al., *Vaccines and Bell's Palsy: A Narrative Review*, 709 THERAPIE 1 (2022)

²¹ Ashwin Kamath et al., *Facial Paralysis Following Influenza Vaccination: A Disproportionality Analysis Using the Vaccine Adverse Event Reporting System Database*, 40 CLINICAL DRUG INVESTIGATION 883 (2020).

²² Norris Newton, Jr. & Abdorassol Janati, *Guillain-Barré Syndrome After Vaccination with Purified Tetanus Toxoid*, 80 SOUTHERN MED. J. 1053 (1987).

²³ Nizar Souayah et al., *Guillain-Barré Syndrome After Vaccination in United States: Data from the Centers for Disease Control and Prevention/Food and Drug Administration Vaccine Adverse Event Reporting System (1990-2005)*, 11 NEUROMUSCULAR DISEASE 1 (2009).

²⁴ Weigong Zhou et al., *A Potential Signal of Bell's Palsy After Parenteral Inactivated Influenza Vaccines: Reports to the Vaccine Adverse Event Reporting System (VAERS) – United States, 1991-2001*, PHARMACOEPIDEMIOLOGY & DRUG SAFETY 505 (2004).

²⁵ Abdurrahman Kaya & Sibel Yildiz Kaya, *A Case of Trigeminal Neuralgia Developing After a COVID-19 Vaccination*, 28 J. NEUROVIROLOGY 181 (2022).

²⁶ Kaavya Narasimhalu et al., *Trigeminal and Cervical Radiculitis After Tozinameran Vaccination Against COVID-19*, 14 BMJ CASE REP. e24344 (2021).

administered, but after four weeks, the patient still had pain. *Id.* “Due to the findings including typical features and localization of the pain and triggering by some actions, the case was considered as [TN].” *Id.* The patient was prescribed pregabalin, but the pain persisted. *Id.* During another hospital admission, the patient was administered methylprednisolone intravenously and discharged with a seven-day tapering course of steroids. *Id.* This treatment resolved all complaints including facial and jaw pain. *Id.* The patient had no recurrence on regular follow-ups for six months. *Id.* Kaya & Kaya described TN, including routine actions such as brushing teeth, eating, and the wind aggravating the symptoms. *Id.* at 2. They also noted TN may be confused with dental causes. *Id.* The authors explained that neurological involvement has been described following COVID-19 vaccinations. *Id.* Although the exact mechanism has not been fully elucidated, it has been attributed to molecular mimicry and immune-mediated inflammatory responses. *Id.* While molecular mimicry “often requires at least 10-14 days to develop,” an immune-mediated inflammatory response “needs less time to develop than [molecular mimicry].” *Id.* In Kaya & Kaya, the authors thought “immune-mediated inflammation [was] a more likely mechanism [in their patient] due to the fairly rapid onset of the symptoms and the response to corticosteroids.” *Id.*

Narasimhalu et al. reported a patient who developed numbness, swelling, and pain over the left side of her face and neck three hours after receiving a COVID-19 vaccine. Pet’r’s Ex. 32 at 1. Petitioner was admitted to the hospital on the third day of her symptoms and an MRI of the trigeminal nerve revealed “an abnormal asymmetric thickening and robust perineural sheath enhancement of the V3 segment of the left trigeminal nerve.” *Id.* Petitioner was ultimately diagnosed with TN as well as sensory radiculitis in her neck. *Id.* Her symptoms gradually improved with steroids although she had residual numbness over the left V3 distribution. *Id.* Like Kaya & Kaya, Narasimhalu et al. explained that while neurological complications after vaccinations have been observed, the exact mechanism behind the development of such remains unclear. *Id.* The authors also noted that molecular mimicry and immune-mediated inflammatory response have been postulated as possible mechanisms. *Id.* at 1–2. They stated that molecular mimicry requires the development of a humoral responses, which is thought to take at least 10 to 14 days to develop, whereas immune-mediated inflammatory response “may require less time to develop than molecular mimicry. *Id.* at 2. Narasimhalu et al. postulated that “immune-mediated inflammatory response rather than molecular mimicry is a more likely mechanism [in their patient] due to the fairly rapid onset of symptoms ([three] hours post vaccination) and the response to corticosteroids.” *Id.* However, they concluded that “[w]hile the temporal association of the development of the radiculitis in close proximity to the vaccination is suggestive that they may be associated, it remains possible that the development of the trigeminal and cervical radiculitis is not related to the vaccination.” *Id.* Dr. Jeret did not compare the COVID-19 vaccine to the Tdap vaccine to extrapolate data from Kaya & Kaya and Narasimhalu et al. to the case here.

Dr. Jeret opined it is “impossible to ascertain whether the inflammatory target is the brainstem or nucleus of the trigeminal nerve . . . or if the nerve itself is the target.” Pet’r’s Ex. 18 at 12. However, he opined “the etiologic role of the vaccine in initiating this cascade is undeniable. This result can target the facial nerve to cause a facial palsy, a cervical nerve root to cause an apparent radiculitis, multiple nerves to cause GBS, or the trigeminal nerve to cause TN.” *Id.* He concluded, “[a]lthough the target(s) may change, the pathogenesis remains the same.” *Id.*

In further support of causation, Dr. Jeret cited to Petitioner's visit with neurologist Dr. Churchill in January 2019. Pet's' Ex. 18 at 6 (citing Pet'r's Ex. 17 at 23). Dr. Churchill noted that "there [was] still the possibility that the initial lesion was a reactive autoimmune trigeminal neuropathy resulting from the vaccine and resulting in either a clinically isolated syndrome^[27] versus MS." Pet'r's Ex. 17 at 23. Dr. Jeret interpreted this finding as Dr. Churchill "hypothesizing that the initial attack of trigeminal neuropathy was due to a demyelinating lesion in the brain affecting the trigeminal nucleus and that it would represent [clinically isolated syndrome]. He [was] also postulating that the vaccine caused the [clinically isolated syndrome], as well as possibly causing MS (if future attacks were to occur)." Pet'r's Ex. 18 at 6. Dr. Jeret believed the Cruccu et al. article covered TN presenting as clinically isolated syndrome; however, Cruccu et al. explained TN is occasionally manifested as clinically isolated syndrome only in the context of patients with MS. Pet'r's Ex. 26 at 5.

Dr. Jeret believed a proximate temporal relationship exists between Petitioner's Tdap vaccine and the onset of her TN. Pet'r's Ex. 18 at 13. Petitioner received the vaccine on May 22, 2018, and her symptoms began on June 5, 2018. *Id.* "Immune responses beginning [three to] 42 days after the vaccine would be consistent with a causal relationship based on molecular mimicry." *Id.*

He also noted that Petitioner's treating neurologist, Dr. Churchill "suggested an autoimmune/inflammatory lesion in the brainstem that caused her TN." Pet'r's Ex. 18 at 10. And that labs excluded any infectious or rheumatologic causes. *Id.* at 5.

2. Respondents Expert, Dr. Jamieson's First Report

Dr. Jamieson opined Petitioner's correct diagnosis is hemicrania continua, not TN. Resp't's Ex. A at 18. She further opined that Petitioner "had the onset of hemicrania continua prior to and unrelated to her Tdap vaccination." *Id.*

a. Diagnosis

Dr. Jamieson discussed several of the diagnoses that were considered by Petitioner's providers with a focus on TN and TACs.²⁸ *See* Resp't's Ex. A at 11–16.

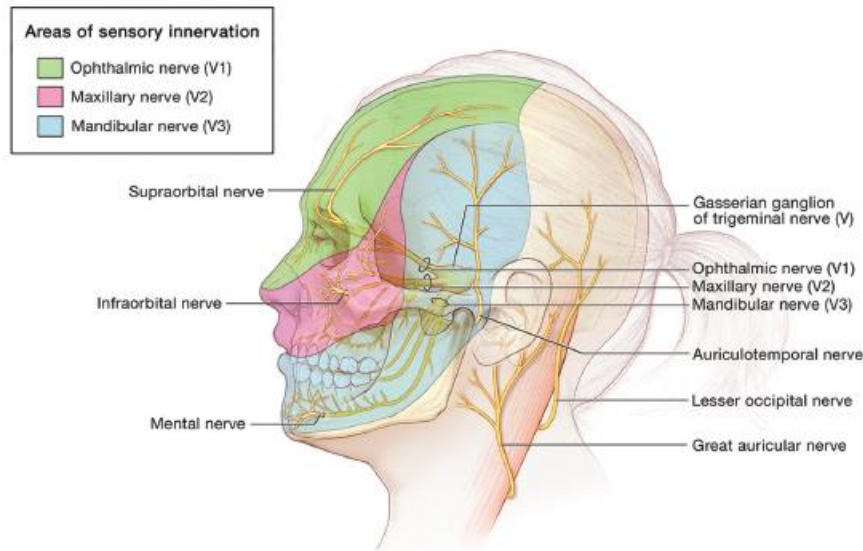
Quoting the International Headache Society ("IHS"),²⁹ Dr. Jamieson wrote that TN is a "disorder characterized by recurrent unilateral brief electric shock-like pains, abrupt in onset and termination, limited to the distribution of one or more divisions of the trigeminal nerve and triggered by innocuous stimuli." Resp't's Ex. A at 12 (quoting Resp't's Ex. A, Tab 2 at 166). Like Dr. Jeret, Dr. Jamieson also listed the ICHD-3 diagnostic criteria for TN. *Id.* at 12–13. The

²⁷ Dr. Jeret defined clinically isolated syndrome as the stage in which an individual has only had one of two attacks required in MS. Pet'r's Ex. 18 at 6.

²⁸ Dr. Jamieson did not believe Petitioner's condition could be classified as tension-type headache or migraine; therefore, I will not include her discussion on those diagnoses. Resp't's Ex. A at 11–12.

²⁹ Headache Classification Committee of the International Headache Society (IHS), *The International Classification of Headache Disorders, 3rd Edition*, 38 CEPHALALGIA 1 (2018).

Robertson³⁰ article provided a figure to show the three divisions of the trigeminal nerve (cranial nerve V).



Resp't's Ex. A, Tab 5 at 10 fig. 7-1. TN involves "the V2 (maxillary) and V3 (mandibular) divisions more than the V1 (ophthalmic) division." *Id.* at 3.

Dr. Jamieson opined many of Petitioner's symptoms are inconsistent with TN. Resp't's Ex. A at 13. First, she noted that Petitioner described pain in her occiput (back of the head) and neck, "which are not areas in the distribution of the trigeminal nerve." *Id.* "She also mentioned symptoms with brushing her hair, which is not stimulation in a trigeminal nerve territory." *Id.* Second, Dr. Jamieson noted Petitioner described a "constant pain, with occasional superimposed exacerbations" that she opined does not fit TN, which is "episodic, lasting for seconds to two minutes, with intervening pain free periods." *Id.* Moreover, she commented that Petitioner did not prominently complain of precipitation of pain by activities stimulating her face, which is typically seen in TN. *Id.* Third, Dr. Jamieson pointed out that Petitioner had autonomic symptoms, such as nasal congestion and tearing in her ipsilateral eye, "which were much more prominent than are seen with [TN]." *Id.* Instead, Dr. Jamieson averred that nasal and eye symptoms as described by Petitioner are more often seen with TACs. *Id.*

Accordingly, Dr. Jamieson determined Petitioner's clinical symptoms were more consistent with a type of TAC than TN. Resp't's Ex. A at 13–16. TACs are characterized by "unilateral headache and prominent cranial parasympathetic autonomic features, which are lateralized and ipsilateral to the headache." *Id.* at 13. Dr. Jamieson believed Petitioner's clinical "symptoms consistent with the diagnosis of a type of TAC were nasal congestion, unilateral eye redness, tearing, and ptosis, which are seen with these cephalalgias." *Id.* at 14. There are different types of TACs that can overlap and evolve. *Id.* at 13–14. The type of TAC that Dr. Jamieson opined

³⁰ Carrie Robertson, *Cranial Neuralgias*, 27 CONTINUUM 665 (2021).

most closely fits Petitioner’s symptoms is called hemicrania continua. *Id.* at 14. The ICHD-3 diagnostic criteria for hemicrania continua are:

- A. Unilateral headache fulfilling criteria B–D
- B. Present for >3 months, with exacerbations of moderate or greater intensity
- C. Either or both of the following:
 - 1. at least one of the following symptoms or signs, ipsilateral to the headache:
 - a) conjunctival injection and/or lacrimation
 - b) nasal congestion and/or rhinorrhoea
 - c) eyelid oedema
 - d) forehead and facial sweating
 - e) miosis and/or ptosis
 - 2. a sense of restlessness or agitation, or aggravation of the pain by movement
- D. Responds absolutely to therapeutic doses of indomethacin
- E. Not better accounted for by another ICHD-3 diagnosis.

Resp’t’s Ex. A, Tab 2 at 45.

For hemicrania continua, “[p]atients generally have a baseline unilateral headache with superimposed episodic headache exacerbations of pain, accompanied by autonomic, as well as migrainous, symptoms.” Resp’t’s Ex. A at 15 (citing Resp’t’s Ex. A, Tab 1;³¹ Resp’t’s Ex. A, Tab 3).³² Restlessness or agitation is seen in 60.2% of patients. *Id.* (citing Resp’t’s Ex. A, Tab 1). Dr. Jamieson noted the pathophysiological mechanism of hemicrania continua is unknown; however, it “appears to have an initial central, as opposed to a peripheral, mechanism of action.” *Id.*

Dr. Jamieson also addressed the importance of indomethacin in the treatment of hemicrania continua. Resp’t’s Ex. A at 14–15. Relying on the Villar-Martinez et al.,³³ she stated that “[h]igh doses of indomethacin, up to 300 mg a day, and prolonged treatment for weeks are needed to evaluate the diagnostic response to this specific treatment for hemicrania continua.” *Id.* at 14. “Headache relief, which may be incomplete even with this specific diagnostic and therapeutic medication, can be delayed for days to weeks after indomethacin treatment and continuous treatment is necessary to prevent recurrence.” *Id.* at 14–15 (citing Resp’t’s Ex. A, Tab 6). Dr. Jamieson opined the “requirement of an absolute response to therapeutic doses of indomethacin in order to make the diagnosis of hemicrania continua is problematic as some patients are unable to tolerate an appropriate therapeutic dose or they may meet the clinical criteria without a complete response to a presumably adequate treatment.” *Id.* at 15. She also noted patients who fulfill the

³¹ Haidar Muhsen Al-Khazali et al., *Prevalence and Clinical Features of Hemicrania Continua in Clinic-Based Studies: A Systematic Review and Meta-Analysis*, 43 CEPHALALGIA 1 (2023).

³² Amit Mehta et al., *Hemicrania Continua: A Clinical Perspective on Diagnosis and Management*, 18 CURRENT NEUROLOGY & NEUROSCIENCE REPS. 95 (2018).

³³ Maria Dolores Villar-Martinez et al., *Indomethacin-Responsive Headaches – A Narrative Review*, 61 HEADACHE 700 (2021).

clinical criteria for hemicrania continua may not respond to indomethacin or have incomplete or temporary relief. *Id.*

In support of her opinions, Dr. Jamieson cited a table from Nahas³⁴ that illustrated the difference between TACs, including hemicrania continua, and other types of headaches, including TN. Resp't's Ex. A at 16 (citing Resp't's Ex. A, Tab 4).

Syndrome	Pain location	Attack duration	Autonomic features	Migrainous features	Exacerbants
Trigeminal autonomic cephalalgias					
Cluster	Unilateral frontal/temporal/periorbital	Minutes to hours	Always	Sometimes	Alcohol, sleep
Paroxysmal hemicrania	Unilateral frontal/temporal/periorbital	Minutes	Always	Sometimes	Neck turning
Short-lasting unilateral neuralgiform headache attack syndromes (SUNHA)	Unilateral V1	Seconds to minutes	Always	Rarely	Cutaneous, thermal, mechanical
Hemicrania continua	Unilateral	Minutes or hours superimposed on baseline pain	Always	Often	Variable
Other primary headache syndromes					
Migraine	Variable, unilateral in 60%	Hours to days	Sometimes	Always	Menses, pregnancy, perimenopause/menopause, stressful life events, strenuous activity, bright/flickering lights
Trigeminal neuralgia	Unilateral (V2-V3 distribution much more often than V1)	Seconds	Rarely	Rarely	Cutaneous, thermal, mechanical
Primary stabbing headache	Variable, but often unilateral frontal/temporal/periorbital	Seconds	Rarely	Rarely	Variable

Resp't's Ex. A, Tab 4 at 2 tbl. 5.1 (emphasis added). In addition to the diagnostic criteria, this further helped form Dr. Jamieson's belief that Petitioner has hemicrania continua, not TN. Resp't's Ex. A at 16. First, as stated earlier, Petitioner had autonomic features "(i.e., nasal congestion, lacrimation, conjunctival injection, ptosis) and migrainous features (i.e., throbbing pain, nausea, photophobia)," which while are rare in TN, "always occur with hemicrania continua." *Id.* at 16.

Second, Dr. Jamieson disagreed with Dr. Jeret's interpretations of how Petitioner described her pain. Resp't's Ex. A at 16–17. She pointed out the varied descriptions of Petitioner's pain in the medical records and opined the one "that most clearly contradicts [a TN diagnosis] and supports the diagnosis of hemicrania continua" was Petitioner's description to Dr. Savani on June 21, 2018. *Id.* at 17. The neurology consultation noted Petitioner had "multiple recurrent, disabling, frontal headaches . . . centered between [her] eyes and [were] associated with nasal congestion and left-sided conjunctival injection." *Id.* (quoting Pet'r's Ex. 8 at 2). NSAIDs provided her with temporary relief but she still felt a "sensation of a mild headache which often spike[d] in intensity

³⁴ Stephanie J. Nahas, *Cluster Headache and Other Trigeminal Autonomic Cephalalgias*, 27 CONTINUUM 633 (2021).

unpredictably.” *Id.* (quoting Pet’r’s Ex. 8 at 2). Dr. Jamieson reiterated that TN pain “lasts for seconds to two minutes, without intervening pain, which [was] not the description of [Petitioner’s] pain in the medical records.” *Id.* Rather, she believed the medical records “document[ed] her continuous pain for longer periods of time with acute exacerbations.” *Id.* According to Dr. Jamieson, “[t]his baseline head pain with superimposed episodic transient exacerbations of head pain is descriptive of hemicrania continua.” *Id.* Additionally, while Dr. Jeret listed Petitioner’s hair brushing triggering her pain as supportive for a TN diagnosis, Dr. Jamieson disagreed. *Id.* While TN is “often triggered by touching within the sensory dermatome of the affected nerve,” Dr. Jamieson noted that as shown in the figure above, the sensory components primarily involved in TN are V2 and V3 which involve the nose and mouth, not the scalp where most hair brushing occurs. Resp’t’s Ex. A, Tab 5 at 3; *see* Resp’t’s Ex. A at 17. The Robertson article wrote that stimulation usually includes chewing/eating, talking, light touch over the face, applying makeup, brushing teeth, or cold wind on the face. Resp’t’s Ex. A, Tab 5 at 3. Accordingly, Dr. Jamieson averred that “the majority of the sensation to the scalp is not subserved by the trigeminal nerve, so hair brushing is not a trigeminal nerve activation trigger.” Resp’t’s Ex. A at 17. She also opined that the potential diagnosis of TN, among other diagnoses, in the medical records and the numerous medications tried to alleviate Petitioner’s symptoms “are not conclusive in establishing [a TN] diagnosis.” *Id.*

Third, Dr. Jamieson opined that restlessness or agitation, which is a characteristic of hemicrania continua, “may have been present on [June 17, 2018] when, during a headache, [Petitioner] eloped from the [ED] with her IV catheter in her arm and on [June 23, 2018] when she was noted to be rocking back and forth.” Resp’t’s Ex. A at 15.

Finally, Dr. Jamieson addressed the diagnostic response to indomethacin. Resp’t’s Ex. A at 14–15.

The diagnosis of an indomethacin responsive headache was considered with [Petitioner], and the suggestion was made to start a course of low dose ([50 mg daily) of indomethacin for a short period of time ([five] days). However, this treatment with a short course of a low dose of indomethacin was not adequately dosed or prolonged to establish a diagnostic response to treatment.

Id. at 15. Dr. Jamieson noted it was unclear from the medical record if Petitioner complied with the prescribed directions. *Id.* Thus the treatment “was inadequate to make the diagnosis of what is clinically hemicrania continua.” *Id.* at 18. Nonetheless, Dr. Jamieson averred that a “lack of response to a few days of a low dose indomethacin does not rule out hemicrania continua” as Petitioner’s diagnosis. *Id.* at 15; *see also id.* at 18 (opining that Petitioner was ineffectively treated with indomethacin so her response to the treatment as an affirmation of the diagnosis cannot be assessed”). Dr. Jamieson and Mehta et al. also described the successful use of SPG in patients with hemicrania continua, a treatment that Petitioner responded well to. *Id.* at 15, 18; Resp’t’s Ex. A, Tab 3 at 5 (reporting on patient whose SPG “treatment failed to provide acute pain relief initially but showed substantial improvement after several weeks of repetitive injections”).

b. Causation

Dr. Jamieson did not believe Petitioner's headaches were related to her Tdap vaccine. Resp't's Ex. A at 18. First, she did not believe Dr. Jeret provided any reliable evidence linking the Tdap vaccine to TN. *Id.* She noted Dr. Jeret's citation to literature describing TN after the COVID-19 vaccine, but that there were no citations of TN following the Tdap vaccine. *Id.* at 17. In response to Dr. Jeret citing case reports of GBS after Tdap vaccination and his invocation of "molecular mimicry to opine that extrapolation to [TN] proves a causative correlation," Dr. Jamieson disagreed. *Id.* She averred, "linking the Tdap vaccine and headaches based on isolated case reports of other nerve disorders occurring after injection of other vaccines, is [not] reliable or supported by any evidence." *Id.* Further, she opined that "[n]o pathophysiological mechanism can explain any causative link between the Tdap vaccine and hemicrania continua," and she could not find any medical literature linking hemicrania continua to Tdap or other vaccines. *Id.* at 16, 18.

Second, she opined that Dr. Jeret's opinion that the Tdap vaccine caused Petitioner's headaches "assumes that [Petitioner's] symptoms started after vaccination" on May 22, 2018. Resp't's Ex. A at 17. However, Dr. Jamieson opined "the medical records clearly document that on [April 27, 2018, Petitioner] complained of 'nasal congestion and headache for the last week and a half.'" *Id.* (quoting Pet'r's Ex. 4 at 215). Thus, her opinion was that Petitioner's "headache and nasal congestion due to hemicrania continua occurred prior to vaccination and was not caused by the Tdap vaccine." *Id.*

3. Dr. Jeret's Second Report

In response to Dr. Jamieson, Dr. Jeret submitted a second expert report mainly addressing diagnosis. Pet'r's Ex. 56. Dr. Jeret pointed out that hemicrania continua was not contemplated by Petitioner's treating providers. *Id.* at 2–3. He again listed the physicians and dates in the record where he believed TN was diagnosed. *Id.* at 1. Dr. Jeret noted that while many treaters thought TN was the most appropriate diagnosis for Petitioner, he conceded that she "did not perfectly fit the TN diagnostic criteria." *Id.* at 2. However, he did not believe she fit the diagnostic criteria for hemicrania continua either. *Id.*

Dr. Jeret highlighted that the ICHD-3 diagnostic criteria for hemicrania continua (1) requires "a sense of restlessness or agitation, or aggravation of the pain by movement," (2) "[r]esponds absolutely to therapeutic doses of indomethacin," and (3) is "[n]ot better accounted for by another ICHD-3 diagnosis." Pet'r's Ex. 56 at 2. He opined, "[r]estless or agitation is not demonstrated in the record. Response to indomethacin is not demonstrated in the record. Multiple practitioners favored another ICHD-3 diagnosis (i.e. TN)." *Id.* He noted that Dr. Jamieson opined that "one practitioner prescribed an inadequate strength of indomethacin for an inadequate length of time without ascertainment of medication compliance as evidence that her diagnosis was implied in the medical record." *Id.* Dr. Jeret disagreed with this line of reasoning, opining instead that "[i]f a physician truly considered that diagnosis, then the appropriate treatment regimen would have been pursued." *Id.* Dr. Jeret explained that when Petitioner saw Dr. Savani on June 21, 2018, he considered TACs and prescribed indomethacin, but at a follow-up, "the diagnosis of TAC was rejected in favor of atypical TN." *Id.* "In other words, a neurologist who personally cared for [Petitioner] considered TAC (like Dr. Jamieson) and then rejected that diagnosis in favor of TN."

Id. Additionally, Dr. Jeret noted that Petitioner was “treated with seizure medications (e.g. Tegretol, Trileptal, gabapentin, and Lyrica) that are often used for nerve pain like TN but never for [hemicrania continua].” *Id.* at 3.

As to causation, Dr. Jeret reiterated that in January 2019, Dr. Churchill “suggested an autoimmune/inflammatory lesion in the brainstem” that caused Petitioner’s TN. Pet’r’s Ex. 56 at 3. Dr. Jeret opined this clinical impression “is consistent with the medical literature on the topic of autoimmunity: Flu vaccine can cause autoimmune issues with the facial nerve, cranial nerve VII (i.e. Bell’s palsy) or all nerves (i.e. GBS), so extrapolating to another cranial nerve is reasonable.” *Id.* He added that TN has been described after the COVID-19 vaccine, that GBS has been described after the Tdap vaccine, and that GBS after flu vaccine is a Table injury. *Id.*; *see, e.g.*, Pet’r’s Exs. 20–21, 23, 30–33, 39, 42). Thus, according to Dr. Jeret “extrapolating to Tdap and cranial nerve V is reasonable.” Pet’r’s Ex. 56 at 3.

Dr. Jaret did not address Dr. Jamieson’s belief that the onset of Petitioner’s condition occurred prior to vaccination.

4. Dr. Jamieson’s Second Report

Dr. Jamieson responded to Dr. Jeret primarily addressing the times Dr. Jeret “believed that ‘trigeminal neuropathy/neuralgia was diagnosed’ in the medical records.” Resp’t’s Ex. C at 1 (quoting Pet’r’s Ex. 56 at 1). She opined that Dr. Jeret “conflate[d] ‘trigeminal neuropathy/neuralgia’ with the distinctly different neurological diagnosis of [TAC], a classification of unilateral headaches that was noted in the medical records.” *Id.* at 1; *see also id.* at 2 (“[H]emicrania continua is a specific type of TAC, a diagnosis that was mentioned numerous times by [Petitioner’s] treating physicians.”); *id.* at 3 (“[T]he diagnosis of an indomethacin responsive TAC, a category that includes hemicrania continua, was considered multiple times by her neurologist.”). Dr. Jamieson did not find any of the below encounters convincing in establishing a diagnosis of TN. *Id.*

Dr. Jamieson opined that neurologist Dr. Savani did not diagnosis Petitioner with TN on June 21, 2018, as indicated by Dr. Jeret. Resp’t’s Ex. C at 2. Rather, she opined that Dr. Savani diagnosed Petitioner with a TAC and prescribed indomethacin, which Dr. Jamieson noted is used to treat hemicrania continua. *Id.* (citing Pet’r’s Ex. 8 at 4). Dr. Savani’s impression that day was that Petitioner was “experiencing episodic new onset headaches which may be associated with one of the [TACs] [] given that she [] noted redness in the eye and nasal congestion. They do not conform to migraine criteria and cluster headaches seem less likely given the relative unpredictable time of onset.” Pet’r’s Ex. 8 at 4.

On June 27, 2018, PA Claude wrote that Petitioner “had no response to indomethacin which makes [TAC] less likely” and questioned whether her symptoms were an atypical form of TN. Pet’r’s Ex. 8 at 11. Dr. Jamieson opined “[t]his misinterpretation of the lack of response to an inadequate trial of indomethacin for hemicrania continua led the PA to consider possible [TN].” Resp’t’s Ex. C at 2. On July 27, 2018, PA Claude notated Petitioner’s symptoms “remain[ed] concerning for potential [TN].” *Id.* (quoting Pet’r’s Ex. 8 at 14). Dr. Jameison opined that the “misdiagnosis of [TN] was carried forward” from here on out. *Id.* at 3.

Dr. Jamieson next opined that Dr. Abedin, an internist, “wrote that [Petitioner] had frequent headaches and [TN], without any indication in his records that he reached a diagnosis of [TN] independently.” Resp’t’s Ex. C at 3 (citing Pet’r’s Ex. 10 at 4).

She wrote that in January 2019, neurologist Dr. Churchill considered that Petitioner might have had “a demyelinating trigeminal nerve injury related to [MS]. However, he wrote that her ‘current symptom set [was] most consistent with chronic migraine, and possible [TN], along with components related to chronic tension headaches.’” Resp’t’s Ex. C at 3 (quoting Pet’r’s Ex. 17 at 23). Dr. Jamieson highlighted that “Dr. Churchill emphasized the headache diagnoses as opposed to [TN].” *Id.*

The ophthalmologist, Dr. Goodglick, noted that Petitioner was “given a diagnosis of [TN].” Resp’t’s Ex. C at 3 (quoting Pet’r’s Ex. 14 at 1). He wrote the etiology of her pain was unclear but “agree[d] [it was] consistent with a diagnosis of [TN].” *Id.* (quoting Pet’r’s Ex. 14 at 1). Dr. Jamieson opined that the “acceptance by a consulting ophthalmologist of the patient’s presenting diagnostic label does not mean that he reached this neurological diagnosis independently.” *Id.*

Finally, Dr. Jamieson opined that on May 4, 2021, “Dr. Savani was unsure if [Petitioner’s] diagnosis was a TAC or [TN].” Resp’t’s Ex. C at 3. While the problem listed was TN, the notes indicated Petitioner’s “symptoms may be associated with [TAC] or [TN].” Pet’r’s Ex. 8 at 44.

Dr. Jamieson referred back to the ICHD-3 diagnostic criteria to support her opinion that Petitioner “fits the diagnostic criteria for hemicrania [continua] more than she fits the diagnostic criteria for [TN].” *Id.* at 4. While Dr. Jeret wrote that a diagnosis of hemicrania continua requires a sense of restlessness or agitation, a response to indomethacin, and is not better accounted for by another ICHD-3 diagnosis, Dr. Jamieson opined his interpretation of this is not accurate. *Id.* (citing Pet’r’s Ex. 56 at 2). Diagnostic criterion C requires either (1) one of the autonomic symptoms or (2) a sense of restlessness, or both. *Id.* (citing Resp’t’s Ex. A, Tab 2 at 45). Thus, a sense of restlessness or agitation is not required for a diagnosis if at least one of the symptoms from C1 is present. *Id.* Nonetheless, Dr. Jamieson opined Petitioner met both C1 and C2 including a sense of restlessness or agitation. *Id.* at 4–5. She also reiterated that Petitioner’s “lack of response to indomethacin was due to inadequate treatment, both in dose and duration.” *Id.* at 5. Dr. Jamieson added that “Dr. Jeret did not acknowledge the inadequate trial of indomethacin that led to the misinterpretation of [Petitioner’s] response to treatment of her TAC.” *Id.* at 1. Dr. Jamieson again concluded that this “insufficient treatment” led to Petitioner being misdiagnosed with TN.” *Id.* at 2.

Dr. Jamieson also disagreed with Dr. Jeret’s interpretation that Dr. Churchill made the “unsupported opinion that the Tdap vaccine caused ‘an autoimmune/inflammatory lesion in the brainstem.’” *Id.* at 5 (quoting Pet’r’s Ex. 56 at 3); *see* Pet’r’s Ex. 17 at 23–24. She added that the “combination of Dr. Jeret’s assumptions that multiple neurological diagnoses can be conflated and that all vaccines should be considered in aggregate does not support an opinion that [Petitioner’s] neurological symptoms were caused by the Tdap vaccine.” Resp’t’s Ex. C at 5.

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.” *La Londe 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 *La Londe*, 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.” *La Londe*, 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.

Petitioner’s treating physicians entertained several diagnoses throughout Petitioner’s clinical course. Neurologist Dr. Savani’s first impression on June 21, 2018, was that Petitioner “ha[d] been experiencing episodic new onset headaches which may be associated with one of the [TACs] [] given that she [] noted redness in the eye and nasal congestion.” Pet’r’s Ex. 8 at 4. On June 27, 2018, PA Claude (from Dr. Savani’s office) noted that Petitioner had no response with indomethacin making TACs “less likely.” *Id.* at 11. PA Claude questioned whether Petitioner’s symptoms were “an atypical form of [TN]” and her impression was “[p]ossible [TN].” *Id.* In July 2018, Petitioner’s diagnosis remained “[p]ossible [TN].” *Id.* at 14. In December 2018, Petitioner received a TN diagnosis along with “frequent headaches” from internist, Dr. Abedin. However, at the next visit with Dr. Abedin in February 2019, he dropped TN from Petitioner’s diagnoses. Neurologist Dr. Churchill’s diagnoses included “[c]ommon migraine without aura with intractable migraine with status migrainosus,” “[c]hronic common migraine without aura,” “CNS demyelinating disorders,” “[t]rigeminal nerve injury,” and neuralgia. Pet’r’s Ex. 17 at 22. In January 2019, he added that her symptoms were most consistent with “possible trigeminal neuropathy,” chronic migraine, and chronic tension headaches. *Id.* at 23. But in February and March 2019, Dr. Churchill opined Petitioner’s symptoms were “most consistent with chronic migraine and tension headaches” *Id.* at 15. In 2021, Dr. Savani and PA Claude maintained that Petitioner’s diagnosis was possible TN or possible TACs. Pet’r’s Ex. 8 at 31, 33, 44.

Thus, with the exception of an internist who subsequently retracted the diagnosis, a TN diagnosis was only provided in terms of a possibility. TACs (of which hemicrania continua is a type of) was also provided in terms of a possibility. The medical records alone do not provide evidence that one diagnosis is more likely than the other.

Both parties filed literature incorporating the ICHD-3 diagnostic criteria and applied them to Petitioner. The first criterion is “[r]ecurrent paroxysms of unilateral facial pain in the distribution(s) of one or more divisions of the trigeminal nerve, with no radiation beyond.” Resp’t’s Ex. A, Tab 2 at 166. Petitioner described the location of her pain on multiple occasions as “left frontal forehead,” “frontal centered between eyes,” and “pain in forehead and behind eyes.” Pet’r’s Ex. 5 at 7; Pet’r’s Ex. 7 at 6; Pet’r’s Ex. 8 at 2. Pursuant to the Robertson and Cruccu et al. articles, the pain described is in the three divisions of the trigeminal nerve consistent with criterion A. *See* Resp’t’s Ex. A, Tab 5 at 10 fig. 7-1, 3; Pet’r’s Ex. 26 at 2 fig. 1. However, inconsistent with criterion A, Petitioner later reported that her “throbbing headache . . . now radiate[d] to the back of her head, neck, and into her facial bones.” Pet’r’s Ex. 7 at 15; *see also* Pet’r’s Ex. 8 at 16 (describing pain on the “left side of her head which radiate[d] into her upper as well as lower face and jaw); Pet’r’s Ex. 16 at ¶ 7 (testifying in her affidavit that her pain radiated to the back of her head).

The second criterion is that the pain has all the following characteristics: (1) “lasting from a fraction of a second to two minutes,” (2) “severe intensity,” and (3) “electric shock-like, shooting, stabbing or sharp in quality.” Resp’t’s Ex. A, Tab 2 at 166. It is undisputed that Petitioner’s pain was severe and that she described it as shock-like and sharp. *See, e.g.*, Pet’r’s Ex. 17 at 24 (describing the pain as “stabbing, shooting”). However, as Dr. Jamieson noted, Petitioner’s duration of pain episodes is inconsistent with the criterion. Petitioner described the nature of her pain to treaters as “persistent” and reported that the “pain would reduce and become intermittent but never completely go away.” Pet’r’s Ex. 7 at 1; Pet’r’s Ex. 6 at 30. Petitioner also reported to Dr. Abedin that her headaches lasted for hours. In her affidavit, Petitioner described “ongoing headache pain . . . for the past week” that was only temporarily relieved by NSAIDs that left a mild headache. Pet’r’s Ex. 16 at ¶¶ 5–6. She also recalled in her affidavit reporting to Dr. Abedin that the pain lasted hours at a time. *Id.* at ¶ 15. She further wrote that her headaches “have lasted over several days.” *Id.* at ¶ 25. These descriptions are at odds with the ICHD-3 criterion requiring episodes of pain lasting seconds to minutes. Although, Cruccu et al. noted that “24 to 49% of patients report continuous or long-lasting pain between paroxysmal attacks,” this is atypical, and neither Dr. Jeret nor Dr. Jamieson contemplated this atypical classification. Pet’r’s Ex. 26 at 4.

The third criterion is that the pain is “[p]recipitated by innocuous stimuli within the affected trigeminal distribution.” Resp’t’s Ex. A, Tab 2 at 166. The medical records indicate Petitioner’s pain flared when she brushed her hair, but Dr. Jamieson opined that hair brushing is usually not in the region of the trigeminal nerve. The top of the scalp, in the V1 division, is an exception to this assertion. Petitioner also reported to Dr. Churchill that she had “a strange dysesthesia when she touche[d] her left cheek,” and that the left side of her face was sensitive to cold air. Pet’r’s Ex. 17 at 21, 24. These areas described are in the V2 and V3 distributions of the trigeminal nerve.

The last criterion is that there is no better ICHD-3 diagnosis. Dr. Jamieson opined hemicrania continua is a better diagnosis. The diagnostic criteria for hemicrania continua largely overlap with TN with two distinctions. First, hemicrania continua requires

C. Either or both of the following:

1. at least one of the following symptoms or signs, ipsilateral to the headache:
 - a) conjunctival injection and/or lacrimation
 - b) nasal congestion and/or rhinorrhoea
 - c) eyelid oedema
 - d) forehead and facial sweating
 - e) miosis and/or ptosis
2. a sense of restlessness or agitation, or aggravation of the pain by movement

Resp’t’s Ex. A, Tab 2 at 45. Dr. Jamieson believed Petitioner satisfied both of these components. Medical records indicate Petitioner had autonomic symptoms, ipsilateral to headache, specifically nasal congestion and left-sided conjunctival injection. Pet’r’s Ex. 8 at 2. Further, the Nahas article, which distinguished TN and hemicrania continua, noted that autonomic features always occur in hemicrania continua but rarely occur in TN. Resp’t’s Ex. A, Tab 4 at 2 tbl. 5.1. Dr. Jamieson also noted two instances of restlessness when Petitioner eloped from the hospital on June 17, 2018, with the IV catheter still in her arm, and when she was observed rocking back and forth on June 23, 2018. *See* Resp’t’s Ex. A at 15. Petitioner further exhibited signs of agitation when she threatened

to sue the providers on June 26, 2018, and appeared “upset” that the doctor had not come to see her within nine minutes. Pet’r’s Ex. 7 at 21–22.

Next, hemicrania continua also requires an “absolute[]” response to “therapeutic doses of indomethacin.” Resp’t’s Ex. A, Tab 2 at 45 (criterion D). On June 21, 2018, Dr. Savani prescribed Petitioner a five-day course of indomethacin, 50 mg, taken three times per day. Pet’r’s Ex. 8 at 4. However, the medical records are unclear as to when Petitioner started taking indomethacin. On June 27, 2018, Petitioner stated she tried indomethacin but had no relief. Pet’r’s Ex. 8 at 8. She did not state how long she took it for. Hereinafter, the medical records indicate that Petitioner did not respond to indomethacin, making TACs less likely. *See id.* at 11, 19. Dr. Savani later noted in 2021 that Petitioner had tried indomethacin, among other medications, “without sustained benefit.” *Id.* at 34. Despite this note, Dr. Jamieson opined this treatment “was inadequate to make the diagnosis of what is clinically hemicrania continua.” Resp’t’s Ex. A at 18. She averred that a “lack of response to a few days of a low dose indomethacin does not rule out hemicrania continua” as Petitioner’s diagnosis. *Id.* at 15, 18. According to Villar-Martinez et al., treatment of indomethacin “usually starts with a minimum does of 25 mg three times per day and, if there is no response, should be increased to a daily dose of at least 150-275 mg to evaluate its efficacy properly.” Resp’t’s Ex. A Tab 6, at 2. The article did not definitively specify how many days a therapeutic dose of indomethacin should be taken for efficacy. *See id.* at 2, 6 tbl. 2. But the authors did discuss retrospective reviews in which patients used indomethacin for weeks at a time and noted the “response to indomethacin may be delayed up to [four] weeks for some patients and an incomplete relief of the symptoms is frequent.” *Id.* at 7. Petitioner’s limited response to a lower end dosage and limited duration of treatment do not contradict the findings in Villar-Martinez et al. However, it appears the requirement of an absolute response to indomethacin as a criterion for hemicrania continua cannot be accurately applied to Petitioner’s case.

After consideration of the medical record, it is clear that several of Petitioner’s treaters thoughtfully considered TN as a differential diagnosis from July 2018 through her evaluation with Dr. Savani on May 4, 2021. Even after several years of treatment, Dr. Savani was unable definitively say whether Petitioner suffers from TACs or TN. Furthermore, the experts highlighted how Petitioner’s condition has consistencies and inconsistencies with both the TN and hemicrania continua diagnostic criteria and criticized each other’s arguments for not completely accounting for Petitioner’s exact symptom presentation. The Federal Circuit has made clear that “identifying [the Petitioner’s] injury is a prerequisite” to the *Althen* analysis. *Broekelschen*, 618 F.3d at 1346. But it is not necessary to diagnose an exact condition. *Astle v. Sec’y of Health & Hum. Servs.*, No. 14-369V, 2018 WL 2682974, at *19 (Fed. Cl. Spec. Mstr. May 15, 2018). In *Lombardi*, the Federal Circuit explained that “[t]he function of a special master is not to diagnose vaccine-related injuries, but instead to determine based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [P]etitioner’s injury.” *Lombardi v. Sec’y of Health & Hum. Servs.*, 656 F.3d 1343, 1351 (Fed. Cir. 2011) (internal quotation marks omitted) (quoting *Andreu*, 569 F.3d at 1382); *see also Broekelschen*, 618 F.3d at 1346 (citing *Kelley v. Sec’y of Health & Hum. Servs.*, 68 Fed. Cl. 84, 100-01 (2005) for the proposition that “the [P]etitioner [is] not required to categorize his injury where the two possible diagnoses [are] ‘variants of the same disorder’”). Furthermore, neither the Vaccine Act nor *Althen* burdens Petitioner with establishing a specific diagnosis. *See Kelley*, 68 Fed. Cl. at 100 (“The Vaccine Act does not require [P]etitioners coming under the non-Table injury

provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury—regardless of the ultimate diagnosis.”). Indeed, in some cases, it may be impossible to definitively identify the exact condition that Petitioner is suffering from. It is only necessary to identify the alleged injury such that the posited causation theory reasonably explains how the alleged vaccination leads to the condition described. I find that Petitioner has provided evidence of the differential diagnoses TN and TAC. However, Petitioner did not propose a causation theory for vaccine-caused hemicrania continua (TAC), and she did not provide preponderant evidence of a scientific or medical theory that answers in the affirmative the question: can the Tdap vaccine cause TN. Therefore, as explained below, even interpreting the evidence in the light most favorable to Petitioner for the purposes of diagnosis, Petitioner is unable to meet her burden pursuant to *Althen*.

B. *Althen* Prongs

1. *Althen* Prong One – Medical Theory

Dr. Jeret opined that the Tdap vaccine can cause TN by molecular mimicry, an immune-mediated inflammatory response, or both. He based this opinion on medical literature about post-vaccination GBS and Bell’s palsy, as well as two case reports of TN after COVID-19 vaccines. I find Petitioner failed to provide preponderant evidence of a sound and reliable medical theory explaining how the Tdap vaccine can cause TN.

Dr. Jeret described molecular mimicry primarily in the context of post-vaccination GBS and Bell’s palsy. An expert may “extrapolate from existing data” where the reasons for extrapolation are transparent and persuasive. *K.O. v. Sec’y of Health & Hum. Servs.*, No. 13-472V, 2016 WL 7634491 (Fed. Cl. July 7, 2016) (quoting *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009)). Here, however, Dr. Jeret only stated that the “[f]lu vaccine can cause autoimmune issues with the facial nerve, cranial nerve VII (i.e. Bell’s palsy) or all nerves (i.e. GBS), so extrapolating to another cranial nerve is reasonable.” Pet’r’s Ex. 56 at 3. He added that TN has been described after the COVID-19 vaccine, that GBS has been described after the Tdap vaccine, and that GBS after flu vaccine is a Table injury, “[s]o extrapolating to Tdap and cranial nerve V is reasonable.” *Id.* Beyond simply stating this, he did not provide any support for *how* extrapolating from one vaccine to another or one condition to another is reasonable.

Program petitioners sometimes present homologies between vaccine components and human tissues to establish cross-reactivity that they then argue is pathogenic. Dr. Jeret did not provide a specific peptide homology between the Tdap vaccine and TN, but such is not required to meet the preponderant standard for a theory of molecular mimicry. There must, however, be some form of preponderant evidence that a cross-reaction between the vaccine and body part at issue can occur. Indeed, “Petitioners cannot simply invoke the concept of molecular mimicry and call it a day. . . . Rather, they need to offer *reliable* and persuasive medical or scientific evidence of some kind . . . that suggests the vaccine components could interact with self-structures as maintained.” *Johnson v. Sec’y of Health & Hum. Servs.*, No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018). Here, Dr. Jeret could not even identify the inflammatory target for TN. Pet’r’s Ex. 18 at 12 (“It is impossible to ascertain whether the inflammatory target is the brainstem or nucleus of the trigeminal nerve . . . or if the nerve itself is the target.”). Yet he

continued, “the etiologic role of the vaccine in initiating this cascade is undeniable. This result can target . . . the trigeminal nerve to cause TN.” *Id.* Dr. Jeret did not explain what “initiating this cascade” means or how it can result in targeting nerves. Again comparing TN to other conditions like Bell’s palsy and GBS, he wrote, “[a]lthough the target(s) may change, the pathogenesis remains the same.” *Id.* He did not explain this further.

To the extent that molecular mimicry is offered as a theory, it must be supported by a sound and reliable medical or scientific explanation.” *Knudsen*, 35 F.3d at 548. There must also be some degree of selectivity. *See W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1360 (2013) (finding that a petitioner cannot prevail by simply invoking a biological term, or by showing that the mechanism is a valid theory to explain how *other* triggers may have induced *other* diseases and determining that a petitioner must produce additional evidence that the mechanism can cause that vaccine to cause a specific disease); *Caves v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 135 (2011), *aff’d*, 463 F. App’x. 932 (2012); *McKown v. Sec’y of Health & Hum. Servs.*, No. 15-1451, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019). Petitioner does not have to provide a specific mechanism, but it must be detailed enough to apply to the administered vaccine and alleged injury in this case. Otherwise, any vaccination, by nature of its purpose to illicit an immune response, could be asserted as the cause of any autoimmune disease that later developed in an individual, and *Althen* prong one “would be rendered meaningless.” *See Caves*, 100 Fed. Cl. at 135; *see also McKown*, 2019 WL 4072113, at *50 (“[M]erely chanting the words ‘molecular mimicry’ in a Vaccine Act case does not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or the vaccine in question.”). Petitioner is not limited to any one type of evidence in support of a molecular mimicry mechanism. A non-exhaustive list of potential evidence includes homology evidence, epidemiology studies, pathogenic antibodies, relevant animal models, or disease etiology specific to the vaccine’s live virus counterpart. *See Broekelschen*, 618 F.3d 1339; *Dougherty v. Sec’y of Health & Hum. Servs.*, 141 Fed. Cl. 223 (2018); *Brayboy v. Sec’y of Health & Hum. Servs.*, No. 15-183, 2021 WL 4453146, (Fed. Cl. Spec. Mstr. August 30, 2021). I reiterate, Petitioner is under no obligation to provide any one or more of those types of evidence. This list serves only to illustrate that even in cases of rare and understudied phenomena, petitioners must provide preponderant evidence of causation in support of any identified mechanism. Here, however, Petitioner did not provide any such evidence.

As to Dr. Jeret’s immune-mediated inflammatory response theory, he simply provided two case reports of TN after the COVID-19 vaccine in which the authors hypothesized that could be the mechanism involved. Case reports alone, even with the same specific vaccination and injury, generally do not represent strong evidence of causation. *See K.O.*, 2016 WL 7634491; *see also Whitecotton v. Sec’y of Health & Hum. Servs.*, 81 F.3d 1099, 1108 (Fed. Cir. 1996). In this case, Petitioner’s expert relies on a vaccine that significantly differs from Tdap in development and components. He does not offer a comparison for analogy, nor does he address any differences. Without further analysis, reliance on COVID-19 vaccination studies is insufficient evidence to meet the preponderant standard.

After consideration of the evidence, I find that Petitioner has not presented preponderant evidence of a sound and reliable medical theory to explain how the Tdap vaccine can cause TN. Therefore, Petitioner does not meet her burden pursuant to *Althen* prong one.

2. *Althen* Prong Three – Temporal Association

Successful arguments pursuant to *Althen* prongs two and three are heavily dependent on a reliable causation theory. Petitioner's inability to meet her burden demonstrating how the Tdap vaccine can cause TN effectively precludes her from being able to show that her symptoms were actually caused by the vaccine and temporally appropriate according to said theory. Here, since Respondent's expert disputes onset occurred after vaccination, I will address *Althen* prong three before turning to *Althen* prong two.

Dr. Jeret opined there was an appropriate temporal association between Petitioner's vaccine and her condition, specifically that the former preceded the latter by 14 days. Conversely, Dr. Jamieson disputed that the vaccine preceded Petitioner's headache condition. Dr. Jamieson argued that Petitioner's complaints of "nasal congestion and headache for the last week and a half" on April 27, 2018, established that the onset of Petitioner's condition "occurred prior to vaccination and was not caused by the [May 22, 2018] Tdap vaccine". Resp't's Ex. A at 17 (quoting Pet'r's Ex. 4 at 215). However, there are no other surrounding records to support that Petitioner's headache from April was as severe as the headaches consistently complained of post vaccination. Thus, they do not appear to be the same. Accordingly, I find the onset of Petitioner's headache condition to be after vaccination.

Dr. Jeret opined a 14-day onset is consistent with a theory based on molecular mimicry. Based on the medical literature filed, Dr. Jeret's assertion that this timeframe is consistent with a theory of molecular mimicry is correct. Therefore, I find that Petitioner has satisfied *Althen* prong three. However, and as discussed more below, since Petitioner not provided preponderant evidence that molecular mimicry can cause TN, Petitioner ultimately fails to show preponderant evidence that her vaccine caused her condition.

3. *Althen* Prong Two – Actual Causation

A temporal association alone is not preponderant evidence of causation. Notwithstanding a temporally appropriate timeframe between vaccination and onset, Petitioner's inability to meet her burden demonstrating how the Tdap vaccine can cause TN effectively precludes her from being able to show that her symptoms were actually caused by the vaccine according to said theory. Even assuming there is preponderant evidence that Petitioner suffered from TN, she did not offer a sound and reliable theory of vaccine causation. Therefore, she cannot demonstrate that her alleged TN arose in a logical sequence of cause and effect or medically acceptable timeframe consistent with vaccine causation.

While Dr. Jeret heavily discussed diagnosis, as reflected above, he did not analyze Petitioner's clinical presentation in the context of his theory. This alone hinders any meaningful discussion on prong two. Moreover, Dr. Jeret asserted that the specifics of the immune pathogenesis of TN are unknown. Petitioner's burden to establish actual causation cannot be met by simply declaring that if a vaccine preceded illness, then the illness is vaccine caused. This acknowledgment that there is no mechanism or subsequent application to Petitioner's presentation best illustrates the lack of preponderant evidence here to satisfy *Althen* prong two.

Further, opinions of treating providers can be helpful in analyzing a logical sequence of cause and effect. However, the first, and only, time a potential cause of Petitioner's condition was addressed in the medical records by a treater was on January 10, 2019, almost eight months post vaccination. At that time, Dr. Churchill noted the "possibility" that Petitioner's condition was "a reactive autoimmune trigeminal neuropathy resulting from the vaccine." Pet'r's Ex. 17 at 23.

Accordingly, there is not preponderant evidence of a logical sequence of cause and effect between Petitioner's vaccination and her headache condition. Therefore, I find that Petitioner has failed to satisfy *Althen* prong two.

VI. Conclusion

After a careful review of the record, Petitioner has failed to provide preponderant evidence that her May 22, 2018 Tdap vaccine caused her TN. Accordingly, Petitioner's claim is **DENIED**. Absent a timely motion for review, the Clerk is directed to enter judgment dismissing this case for insufficient proof in accordance with Vaccine Rule 11(a).³⁵

IT IS SO ORDERED.

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

³⁵ 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.