

For the reasons discussed in this decision, I find there is not preponderant evidence that Petitioner has Autoimmune Inner Ear Disease (AIED), or that her flu vaccine caused her condition.

I. Procedural History

On June 1, 2017, this case was assigned to Special Master Sanders, who issued an initial order. ECF Nos. 4, 5. Petitioner filed medical records on June 1 and 8, 2017 and a statement of completion on June 8, 2017. Exs. 1-25, 52-53. On June 2, 2017, Petitioner filed an expert report from Dr. Eric Gershwin and cited medical literature. Exs. 26-45. Petitioner filed additional medical records on September 20, 2017 and November 13, 2017. Exs. 54-55; 56-65.

On November 29, 2017, Respondent filed a Rule 4(c) Report recommending that compensation be denied. Resp't's Rep. at 1.

Petitioner filed additional medical records January 16, 2018 and March 15, 2018. Exs. 66-74.

On March 15, 2018, Respondent filed an expert report written by Dr. Michael Phillips and cited medical literature. Exs. A, A1-12. On April 3, 2018, Respondent filed additional medical literature. Exs. A13-24.

On April 30, 2018, Petitioner filed a supplemental expert report from Dr. Gershwin. Ex. 75.

On May 16, 2018, Petitioner filed a motion for an order to 1) strike portions of Dr. Phillips' expert report or 2) compel production of documents in support of Dr. Phillips' expert opinion. ECF No. 41. On May 30, 2018, Respondent filed a response to Petitioner's motion. ECF No. 45. On June 1, 2018, Petitioner filed a reply. ECF No. 47. Special Master Sanders denied Petitioner's motion on June 21, 2018. ECF No. 48.

Petitioner filed medical records on 5/22/2018, 5/24/2018, 8/22/2018, 1/16/2018, 10/9/2019, 10/10/2019, 2/27/2020. Exs. 84-86, 88-91, 92-94, 116-119.

On October 15, 2018, Respondent filed a supplemental report from Dr. Phillips. Ex. C. Petitioner filed a supplemental expert report from Dr. Gershwin on December 12, 2018. Ex. 95.

On January 29, 2019, Petitioner filed a motion to amend the caption to reflect Petitioner's name change. ECF No. 56. Special Master Sanders granted that motion on January 30, 2019. ECF No. 57.

On December 3, 2019, an entitlement hearing was set for November 18-20, 2020.

On January 31, 2020, Respondent filed a white paper by Dr. Lindsay Whitton. Ex. D. On February 7, 2020, Respondent filed an expert report from Dr. Yu-Lan Mary Ying. Ex. F.

On May 26, 2020, this case was re-assigned to my docket. ECF No. 72. On June 1, 2020, I held a status conference with the parties to discuss relocation of the entitlement hearing or proceeding virtually. *See* Scheduling Order dated 6/1/2020, ECF No. 73. Respondent was to file a status report by July 1, 2020 indicating his position regarding ADR.

On June 30, 2020, Respondent filed a status report stating he was not amenable to mediation and would prefer to proceed remotely with a virtual hearing. Resp't's Status Rep. at 1, ECF No. 74.

On August 12, 2020, Petitioner filed an unopposed request to schedule a ruling on the record after briefing in lieu of an entitlement hearing. ECF No. 76. On August 25, 2020, I cancelled the scheduled entitlement hearing and issued an order for the parties to file a joint status report with their proposed briefing schedule. *See* non-PDF Scheduling Order dated 8/25/2020. On September 2, 2020, the parties filed a joint status report with their proposed briefing schedule. ECF No. 78.

On September 14, 2020, Petitioner filed a motion for a ruling on the record. ECF No. 81. On October 16, 2020, Respondent filed a response to Petitioner's motion. ECF No. 83. On November 16, 2020, Petitioner filed a reply brief. ECF No. 84.

On June 15, 2021, Petitioner filed additional medical records. Ex. 145.

This matter is now ripe for a decision.

II. Medical History

Ms. Henry's prior medical history includes allergies, rosacea, osteoarthritis, degenerative joint disease, breast cancer in 2011, an ankle fracture, anxiety, GERD, sciatica, and dry eye syndrome. She was 49 years old at the time of vaccination.

On November 20, 2014, Petitioner received the seasonal flu vaccine in her right deltoid after having her annual physical with her primary care physician ("PCP"), Dr. Neil Farber. Ex. 9 at 1.

On November 21, 2014, Petitioner sent an email to her PCP noting that her right ear had been ringing since 4am that morning. Ex. 5 at 1. A nurse answered her email stating that ringing in the ears could be a side effect of the vaccine and that it would last one to two days; the nurse advised Petitioner to call if the symptoms worsened. *Id.*

On December 11, 2014, Petitioner visited Carlsbad Optometry and saw Lucia Millet, O.D., for a "really red right eye." Ex. 1 at 4-5. Ms. Henry stated she was not experiencing headaches, double vision, blurry or uncomfortable vision. *Id.* at 4. Dr. Millet diagnosed Petitioner with subconjunctival hemorrhage and instructed her to return if it worsened after a week but was warned it may look worse before it gets better. *Id.* at 5.

On December 30, 2014, Ms. Henry returned Carlsbad Optometry for eye redness. Ex. 1 at 6-7. Petitioner reported her right eye had been red since 12/11 and she had been dealing with a cold/cough. *Id.* at 6. Petitioner was recommended to treat with artificial tears and was told that her coughing/sneezing may be re-aggravating the original hemorrhage, causing slower healing. *Id.* at 7.

On January 2, 2015, Petitioner returned to Dr. Farber for five days of cough and congestion from an upper respiratory infection. Ex. 9 at 4-6. Petitioner also complained of candida intertrigo under her breasts that she used a nystatin cream to treat. *Id.* at 4. Petitioner also denied hearing loss, ear pain, or aural discharge but admitted to intermittent tinnitus. *Id.* at 5. An ear exam was normal. *Id.*

On January 20, 2015, Petitioner visited the Tri-City Medical Center Emergency Department after a car accident. Ex. 20 at 15-16. Ms. Henry's chief complaint was left sided neck pain, lumbar back pain and general body aches, cough, and chest congestion. *Id.* at 15. Petitioner also reported she had a cough for the past three weeks as well as nasal congestion. *Id.* There was no mention of tinnitus or any auditory issues. *See id.* at 15-16. A chest x-ray performed that same day had no acute findings. *Id.* at 17.

On January 23, 2015, Petitioner returned to the Tri-City Medical Center Emergency Department for abdominal pain. Ex. 20 at 9-10. Petitioner reported that she was rear-ended a few days ago and began experiencing rib pain the day after. *Id.* at 10. Petitioner had a chest x-ray which revealed no rib fracture but hiatal hernia. *Id.* at 12. Petitioner was discharged the same day. *Id.* at 12.

On January 30, 2015, Petitioner returned to Dr. Farber after a motor vehicle accident with pain under her right breast, radiating to her left, which was determined to be costochondritis³ from her seatbelt. Ex. 9 at 6-9. Petitioner reported she had a persistent cough but no other URI symptoms. *Id.* at 6. Petitioner denied a history of hearing loss, ear pain, tinnitus, or aural discharge during this visit. *Id.* at 7. Petitioner was recommended to continue NSAIDs and use of a warm compress for her costochondritis, Flonase for her allergies, and Advair for her post-viral cough syndrome. *Id.* at 8.

On March 12, 2015, Petitioner visited Dr. Richard Schwab, her oncologist, to follow up on her breast cancer. Ex. 10 at 61-64. Petitioner reported she had "a bad cold over the Winter and has been having some issue with ear pain and cough since. Otherwise she is doing well." *Id.* at 61.

On June 18, 2015, Ms. Henry presented to the UC San Diego Otolaryngology Head & Neck Surgery Clinic for a consultation. Ex. 4 at 1-3. Petitioner stated she had several months of tinnitus in her "right>left ear" and that it had started after receiving her flu shot but eventually resolved. *Id.* at 1. Petitioner described the sounds as a "water rushing sound" in her right ear and a

³ Costochondritis is the "inflammation of the cartilaginous junction between a rib or ribs and the sternum." *Costochondritis*, Dorland's Online Med. Dictionary, <https://www.dorlandonline.com/dorland/definition?id=11357> (last accessed April 15, 2022).

“hissing sound” occasionally in her left. She stated that it comes and goes and ranges in loudness. *Id.* Petitioner also reported an occasional bubbling/cracking sound in the right ear. *Id.* Petitioner reported she doesn’t notice it much at work but it bothers her when she is sleeping. *Id.* Petitioner had no otalgia, otorrhea, or vertigo, and flew with no issues on ascent/descent. *Id.* The assessment was that Petitioner had left Eustachian tube dysfunction and bilateral tinnitus. *Id.* at 2.

On June 23, 2015, Petitioner visited Pacific ENT Medical Group and saw Dr. Moses Salgado complaining of “plugged ears,” but specifically “within her left ear since last Thursday.” Ex. 11 at 1-2. Petitioner also reported having a hissing noise within her ear, that she could only hear muffled low sounds, and that she was experiencing nasal congestion and nasal drip. *Id.* at 1. Petitioner denied any drainage or hearing loss. *Id.* Dr. Salgado’s assessment was tinnitus and headache, specifically left sided constant tinnitus. *Id.* at 2. Petitioner’s ear examination was normal except for mild ETD (Eustachian tube dysfunction) and negative pressure on tympanometry. *Id.* Petitioner was instructed to start Nasonex because she had no improvement with Flonase. *Id.*

On June 24, 2015, Petitioner saw Dr. Karen Cadman⁴ to establish new care. Ex. 7 at 1-14. Dr. Cadman noted that Ms. Henry’s current problem list included allergic rhinitis, breast cancer, costochondritis, GERD, gynecological disorders, intertrigo, obesity, palpitations, rosacea, and temporomandibular joint pain dysfunction syndrome (left). *Id.* at 1. Dr. Cadman noted that Petitioner had seen two ENT specialists in the last few weeks and that her symptoms went away during a trip to New Orleans, but returned when she came back. *Id.* Petitioner also stated she caught a cold while in New Orleans. *Id.* Petitioner stated she had two beers in the last week which made the hissing sound in her left ear worse and was avoiding NSAIDs because they “upset[] tinnitus”. *Id.* Petitioner was still experiencing the rash under her breasts and had a cough. *Id.*

On July 8, 2015, Petitioner returned to Carlsbad Optometry reporting eye redness once again. Ex. 1 at 10-11. Petitioner reported she woke up feeling like something was in her right eye, which was also blurry, and described that she rubbed her eye. *Id.* at 10. She then noticed her right eye was very red and in the same place as last time (Dec. 2014) but the blurriness disappeared within one hour. *Id.* Petitioner’s optometrist noted that Petitioner “has an array of chronic symptoms lately, seems to be since she had a flu shot last November: ears feel plugged, tinnitus, headaches, light sensitivity, rash post flu shot, etc.” *Id.* Petitioner also noted that her subconjunctival hemorrhage took three months to clear up. *Id.* The optometrist believed the “likely cause of heme is dryness/foreign body that she then rubbed and caused heme,” and the likelihood that it was related to her other systemic issues was low but that it would be monitored. *Id.* at 11.

On July 14, 2015, Petitioner returned to Dr. Salgado for ear congestion and ringing, also reporting that Nasonex was not helping her symptoms. Ex. 11 at 3-4. Dr. Salgado noted that Petitioner had persistent tinnitus, worse in her left ear, and recommended imaging since her examination was normal. *Id.* at 4.

On July 30, 2015, Ms. Henry visited Dr. Marc Lebovits at North County Ear, Nose & Throat Head and Neck Surgery Inc. Ex. 19 at 1-3. Under the HPI, Dr. Lebovits noted the November

⁴ Dr. Cadman is an internal medicine doctor: <https://providers.ucsd.edu/details/22207/primary-care-internal-medicine> (last accessed April 15, 2022).

2014 flu shot and that Petitioner experienced tinnitus in both ears which was off and on since, along with scleral bleeding. In May 2015, Petitioner noted water noise intermittently in her left ear and in June 2015 hissing in her right ear. *Id.* at 1. Petitioner reported that her symptoms disappeared when she flew to New Orleans, but returned when she flew back. *Id.* Petitioner also had an upper respiratory infection in December 2014 and June 2015; head trauma a few months ago when she tripped, and whiplash/neck aches from January 2015. *Id.* Dr. Lebovits' impression was that Petitioner had multiple problems that could be associated with the tinnitus, specifically her cervical musculoskeletal problems and associated neck ache, and her bruxism with TMJ dysfunction were the most likely major contributors. *Id.* at 2. Dr. Lebovits also noted "Other than time course, I cannot relate the tinnitus to her flu shot." *Id.* Dr. Lebovits indicated that Petitioner's rhinitis with Eustachian tube dysfunction and mild sensory hearing loss may also be contributing to her tinnitus. *Id.*

On August 4, 2015, Petitioner saw Dr. Robert Olson, a chiropractor, for aching and tightness in the back of her neck, intermittent aching in her upper back, and aching in her left and right temporomandibular joints. Ex. 6 at 18. Petitioner returned to Dr. Olson on 8/10/2015, 8/12/2015, 8/14/2015, 8/17/2015, 8/20/2015, 9/1/2015, 9/8/2015, 9/22/2015, 9/29/2015, 10/1/2015, 10/6/2015, 10/13/2015, 11/10/2015, 12/2/2015, with varying levels of pain. *Id.* at 11-17.

On August 7, 2015, Ms. Henry went to Imaging Healthcare Specialists for a brain MRI for bilateral tinnitus. Ex. 12 at 1-3. The MRI revealed

1. No acoustic schwannoma⁵ or other posterior fossa mass. 2. Trapped fluid or granulation tissue in the right⁶ mastoid air cells. No focal mass. Consider dedicated CT imaging of the petrous temporal bones for further assessment in the appropriate clinical context. 3. No other remarkable acute or chronic intracranial findings.

Id. at 1-2. She returned on September 15, 2015 for a computed radiography (CR) of the sinus, which was revealed to be normal. *Id.* at 4.

On August 18, 2015, Petitioner visited Dr. Salgado to review her audiogram but noted there was no audiogram was available for review. Ex. 11 at 5-6. Dr. Salgado recommended antidepressants for mood changes and tinnitus, a neurologist for her atypical migraine, and an allergist/immunologist for concerns regarding mold. *Id.* at 6.

On August 21, 2015, Ms. Henry visited Dr. Erik Viirre for her auditory issues. Ex. 10 at 69-71. Dr. Viirre noted

⁵ A schwannoma is "a neoplasm originating from Schwann cells (of the myelin sheath) of neurons." *Schwannoma*, Dorland's Online Med. Dictionary, www.dorlandsonline.com/dorland/definition?id=44932 (last accessed April 26, 2022).

⁶ The medical record has "left" written on top of "right" but also appears to be crossed out. An addendum was added to specify that it was the right ear. Ex. 12 at 3.

November, 2014 had flu shot in right and that evening developed tinnitus AD “Hissing”. May, 2015 AD “running water” and then AS “hissing” intermittently. The spontaneously flared up AU tinnitus hissing. Chronic sinus congestion. Jaw clenching/bruxism. Occasional “brain zap” buzzing sounds and motion sensation. Some post-auricular tenderness and neck pain. No dizziness or unsteadiness.

Id. at 69. Petitioner’s audiogram revealed mid frequency hearing loss. Dr. Viirre’s assessment was that Petitioner could have viral labyrinthitis, hearing change with secondary tinnitus, or somatosensory tinnitus. *Id.* Dr. Viirre prescribed Petitioner with valacyclovir and a Medrol Dosepak. *Id.*

On September 15, 2015, Ms. Henry visited the Allergy and Immunology Medical Group for a skin prick test for allergens. Ex. 13 at 1.

On October 21, 2015, Petitioner visited Dr. Vu Nguyen at Carlsbad Vista Dermatology complaining of a bump or “wart” on her right arm. Ex. 8 at 26-27. The bump was diagnosed as an inflamed seborrheic keratosis which was treated by using liquid nitrogen. *Id.* at 26.

On December 9, 2015, Petitioner visited Spinezone for neck pain and tinnitus. Ex. 70 at 7-10. It was noted that Petitioner was rear ended in January 2015 and diagnosed with whiplash; “[b]y May her tinnitus became constant.” *Id.* Petitioner had been in four other motor vehicle accidents, two of which resulted in the cars being totaled. *Id.* Petitioner also reported paresthesias and weakness in her extremities. *Id.* Ms. Henry began a lumbar strengthening program during this visit. *Id.* Ms. Henry returned on 12/14/2015, 1/6/2016, and 1/14/2016 for treatment. *Id.* at 9-13.

On January 26, 2016, Petitioner returned to Dr. Olson for treatment. Ex. 6 at 10. Dr. Olson noted that Petitioner believed her chronic neck pain started after getting a flu shot in November 2014. *Id.* Dr. Olson recommended scheduling two sessions of physical therapy per week for four weeks. *Id.* Petitioner returned for treatment on 2/3/2016, 2/6/2016, 2/16/2016, 3/1/2016, 3/15/2016, 4/15/2016, 6/22/2016 and 7/13/2016. *Id.* at 2-8. Petitioner returned on 1/10/2017 and 1/25/2017 but all that is noted in her records was that “Darlene reported to the office with no complaints.” *Id.* at 1.

On February 9, 2016, Petitioner went to North County Acupuncture for treatment of pain and pressure and tinnitus. Ex. 14 at 1-3. It was noted that Petitioner also got rear-ended in January 2015 and she was experiencing a constant hissing sound. *Id.* at 3. Petitioner returned on 2/11/2016, 2/16/2016, and 2/18/2016, noting that treatment did decrease her pain and symptoms for a few hours but returned and often was worse than before treatment. *See* Ex. 14 at 1-2.

On March 9, 2016, Petitioner returned to Dr. Nguyen at Carlsbad Vista Dermatology for a follow-up. Ex. 8 at 24-25. Petitioner complained about itching all over her body for the past two days, had a rash on her face, and had previously been diagnosed with rosacea. *Id.* at 24. Petitioner also complained of a bump on her right forearm, which was diagnosed as inflamed seborrheic keratosis. *Id.* Petitioner was encouraged to continue use of Metronidazole cream for her rosacea and was treated with liquid nitrogen for her inflamed seborrheic keratosis. *Id.*

On June 7, 2016, Petitioner visited Dr. Joshua Alexander at Scripps Neurology Department for tinnitus, TMJ, cervicalgia, segmental and somatic dysfunction of head and cervical region. Ex. 21 at 12-15.

On June 14, 2016, Petitioner returned to Dr. Alexander at Scripps Neurology with a new complaint of having difficulty swallowing, and to follow up on her tinnitus. Ex. 21 at 9-11. Dr. Alexander noted “Following an aggressive massage and physical therapy her tinnitus is improving. This supports the diagnosis of somatosensory tinnitus.” *Id.*

On June 15, 2016, Petitioner visited the ENT Associates Medical Group for an audiology report. Ex. 17 at 11-13. Petitioner was noted to have tinnitus matching 3kHz. *Id.* at 11.

On July 20, 2016, Petitioner visited Dr. Joshua Alexander at the Scripps Neurology Department for somatosensory tinnitus. Ex. 21 at 1-4. Dr. Alexander’s summary of the appointment stated:

51-year old female with somatosensory tinnitus responding well to mesial skeletal interventions.... Osteopathic diagnosis: somatic dysfunction was identified on today’s examination which will be treated with OMT. Based on careful review of the history, physical examination and relevant imaging, I believe the [patient’s] complaints may be attributed in part to underlying Osteopathic somatic dysfunction as described above. Physical and structure objective findings indicated changes in somatic complains and a medical decision was made during visit that Osteopathic Manipulative Treatment (OMT) would be necessary due to such changes.

Id. at 1. Dr. Alexander noted that Petitioner had other active problems, to include cervicalgia, post-nasal drip, a scalp injury, and segmental and somatic dysfunction of the cervical region. *Id.*

On August 10, 2016, Petitioner visited Dr. Nguyen for a bump on her left dorsal foot and bug bites on her medial shin. Ex. 8 at 22-23. Petitioner had been experiencing bites for the past month that had resolved. *Id.* at 22. Petitioner was diagnosed with molluscum contagiosum⁷ (“MC”) and bug bites. *Id.* Petitioner was treated with liquid nitrogen to remove the MC. *Id.* Petitioner returned on 8/11/2016, 8/19/2016, and 9/1/2016 for follow-ups related to MC. *Id.* at 15-21.

On September 29, 2016, Petitioner returned to Dr. Nguyen at Carlsbad Vista Dermatology for a MC follow-up. Ex. 8 at 13-14. Petitioner also mentioned that she had a “bug bite” on her left superior forehead. *Id.* at 13. Petitioner reported that she had seen her PCP, Dr. Cadman three days prior, who ordered a bacterial culture, which was negative for growth. *Id.* Dr. Nguyen’s assessment was “zoster without complications” and “molluscum contagiosum”; Dr. Nguyen prescribed Famcyclovir for treatment. *Id.* at 13-14. Petitioner returned on October 2, 2016, for a follow-up

⁷ Molluscum contagiosum is defined as “a common, benign, usually self-limited viral infection of the skin and occasionally the conjunctivae by a poxvirus, transmitted by autoinoculation, close contact, or fomites.” *Molluscum contagiosum*, Dorland’s Online Med. Dictionary, <https://www.dorlandsonline.com/dorland/definition?id=89547> (last accessed April 15, 2022).

and was prescribed Clobetasol for zoster and advised to complete her course of Famcyclovir. *Id.* at 11-12.

On October 4, 2016, Petitioner presented to Dr. Janie Bodman at Morris Eye Group with shingles in her eyes. Ex. 18 at 1-6. Petitioner had a dermatology appointment where she was diagnosed with shingles; she was prescribed Famcyclovir which helped her symptoms but she was still experiencing irritation in her eyes. *Id.* at 1. Dr. Bodman's assessment was dry eye syndrome; he recommended liquid tears. *Id.* at 5.

On October 11, 2016, Petitioner visited Dr. Nguyen for bumps and tenderness on her left cheek, with a duration of two weeks, a spot on her left hand, with a duration of a few days, and spot on her right upper back. Ex. 8 at 9-10. Dr. Nguyen's assessment was rosacea and inflamed seborrheic keratosis. *Id.* at 9. Dr. Nguyen prescribed SulfaCleanse and Metronidazole for the rosacea and recommended continued use of Cordran lotion. *Id.* at 8-9. Petitioner returned on October 18, 2016 for red bumps on her forehead which was determined to be allergic contact dermatitis. *Id.* at 7-8. Petitioner reported that she stopped using SulfaCleanse due to a burning sensation. *Id.* at 7.

On October 20, 2016, Petitioner received a chest x-ray at San Diego Imaging. Ex. 16 at 1. The chest x-ray revealed a hiatal hernia but was otherwise normal. *Id.*

On November 15, 2016, Petitioner returned to Dr. Nguyen with red bumps on her forehead, which was determined to be acne vulgaris. Ex. 8 at 5-6. Petitioner was also treated for seborrheic keratosis on her left thumb and was recommended a dry skin/bathing regimen for xerosis⁸ cutis. *Id.* at 6. Petitioner returned on November 23, 2016, where Dr. Nguyen reiterated her belief that it was likely acne and not folliculitis. *Id.* at 3-4. Petitioner was given additional instructions regarding at home treatment and use of non-comedogenic makeup. *Id.* at 3.

On November 29, 2016, Petitioner presented to Dr. Bruce Reisman at ENT Associates Medical Group for her ongoing symptoms. Ex. 17 at 1-3. Petitioner reported that she had "a long history of fullness in the ears and tinnitus that took a turn for the worse in June 2015". *Id.* at 1. The tinnitus was "felt to be secondary to TMJ"; Petitioner received TMJ therapy including splint therapy. *Id.* She also reported that she flew on October 18 and had difficulty equalizing, which caused a significant increase in her symptoms; Petitioner stated she had not felt normal since. *Id.* Petitioner also reported having shingles in September that was diagnosed and treated with Farnvir. *Id.* Dr. Reisman's assessment was: 1. Subjective tinnitus of both ears; 2. Dysfunction of both Eustachian tubes; 3. TMJ; 4. DJD (degenerative joint disease) of cervical spine; 5. Patulous Eustachian tubes; 6. Allergic rhinitis. *Id.* at 3. Dr. Reisman recommended TMJ therapy and referral for allergy management. *Id.*

On December 8, 2016, Ms. Henry visited North Coast Physical Therapy for treatment. Ex. 15 at 1-3. Petitioner reported 1.5 years of tinnitus and TMJ pain, left side greater than right, and

⁸ Xerosis is "abnormal dryness, as of the eye, skin, or mouth." *Xerosis*, Dorland's Online Med. Dictionary, <https://www.dorlandonline.com/dorland/definition?id=53880> (last accessed April 15, 2022).

that she wears a night guard to avoid clenching. *Id.* at 1. The physical therapist noted that Petitioner presented with “L TMJ hypomobility and movement dysfunction secondary to chronic postural stress and muscle imbalances at the cervicothoracic junction and mid cervical spine.” *Id.* at 2. The treatment plan included body mechanics/posture, core strengthening, stretching exercises, and other exercises. *Id.* Petitioner returned on 12/15/2016, 12/21/2016, and 1/4/2017 for treatment noting some improvement. *Id.* at 4-9.

On December 16, 2016, Petitioner visited Dr. Nguyen with no improvement regarding her acne. Ex. 8 at 1-2. Petitioner was given new instructions and medications for her perioral dermatitis⁹ and xerosis cutis. *Id.*

On December 29, 2016, Petitioner had a tinnitus evaluation at Balance & Hearing Specialty Group. Ex. 23 at 4-6. Petitioner was noted to have hearing in the borderline normal range bilaterally. *Id.* at 4. Petitioner was diagnosed with category 1 tinnitus: “bothersome tinnitus and mild or no hearing difficulties.” *Id.* at 5. Petitioner also self-scored her “tinnitus handicap inventory score” at 64 (out of 100), which is equivalent to a Grade 4 score, where Petitioner stated that she almost always has tinnitus, has difficulty sleeping, and the tinnitus interferes with her daily activities. *Id.* Ms. Henry “report[ed] sudden onset tinnitus and hyperacusis in her right ear over the past 2 years with escalation of tinnitus to both ears since June 2016.” *Id.* at 4.

On February 1, 2017, Petitioner visited Dr. Kurisu for a multitude of problems including tinnitus. Ex. 25 at 3-8. Dr. Kurisu noted under HPI that Petitioner had a flu shot in November 2014 in her right arm and that evening developed tinnitus and hissing in the right ear. *Id.* at 6. In May 2015, right ear had a “running water” sound and in her left ear was an intermittent hissing sound. *Id.* Petitioner also informed Dr. Kurisu that her tinnitus was getting slightly worse and that she was stressed. *Id.* Petitioner reported more pain and worse ringing in her ears; right ear sounds like freight train and left ear sounds like waterfall. *Id.* Dr. Kurisu noted that Petitioner’s complaints may be attributed “in part to underlying somatic dysfunction.” *Id.* at 8. Dr. Kurisu wrote a letter exempting Petitioner from vaccinations. Ex. 3. He wrote that Petitioner “has been suffering from somatosensory tinnitus since 2014 and has attributed her symptoms after receiving the influenza vaccination at the time.” *Id.*

On February 15, 2017, Petitioner returned to Balance & Hearing Specialty Group for another evaluation. Ex. 23 at 1-3. The test noted borderline normal gently sloping mild SNHL in both ears. *Id.* at 2. Petitioner’s tinnitus handicap inventory score was also changed to Grade 5. *Id.* Ms. Henry reported she continued to experience “a constant hissing high frequency tinnitus bilaterally with an intermittent clicking tinnitus in her left ear,” which is worse in the morning. *Id.* at 1.

⁹ Perioral dermatitis is “a papular eruption on the face, of unknown etiology and seen most often in young women; papules and pustules develop slowly and progress to erythema and scaling. It is usually confined to the area about the mouth, but may also spread to involve the eyelids and forehead.” *Perioral dermatitis*, Dorland’s Online Medical Dictionary, <https://www.dorlandsonline.com/dorland/definition?id=69312> (last accessed April 26, 2022).

On February 16, 2017, Petitioner visited Dr. Brittany Grovey for chronic neck and bilateral jaw pain. Ex. 25 at 13. Dr. Grovey noted “her neck pain seems myofascial in etiology and her jaw pain is likely 2/2 TMJ.” *Id.*

On August 2, 2017, Ms. Henry was seen by Andrew Inocelda, PA, for a neurology consult. Ex. 55 at 22-26. Petitioner recounted the timeline of her tinnitus. *Id.* at 22-23. Mr. Inocelda noted that,

[Petitioner] associates onset of tinnitus with receiving flu shot back in November 2014. She could've had an opportunistic viral syndrome back then that caused damage to the cochlear nerve or caused hypersensitization at the brainstem. I discussed in great detail there is likely nothing that we can do to reverse this problem.... Anxiety could be what predisposed [Petitioner] to have persistent tinnitus as we have seen pre-existing anxiety predispose patients to have post-concussive syndromes compared to those that do not have pre-existing anxiety.

Id. at 26. Mr. Inocelda discussed treatment options with Petitioner, and she agreed to a trial of clonazepam. *Id.*

Petitioner had hearing tests completed on 2/15/2017, 3/2/2017, 4/2/2017, 5/25/2017, 6/29/2017, 9/16/2017, 9/21/2017, and 10/17/2017. Ex. 65. The audiological report on October 17, 2017 revealed continued bilateral mild sensory neural hearing loss. Ex. 65 at 14.

On October 4, 2017, Ms. Henry returned to Dr. Kurisu for a number of issues, with a new condition of mild obstructive sleep apnea. Ex. 68 at 1-6. On November 29, 2017, during another visit with Dr. Kurisu, Petitioner was noted to be experiencing “less [symptoms] but feels still stressed at times.” *Id.* at 13.

On December 11, 2017, Dr. Kurisu wrote a letter for Petitioner in which he noted Petitioner was suffering from an extreme version of tinnitus and had tried and failed multiple medication regimens. Ex. 68 at 22. He also stated that Petitioner “does get relief from neurological electronic auditory reprogramming and has benefited greatly from using devices that can help her with this. Her symptoms are much less when she is using these devices resulting in less stress on her and also on the health care system.” *Id.*

On January 16, 2018, Petitioner visited Mr. Inocelda for her obstructive sleep apnea syndrome. Ex. 89 at 1-4. The medical record notes that her left ear tinnitus worsened after recent dental work and returning to work. *Id.* at 1.

On January 31, 2018, Ms. Henry returned to Dr. Kurisu for OMT treatment. Ex. 91 at 27-32. Dr. Kurisu noted “Interestingly when she had two weeks off of work she did [not] have symptoms.” *Id.* at 31.

On March 7, 2018, Petitioner visited Dr. Kurisu and received OMT treatment. Ex. 84 at 1-6. Dr. Kurisu discussed Petitioner’s work situation and how the stress affects her work life balance. *Id.* at 6. Dr. Kurisu noted, “She is definitely having so much stress that it is causing her to have

more symptoms overall.” *Id.* In other OMT appointments with Dr. Kurisu, the medical records note that Petitioner was still stressed from work and “[h]as been having less symptoms on days that she does not have work.” Ex. 91 at 79; Ex. 93 at 5.

On April 4, 2018, Ms. Henry returned to Balance & Hearing Specialty Group for an audiological follow-up. Ex. 92 at 1-2. Petitioner complained that her tinnitus flared up again because she was situated next to a loud printer at work. *Id.* Petitioner also reported that she had progress in her tinnitus during vacation and extended weekends but would regress when she returned to work and sat next to the loud printer. *Id.*

Petitioner filed many additional medical records that relate to her medical issues but ultimately do not contribute to her diagnosis or theory of causation.

III. Expert Opinions and Qualifications

A. Petitioner’s Expert: Dr. Eric Gershwin

1. Qualifications

Dr. Gershwin received his medical degree from Stanford University in 1971 and is board certified in internal medicine, rheumatology, and allergy and clinical immunology. Ex. 27 (hereinafter “Gershwin CV”) at 1-2. He is currently the Jack and Donald Chia Professor of Medicine and a Distinguished Professor of Medicine the University of California, Davis. *Id.* at 2. Dr. Gershwin has won numerous awards including a Doctor of Philosophy Honoris Causa from the University of Athens, for his contribution in immunology and medicine, and is the Professor Henry N. Neufeld Memorial Award from the United States-Israel Binational Science Foundation in 2014. *Id.* at 1. Dr. Gershwin has ten patents and serves as the editor-in-chief for Clinical Reviews in Allergy, Reviews in Autoimmunity, Autoimmunity Reviews, and Journal of Autoimmunity, as well as an ad hoc editor for numerous other publications. *See id.* at 5-7. Dr. Gershwin has published more than 900 papers, 162 book chapters, and 69 books/monographs. *See id.* at 8-12, 13-91, 92-106.

2. Dr. Gershwin’s First Expert Report

In Dr. Gershwin’s first report, he defined tinnitus as a “sound in the head or ears that occurs in the absence of any external acoustical source.” Ex. 26 at 1 (hereinafter “First Gershwin Rep.”), *citing* Ex. 28, Tab 1, McCormack et al., *A systematic review of the reporting of tinnitus prevalence and severity*, 337 HEARING RESEARCH 70-79, 71 (2016). Dr. Gershwin noted that because of the broad definition and different criteria used to define tinnitus, studies show that anywhere from 6%-30% of women, and 10%-49% of men suffer from tinnitus. First Gershwin Rep. at 2, *citing* Ex. 32, Duijvestijn et al., *Definition of Hearing Impairment and its Effect on Prevalence Figures: A Survey Among Senior Citizens*, 119 ACTA OTOLARYNGOLOGY 420-23 (1999).

Dr. Gershwin next addressed the autoimmune basis of vestibular dysfunction, stating that “the significant pathology in this syndrome is within the inner ear and there appeared [sic] to be a spectrum of clinical features which can include a rapidly progressing sensorineural [sic] hearing

loss, but also can show a spectrum of other inner ear dysfunction, including a decrease in otoacoustic emissions, an increase in ECoG signals, as well as clinical features consistent with an inner mediated vertigo syndrome.” First Gershwin Rep. at 2. He noted that the

association of tinnitus] with autoimmunity is well-known” and that “autoimmune activity in patients with idiopathic hearing loss has been assessed by several different laboratory techniques. Viral infections of the labyrinth are considered a major cause of auditory and vestibular system pathology. Theoretically, an immune response directed against a virus might cross-react with self-protein or autoantigen, evoking an autoimmune response.

Id. at 3, citing Ex. 45, Bernstein, et al., *Further observations on the Role of the MHC Genes and Certain Hearing Disorders*, 116 ACTA OTOLARYNGOLOGY 666-71 (1996) (stating that “several studies seem to demonstrate that genetically controlled aspects of the immune system may increase or otherwise be associated with increased susceptibility to different inner ear diseases.”). Dr. Gershwin concluded by stating that there is therefore “strong evidence to suggest that immune mechanisms are involved in the actiopathogenesis of inner ear damage.” First Gershwin Rep. at 3-4, citing Ex. 46, Garcia-Berrocal et al., *Does the Serological Study for Viral Infection in Autoimmune Inner Ear Disease Make Sense*, 70 ORL. J. OTORHINOLARYNGOLOGY RELAT SPEC 16-19 (2008).

Dr. Gershwin also opined that Petitioner’s correct diagnosis was autoimmune inner ear disease (“AIED”). First Gershwin Rep. at 3-4. He cited literature which states that since 1981 “28 patients have been diagnosed with autoimmune ear disease.” First Gershwin Rep. at 3, citing Ex. 38, Hughes et al., *Autoimmune Vestibular Dysfunction: Preliminary Report*, 95 LARYNGOSCOPE 893-97 (1985). While Dr. Gershwin did not discuss the specific symptoms Petitioner suffered from that would trigger a finding of AIED, he noted that:

The hallmark of this clinically diagnosed condition is the presence of a rapidly progressive, often fluctuating, bilateral sensorineural hearing loss (SNHL) over a period of weeks to months. The progression of hearing loss is too rapid to be diagnostic for presbycusis and too slow to conclude a diagnosis of sudden SNHL. Vestibular symptoms, such as generalized imbalance, ataxia, positional vertigo and episodic vertigo may be present in almost 50% of patients. Occasionally only one ear is affected initially, but bilateral hearing loss occurs in most patients, with symmetric or asymmetric audiometric thresholds. Almost 25-50% of patients also have tinnitus and aural fullness, which can fluctuate. Systemic autoimmune diseases coexist in 15-30% of patients.

Id. at 3, citing Ex. 39, Bovo et al., *Immune-mediated Inner Ear Disease*, 126 ACTA OTOLARYNGOLOGY 1012-21 (2006). He noted that AIED was an immunologically mediated disease, stating that:

The mechanism of action of this immunological reaction is most consistent with an antibody response and, in particular, the initial production of an autoantibody which cross reacts with a component of her viral infection and a self antigen, in this case

a component in the auditory nerve. This would produce inflammation, which would lead to auditory dysfunction and is more likely than not an IgM response because it occurred relatively quickly following the vaccine.

First Gershwin Rep. at 4. Dr. Gershwin noted that that “it normally takes 24-48 hours to begin to see a significant IgM response” and acknowledged that Petitioner’s symptoms “began 20 hours after vaccination”. *Id.* Dr. Gershwin opined that in Petitioner’s case, this response occurred more rapidly than normal because Petitioner had a viral infection at the time of vaccination. He opined as follows:

I have already noted that she had a subconjunctival hemorrhage and this was a manifestation of a mild viral infection. I do not believe that the viral infection alone would have produced this magnitude and duration of clinical tinnitus....The influenza vaccine includes recruitment of a variety of bystander cells based on the ability of the vaccine to elicit cytokine production and elicit an immune response. This process would amplify an immune response, including polyclonal B cell activation, which would accentuate and facilitate loss of tolerance including a viral induced self response. The concurrent vaccination would as part of the polyclonal activation facilitate the class switch from IgM to IgG and thus the perpetuation of the injury.

First Gershwin Rep. at 4.

Dr. Gershwin concluded his report by stating his theory of Petitioner’s case:

[The] autoantibody produced by [Petitioner], in response to the breakage of tolerance to a self-antigen, was a viral infection for whom loss of tolerance and cross reactivity was induced and perpetuated by the bystander cellular and cytokine response elicited by the influenza vaccine.

First Gershwin Rep. at 4.

3. Dr. Gershwin’s Second Expert Report

In Dr. Gershwin’s second report, he responded to Dr. Phillips’ first report. Ex. 75 at 1 (hereinafter “Second Gershwin Rep.”). He noted that, while Dr. Phillips “appears to require evidence-based research as a criteria for him to associate an adverse event with vaccination”, Dr. Phillips does not take “into account the issue of power calculations, the number of subjects, and rare events.” *Id.* Dr. Gershwin noted that “the very basis of the vaccine program is to recognize that rare events occur.” *Id.*

Dr. Phillips stated that “there are no physicians that have linked [Petitioner’s] reaction to the influenza vaccination.” However, Dr. Gershwin pointed out that Dr. Kurisu, Petitioner’s treating physician, stated that he “does not recommend that [Petitioner] receive vaccinations in the future.” Second Gershwin Rep. at 1.

Dr. Gershwin next addressed several of Dr. Phillips' arguments regarding Petitioner's injury. Second Gershwin Rep. at 2. He noted that Petitioner's teeth grinding began "after the onset of the tinnitus" and that, while Dr. Phillips opined that "the failure [of Petitioner] to respond to steroids militates against an autoimmune basis for the tinnitus", "Dr. Phillips does not take into account that [Petitioner] was unable to take steroids because of the side effects and thus had to stop them." *Id.* at 1-2.

In addressing Dr. Phillips' arguments regarding the temporal interval between Petitioner's vaccination and her symptoms, Dr. Gershwin stated that "the temporal relationship described in the medical records is consistent with the timing expected based entirely on the mechanisms that I have proposed." Second Gershwin Rep. at 2. He concluded his analysis of Dr. Phillips' report by restating several of Dr. Phillips' arguments and then opining:

it is difficult to respond to Dr. Phillips because of his reliance on epidemiology and his failure to criticize the plausible mechanisms of action. For example, he seems to argue that reactions in the skin would not cause cochlear reactions. There is no argument that cochlear antigens are not in the blood. It is rather the immune response which can be transmitted through the lymphatics or the blood that lead to this reaction. The clinical epidemiologic studies do not provide assurance of events as rare as AIED. Furthermore, the data on the immune response following influenza vaccination in reference #4, would indicate that any such study would have to have a homogeneous group consisting of women of a similar age range as [Petitioner]. This in fact is even further supported by data emphasizing that the breakdown of immune tolerance is in large part purely stochastic.

Second Gershwin Rep. at 3-4. Dr. Gershwin concluded this report by stating, "I continue to submit that although rare, [Petitioner] would not have suffered from AIED were it not for her seasonal flu vaccination." *Id.* at 4.

4. Dr. Gershwin's Third Expert Report

In his third expert report, Dr. Gershwin responded to Dr. Phillips' second expert report. Ex. 95 at 1 (hereinafter "Third Gershwin Rep."). In response to Dr. Phillips' assertion that molecular mimicry is not a valid hypothesis, Dr. Gershwin stated that "In order to get the evidence (aka "certainty") desired by Dr. Phillips [to confirm molecular mimicry as a valid hypothesis], such would be very time consuming and expensive and would definitely not be done on humans." Third Gershwin Rep. at 3.

Dr. Gershwin next clarified the theory of "molecular mimicry and cross-reactivity", stating that:

It should be emphasized that molecular mimicry and cross reactivity, using only homology with proteins, is essentially an anachronism. It does not take into account T cell recognition. In order to fully understand how diverse an individual's immune system is, it will become mandatory to characterize the T cell receptor (TCR) repertoire to truly understand genetic susceptibility.

Third Gershwin Rep. at 3. He noted that it is impossible to provide a complete description of TCRs due to the limitations of current technology, but in general:

The process of TCR production requires recombination of the variable (V), joining (J) and the constant (C) regions which play a pivotal role in diversity in T-cells. Each of these regions is recombined, with extra nucleotides additions and/or deletions, to generate each rearranged TCR, which ultimately generates high T-cell diversity. This process allows the recognition of thousands of self and non-self-antigens. The identification of diversity of TCR is challenging since the variability of TCR due to rearrangement reduces the odds to find a unique profile of TCRs.

Id. He noted that one study “using massively parallel sequencing, found that two samples taken from the same subject within 1 week of difference, were similar in only 35%, exhibiting the difficult scenario of characterizing diversity of TCRs.” *Id.*, citing Ex. 100, Warren et al., *Exhaustive T-Cell Repertoire Sequencing of Human Peripheral Blood Samples Reveals Signatures and a Directly Measure Repertoire Size of at least 1 Million Clonotypes*, 21 GENOME RES 790-97 (2011).

Noting that there are several challenges associated with estimating TCR diversity, Dr. Gershwin outlined two of the estimators:

[P]arametric and non-parametric estimators have been used. In the former, Poisson abundance models and power laws have been the most widely used to estimate a clonotype frequency distribution based on the assumption that T-cell diversity distribution follows a[] uniform predictable shape (1). Non-parametric estimators include the Chao1, Chao2, abundance-based coverage estimator (ACE), and the capture–recapture strategies. Although these strategies are thought-provoking, these estimators require true numbers of T-cell clonotypes to be validated, thus their usefulness in autoimmunity is limited.

Third Gershwin Rep. at 4 (omitting internal citations).

In conclusion, Dr. Gershwin stated “that the etiology of [Petitioner’s] cochlear damage was her vaccination [and that] the rarity of these events is only explicable by the variants of human immunity.” Third Gershwin Rep. at 4. He further stated that “[o]bviously, it is difficult to conclude with 100% confidence what caused [Petitioner’s] disease. The mechanisms involved are necessarily dependent on a person’s genetic makeup and immune response, and both of these vary from person to person.” *Id.* at 4. He noted that 100% confidence is not necessary in the Vaccine Program, “we need that such occurred, more probable than not. I maintain and continue to maintain that it is more likely than not that the Flu vaccine given to [Petitioner] caused the cochlear damage.” *Id.* Finally, he stated that “[s]imply because a disease process is rare does not mean that we cannot conclude to a reasonable degree of probability what causes disease in a particular person.” *Id.*

5. Dr. Gershwin’s Fourth Expert Report

In Dr. Gershwin's fourth expert report, he responded to the expert report of Dr. Whitton. Ex. 134 (hereinafter "Fourth Gershwin Rep."). After noting that Dr. Whitton was critical of the fact that Dr. Gershwin associated tinnitus and hearing loss, Dr. Gershwin stated that the literature "strongly" associates tinnitus with hearing issues. Fourth Gershwin Rep. at 1, *citing* Tan et al., *Tinnitus and Patterns of Hearing Loss*, 14 J. ASSOC. RES. OTOLARYNGOLOGY 275 (2013) (filed as Ex. 135). He also noted that there was support in the medical records for his theory, stating that on June 18, 2015, "Dr. Nguyen noted Normal sloping to mild mid frequency SNHL (Sensory Neuronal hearing loss), improving to normal. (Exhibit 4, 001-003.) Dr. Harris, who Dr. Whitton lauded, also noted SNHL AU." *Id.* Dr. Gershwin also cited the medical records of Dr. Viirre, who "acknowledged the mid frequency SNHL and autoimmunity was in his differential and recommended an autoimmune workup." *Id.* at 1-2.

Dr. Gershwin next addressed Dr. Whitton's concerns that the Nachamkin article was not reproduceable. Fourth Gershwin Rep. at 1. Citing an article by Wang et al., Dr. Gershwin noted that "In Nachamkin, they show that if you inject mice with vaccines that contain H1N1, the mice make anti-ganglioside responses" while in the Wang article, it was shown that in rare cases, healthcare workers (humans) also make anti-ganglioside responses when injected with H1N1 vaccination, which, according to Dr. Gershwin, constituted a reproduction of the Nachamkin results. *Id.*, *citing* Wang et al., *No Evidence of a Link between Influenza Vaccines and Guillain-Barre syndrome-associated antiganglioside antibodies*, 10 INFLUENZA J. 1111, 1750-2659 (2011) (filed as Ex. 141).

Dr. Gershwin next cited Dr. Phillips' report in which Dr. Phillips pointed out:

VAERS...showed 154 cases of tinnitus occurring with Flu Vaccination. Ten occurred within the first 24 hours following vaccination. Given the frequency of tinnitus of 54:100,000) and the number of vaccinations during this period (>1,800,000,000) a total of 97,200 cases of tinnitus juxtaposed to flu vaccination would coexist. Even given inadequacies of reporting, this number of SSNHL or tinnitus reports with flu vaccine is reassuring that no significant risk exists.

Fourth Gershwin Rep. at 2, *citing* First Phillips Rep. at 19. Dr. Gershwin took this to indicate "a concession [by Respondent's expert] that tinnitus within the first 24 hours does happen", even if the risk is small. *Id.*

Finally, Dr. Gershwin addressed Dr. Whitton's concern that onset of tinnitus was far too rapid for it to be connected to Petitioner's flu vaccine. Fourth Gershwin Rep. at 3. He stated:

You cannot have an adaptive response without an innate response. That innate response includes local production of IgM and occurs quite rapidly. Although it is true that IgM may not be detected in the sera for 2-3 days, it is still being produced in the local environment. The normal sequence of events following vaccine administration is that there is first antigen uptake within the regional lymph nodes adjacent to the injection. That can be called "local cell stimulation" and it occurs quite rapidly.... These cells will then drain to regional lymph nodes and traffic

throughout the body. In addition, there is passage or production of cytokines, C-reactive protein and prostaglandins, which likewise occurs and spreads throughout the body. The levels of CRP, for example, found in the blood will peak as early as 24 hours and similar increases in circulating cytokines have been found within hours. Hence, the innate immune system is an active and viable immune pathway, not only in the local lymph node, but potentially throughout the body. Activation of innate immune cells can certainly occur well before 24 hours and the literature reflects that it occurs within hours of a vaccination. If there was a co-existing viral infection, which is more likely than not, then bystander activation, which Dr. Whitton has already written about and published, would accelerate the process.

Id. He also noted that literature has shown that “[i]n animals, first responder, or innate immune cells, are readily found as early as three hours after immunization.” *Id.*

Dr. Gershwin concluded his report by stating that Petitioner’s symptoms (loud ringing in her right ear) “began around 20 hours after her vaccination. But, one should not forget that it got progressively worse, and spread to left ear and got worse with hissing, clicking and whooshing sounds.” Fourth Gershwin Rep. at 3.

B. Respondent’s Expert: Dr. S. Michael Phillips

1. Qualifications

Dr. Phillips received his medical degree from the University of Wisconsin and completed his residency at the University of Pennsylvania. Ex. B (hereinafter “Phillips CV”) at 1. Dr. Phillips has had a number of faculty and academic positions over the years including (but not limited to) Director of Medical International Health, Director of Allergy and Immunology Clinical Services at the University of Pennsylvania. *Id.* at 1-2. Dr. Phillips is board certified in internal medicine and allergy and immunology. *Id.* at 2. Dr. Phillips has published over 130 peer-reviewed papers and two books (as of 2017). *Id.* at 5-14.

2. Dr. Phillips’ First Expert Report

Dr. Phillips submitted his first report on March 15, 2018. Ex. A, ECF No. 35-1 (hereinafter “First Phillips Rep.”). After reviewing Dr. Gershwin’s conclusion that “the autoantibody produced by [Petitioner], in response to the breakage of tolerance to a self antigen, was a viral infection for whom loss of tolerance and cross reactivity was induced and perpetuated by the bystander cellular and cytokine response elicited by the influenza vaccine,” Dr. Phillips concluded that this statement “is uninterpretable and meaningless.” First Phillips Rep. at 11. Upon reviewing Dr. Gershwin’s referenced literature, Dr. Phillips opined that “none of his references are germane to the specifics of this case and none of them support the proposition that vaccines per se can and do cause tinnitus or SSNHL.” *Id.* He noted that the articles cited by Dr. Gershwin: 1) “Do not address any role for any vaccines in SSNHL or tinnitus;” 2) “Suggest that [Petitioner] did not have AIED;” 3) “Do not address the facts of this case;” 4) “Provide[] no evidence for vaccine/viral synergy in obviating immunoregulation;” [and] 5) “Provide epidemiological evidence which strongly suggests the [f]lu vaccine and the clinical problem of [Petitioner] are mathematical coincidences.” *Id.* at 15.

Dr. Phillips next addressed the causal relationship between the flu vaccine and SSNHL/tinnitus. First Phillips Rep. at 15. To establish a causal relationship, Dr. Phillips stated that several criteria are necessary: First, there must be “a known precipitating event.” *Id.* Dr. Phillips stated that “there is no evidence that [Petitioner] had any antecedent autoimmune disease, clinical infection, vascular compromise, allergy, or other disease which would predispose her to develop cochlear disease in the form of SSNHL or Tinnitus...[nor] a concurrent infection at the time of infection.” *Id.* at 15-16.

Second, Dr. Phillips opined that there must be a logical causal relationship. First Phillips Rep. at 16. Dr. Phillips stated that “immune reactions require the interaction of a complex series of cellular recognition by receptors for specific antigen[s].” *Id.* He noted that no such antigens “have been identified” in this case, nor were any studies that would establish an immune mechanism performed. *Id.* He noted that:

The flu vaccine was injected into [Petitioner’s] arm. Therefore, the reaction would occur in her arm, not exclusively in her cochlea. There was no reaction in her arm. If she absorbed the antigen and had a systemic reaction, signs and symptoms would occur elsewhere...[and] these systemic reactions were not in evidence. Many immune mediated reactions can occur at a later time, i.e. leukotriene mediated delayed reactions. These take several hours. [Petitioner] suggested symptoms in a few hours, far too fast for these latter vasculitic mechanisms.

Id. at 17.

Third, Dr. Phillips noted that:

Autoimmune forms of sudden hearing loss are due to reactions of the immune system to specific antigens in the cochlea. These antigens are in the cochlea or acoustic apparatus. They are not in the [f]lu [v]accine and therefore, a reaction to the flu vaccine would not localize in the cochlea or acoustic apparatus...If [Petitioner] had a reaction to absorbed flu antigen, she would have had to have a local reaction to the flu antigen in her arm where the concentration of flu antigen would be much higher. She did not.

First Phillips Rep. at 17. Dr. Phillips stated that “the phenomenon of molecular mimicry has never been shown in this case and is now known to be a theoretically implausible explanation.” *Id.* at 17.

Dr. Phillips next stated that “an acute localized vascular obstruction in the cochlea is a plausible explanation for the events in this case.” First Phillips Rep. at 17. However, he noted that Dr. Gershwin’s theory, that if this reaction was immunologically mediated by “some cytokine”, it would occur outside the blood supply in the tissues where the vaccine is administered, not in the cochlea. *Id.* He stated that “The cochlear and vaccine antigens are not in the blood vessels, so reactions against them will not cause occlusion.” *Id.*

Dr. Phillips then described the statistical probability of developing tinnitus on the day of vaccination, stating that based on the number of people who receive the flu vaccine per year, and the number of people who develop tinnitus in a year, “54 patients would be expected to develop tinnitus per day at random on the day of vaccination.” First Phillips Rep. at 18, *citing* CIDRAP News, *CDC confirms Record Doses of Flu Vaccine were Given*, CDC.com; *see also* Martinez et al., *Incidence Rates of Clinically Significant Tinnitus: Ten-Year Trend from a Cohort Study in England*, 30 EAR HEAR e69 (2015).¹⁰ Additionally, in reviewing literature regarding the flu vaccine and adverse events, Dr. Phillips found “no evidence to suggest that the flu vaccines cause[] vasculitis or neuropathy.” *Id.* at 18.

Dr. Phillips also noted the lack of epidemiological evidence causally connecting the flu vaccine and SSNHL/tinnitus. First Phillips Rep. at 19. He cited the Baxter article, which studied the occurrence of sudden sensorineural hearing loss in over 20 million vaccinations; approximately eight million people received the flu vaccine. *Id.*, *citing* Ex. A, Tab 21, Baxter et al., *Sudden-onset Sensorineural hearing loss after Immunization: A Case-Centered Analysis*, 155 OTOLARYNGOLOGY HEAD AND NECK SURGERY 81-86 (2016) (hereinafter “Baxter”). The authors of the Baxter article found “no evidence of increased risk of [sensorineural hearing loss] after immunization compared with matched controls.” First Phillips Rep. at 19. Dr. Phillips also stated:

Similarly, the VAERS report showed 154 cases of tinnitus occurring with Flu Vaccination. Ten occurred within the first 24 hours following vaccination. Given the frequency of tinnitus of 54:100,000) and the number of vaccinations during this period (>1,800,000,000) a total of 97,200 cases of tinnitus juxtaposed to flu vaccination would coexist. Even given inadequacies of reporting, this number of SSNHL or tinnitus reports with flu vaccine is reassuring that no significant risk exists.

Id. After reviewing the literature, Dr. Phillips concluded that “the epidemiological evidence clearly shows that there is no increased occurrence of vasculitis or peripheral neuropathy due to flu vaccination.” *Id.* at 20.

Dr. Phillips also noted that Petitioner’s medical records did not include any laboratory data to substantiate the association between Petitioner’s injury and her flu vaccination. First Phillips Rep. at 20 (“There was no imaging, biopsy or laboratory evidence in this case to suggest any type of adverse immunological reaction to the flu vaccine in this case.”). Furthermore, he noted that none of Petitioner’s physicians concluded that Petitioner’s concerns that her flu vaccination caused her SSNHL and/or tinnitus were valid:

Indeed the physicians advanced a number of alternative, non-vaccine related, explanations. These diagnoses included viral labyrinthitis, adjustment disorder, GERD, somatic dysfunction, TMJ dysfunction, Whiplash with neck injury, jaw clenching, bruxism, mastoiditis (fluid and scaring). She was treated for several of these modalities and clinical improvement was noted. Conversely, autoimmune ear disease was considered. However, when she was treated for this possible condition,

¹⁰ This article does not appear to have been filed into the record.

with steroids and antiviral agents such as Valacyclovir, no improvement was noted. This observation dissuaded the acceptance of this diagnosis.

Id.

Dr. Phillips concluded his report by stating that the etiology of SSNHL is usually unknown, and there “is no valid evidence to support the assertion that tinnitus or SSNHL can be caused by [f]lu [v]accine.” First Phillips Rep. at 21. He stated that “the arguments of Dr. Gershwin are totally unsubstantiated, very misleading, and not applicable specifically to this case. In this context, the general medical community does not accept them.” *Id.*

3. Dr. Phillips’ Second Expert Report

Dr. Phillips’ second report was filed in response to Dr. Gershwin’s second report on October 15, 2018. Ex. C, ECF No. 50 (hereinafter “Second Phillips Rep.”).

Dr. Phillips began his report by addressing Dr. Gershwin’s contention that Dr. Phillips “seems to require epidemiology and statistical analysis without taking into consideration’ basic issues of epidemiology relating to rare events.” Second Phillips Rep. at 2, *citing* Second Gershwin Rep. at 3. Dr. Phillips noted that he has considered the possibility of rare events, but that “[s]tudies which have been performed have established that the probability of flu vaccine causing SSNHL or tinnitus is well under 1%; i.e. >than 99 % improbable”; therefore rendering even the rarest of events all but a mathematical improbability. *Id.* Further addressing the point that he has considered rare events, Dr. Phillips noted that he has studied VAERS cases and mathematical models, neither of which provided any support for the proposition that AIED could even be considered a rare consequence of the influenza vaccine. *Id.* at 16-17.

Dr. Phillips next addressed Dr. Gershwin’s contention that “his opinions ‘are based on medical and biologically plausible mechanisms that would explain causation in the adverse events that occurred in [Petitioner].’” Second Phillips Rep. at 3, *citing* Second Gershwin Rep. at 3. Dr. Phillips stated that “Dr. Gershwin simply makes up arbitrary associations, with no proven literature associations.” Second Phillips Rep. at 3. He further stated that “no one has ever made the associations, postulated by Dr. Gershwin, and tested them scientifically.” *Id.* at 4.

In addressing Dr. Kurisu’s alleged recommendation that Petitioner not receive flu vaccines in the future, Dr. Phillips stated that “Dr. Kurisu was acting out of caution and not based [on] scientific data” and that “Dr. Kurisu did not ascribe [Petitioner’s] problems to the vaccine.” Second Phillips Rep. at 3.

Dr. Phillips also addressed the concept of molecular mimicry in his second report. Second Phillips Rep. at 5. He stated his understanding of Dr. Gershwin’s principal argument as follows:

[C]ochlear damage is an acute autoimmune inflammatory event of the CNS, which causes localized inflammation and profound disease. The genesis of disease is due to an immune response to antigens, which are shared between the vaccine and the cochlea/inner ear. This cross-reaction causes immunologically mediated

destructive inflammation and clinical disease. This process is known as molecular mimicry. In support of this hypothesis, he suggests studies, would show common linear epitopes between CNS derived antigen with a vaccine component. These studies are predicated on the assumption that there are topographical analogies between components of vaccines or infectious agents and components of the human body. The immune system is stimulated by the vaccine and then cross-reacts with analogous structure in the body, causing an autoimmune reaction against these cross-reacting antigens. This would lead to the production vasculitis, which leads to localized immunopathology and clinical disease. Thus, a vaccine would cause autoimmune diseases.

Id. Dr. Phillips rebutted this argument with several points, and ultimately reached the conclusion that “molecular mimicry is too common an occurrence to be a major biological event,” and it “has not been shown to cause Cochlear or inner ear pathology thru [sic] cross reactions between human neurological antigens or [f]lu [v]accine.” *Id.* at 9-10. Furthermore, Dr. Phillips stated that “there is no evidence for molecular mimicry existing in the case of [Petitioner].” *Id.* at 10.

In addressing Petitioner’s diagnosis, Dr. Phillips stated that he does not believe that Petitioner suffered from AIED; rather “other explanations are far more likely.” First Phillips Rep. at 11. He also restated his conclusion that based on the epidemiological data, “an etiological connection between vaccine[s] and tinnitus [is] very, very unlikely.” *Id.*

Dr. Phillips also spent time considering Dr. Gershwin’s filed literature. First Phillips Rep. at 12-14. Following analysis of the literature, he stated that “there is no evidence that flu vaccine breaks tolerance and causes autoimmune disease.” *Id.* at 14. He concluded his report by stating that “[t]he criteria necessary to establish a causal relationship between flu vaccination and SSNHL/AIED or tinnitus were not demonstrated” and that “[t]he postulate that Flu Vaccine causes SSNHL or tinnitus is unsubstantiated in the general medical case and in this specific case.” *Id.*

C. Respondent’s Expert: Dr. J. Lindsay Whitton

1. Qualifications

Dr. Whitton received his M.B., Ch.B. and Ph.D. from the University of Glasgow, Scotland. Ex. E (hereinafter “Whitton CV”) at 1. Dr. Whitton is currently a professor in the Department of Immunology and Microbial Science at the Scripps Research Institute. *Id.* Dr. Whitton is a member of a number of professional societies, including the American Association of Pathologists, American Associates of Immunologists, American Society of Virology, among others. *Id.* Dr. Whitton is also on the editorial boards of scientific journals and has published nearly 200 papers. *See id.* at 1, 2-14. Dr. Whitton is not licensed to practice medicine in the United States.

2. Dr. Whitton’s Expert Report

Dr. Whitton filed one expert report in this case. Ex. D (hereinafter “Whitton Rep.”). In this report, he noted that tinnitus is a relatively common condition with many causes, including infection, trauma, and autoimmune diseases such as SLE; vaccinations have not been associated

with tinnitus. Whitton Rep. at 3. In comparison, AIED is a rare disease, causing less than 1% of all SNHL, and is associated with a variety of systemic autoimmune disorders. *Id.* There is no test to confirm an AIED diagnosis, but one molecule associated with 33% of AIED cases was tested and Petitioner was negative. *Id.*

Dr. Whitton disagreed with a number of points in Dr. Gershwin's expert reports. In Dr. Gershwin's first report (Ex. 26), he opined regarding vestibular dysfunction, which Petitioner does not have. *Id.* at 7; *see also* First Gershwin Rep. at 2. Vestibular dysfunction generally presents with vertigo, dizziness, and unsteadiness, which are largely undocumented in Petitioner's medical records.¹¹ Whitton Rep. at 7. Dr. Whitton further noted that Dr. Gershwin introduced AIED, which presents with both vestibular signs and symptoms (which Petitioner does not have) and tinnitus. *Id.* AIED is commonly treated with high-dose steroids and Petitioner was given low-dose steroids on 9/10/2015, which aggravated her tinnitus. *Id.*; *see also* Ex. 2 at 50. Contrary to Dr. Gershwin's belief, Petitioner has also never been diagnosed with AIED, despite the numerous doctors she has seen throughout the years. Whitton Rep. at 7.

Dr. Whitton additionally challenged Dr. Gershwin's opinion that Petitioner's subconjunctival hemorrhage was an infection. Whitton Rep. at 8. Petitioner first sought treatment for her red eye on December 11, 2014, three weeks post-vaccination, where she stated she bent over to water her Christmas tree. *Id.*; *see also* Ex. 1 at 4-5. During another optometry appointment on December 30, 2014, under history of present illness, Petitioner's optometrist noted "Infection". The record further indicates that Petitioner had a cold and cough the prior week and had been coughing and sneezing regularly; according to Dr. Whitton, none of this suggests Petitioner had an ocular infection. Whitton Rep. at 8; *see also* Ex. 1 at 7-8. Dr. Whitton also noted that Petitioner did not receive any treatment for an ocular infection during this visit. Whitton Rep. at 8.

Dr. Gershwin's theory is predicated on the existence of a viral infection in order for the onset of Petitioner's tinnitus to have occurred 20 hours after vaccination. Whitton Rep. at 9. Dr. Whitton reiterated that there was no evidence of a viral infection at the time of vaccination or that Petitioner has ever had AIED. *Id.* In fact, Dr. Gershwin stated that the viral infection alone would not produce her clinical level of tinnitus, but does not provide evidence on this point. *See* First Gershwin Rep. at 4. Dr. Gershwin further argued that the flu vaccine amplified the underlying viral infection. Dr. Whitton opined that in most cases, a replicating virus provides a stronger immune stimulus than a non-replicating vaccine. Whitton Rep. at 9. Dr. Whitton asserted that he and Dr. Gershwin agree that Dr. Gershwin's theory is not viable without a preceding viral infection. *Id.* at 11.

It is Dr. Whitton's opinion that onset in one to three days is too soon for antibodies to cause an autoimmune disease. Whitton Rep. at 11. Four to five days is in the gray area, but six days is supported by scientific data. *Id.* Dr. Whitton cited to a study that demonstrated in an animal model an injection with a strong adjuvant and antigen took seven days to produce enough IgM antibodies to trigger disease. *Id.* Dr. Whitton added that there are no epidemiological studies that document any association between sudden onset SNHL/SSHL and the flu vaccine or any vaccine. *Id.* at 12-13.

¹¹ *See* Whitton Rep. at 7; *see also* Ex. 2 at 44; Ex. 11 at 1; Ex. 2 at 47, Ex. 84 at 4; Ex. 65 at 12.

Dr. Whitton also opined regarding the Nachamkin paper (Ex. 113) that Dr. Gershwin cited in support of his molecular mimicry theory. Whitton Rep. at 13-14. The Nachamkin paper hypothesized that the 1976 H1N1 vaccine would induce anti-ganglioside antibodies if injected into mice. *Id.* at 13. Dr. Whitton stated that “although a genuinely interesting idea, the authors’ overall hypothesis was not supported by the facts – there was no association between a vaccine’s ability to induce anti-ganglioside antibodies and its ability to cause neurological disease.” *Id.* at 14. Dr. Whitton opined that the data from the Nachamkin study did not provide significant support for Dr. Gershwin’s molecular mimicry theory. *Id.*

Finally, Dr. Whitton disagreed with Nurse Lin, who told Petitioner that ear ringing was a possible side effect of the flu vaccine. Whitton Rep. at 15. Dr. Whitton noted that neither ear ringing nor tinnitus are mentioned in the packet insert for the Fluzone vaccine. *Id.*; *see also* Ex. D, Tab 6.

D. Respondent’s Expert: Dr. Yu-Lan Mary Ying

1. Qualifications

Dr. Ying received her medical degree from SUNY Stony Brook School of Medicine. Ex. G (hereinafter “Ying CV”) at 1. She completed an otolaryngology residency and a general surgery internship at the University of Pittsburgh, as well as an otology/neurotology fellowship at Pittsburgh Ear Associates and a neurotology fellowship at the Baylor College of Medicine. *Id.* at 2. Dr. Ying is currently an Assistant Professor in the Department of Otolaryngology-Head and Neck Surgery at the Rutgers-New Jersey Medical School. *Id.* Dr. Ying is board certified in neurotology and otolaryngology. *Id.* at 3. Dr. Ying is actively involved in research with grants including from the NIH, Rutgers Brain Health Institute, and New Jersey Health Foundation, Inc. *Id.* at 10-11. Dr. Ying has 25 published papers, six book chapters, and four abstracts (as of 2020). *Id.* at 11-14.

2. Dr. Ying’s Expert Report

Dr. Ying filed one expert report in this case. Ex. F (hereinafter “Ying Rep.”). Dr. Ying highlighted what she believed were the most relevant medical records concerning Petitioner’s tinnitus and diagnosis. *Id.* at 1-10. Dr. Ying opined that there are several potential causes for Petitioner’s tinnitus: 1) her temporomandibular disorder (TMJ); 2) Eustachian tube dysfunction; 3) cervical spine musculoskeletal problems; 4) bilateral mild mid frequency SNHL; and 5) work/life stress. *Id.* at 11. Dr. Ying noted that there were records where Petitioner’s TMJ tightness was linked to her cervical spine stiffness/pain, which was aided by wearing a mouth guard; Dr. Ying further noted that she received Osteopathic Manipulative Treatment (OMT) and physical therapy (PT). *Id.*

Dr. Ying opined that Dr. Gershwin linked Petitioner’s onset of tinnitus to the flu vaccine “simply based on time course of events.” Ying Rep. at 11. She further noted that the onset of tinnitus within 24 hours is a medically inappropriate timeframe to infer vaccine causation. *Id.*

Further, Dr. Ying disagreed with Dr. Gershwin that Petitioner's symptoms qualify for an autoimmune inner ear disease diagnosis. *Id.*

Dr. Ying noted that AIED is a diagnosis of exclusion. Ying Rep. at 12. Petitioner's only consistent symptom was tinnitus which started the night of her vaccination in her right ear and progressed to both ears. *Id.* Petitioner never reported hearing loss, which is the primary clinical sign of AIED. *Id.* This is demonstrated in Petitioner's first audiogram, where she exhibited bilateral normal sloping to mild mid frequency SNHL, improving to normal. *Id.* Her next audiogram, a year later, showed no hearing loss. *Id.* at 13. There was no documented progressive sensorineural hearing loss or even hearing threshold fluctuations to substantiate an AIED diagnosis. *Id.* Other than a positive ANA in January 2016, none of Petitioner's laboratory results support a diagnosis of AIED. *Id.*

Petitioner was also offered steroids (Medrol pack) for her symptoms, and reported no improvement. Ying Rep. at 13. In fact, Petitioner reported that her tinnitus was aggravated by the Medrol dose pack. *Id.* AIED is typically responsive to steroid treatments. *Id.* Dr. Ying also disputed Dr. Gershwin's opinion that Petitioner's right subconjunctival hemorrhage was a manifestation of a mild viral infection. *Id.* at 14. Petitioner's optometrist noted that the cause of Petitioner's condition was dryness/foreign body that caused Petitioner to rub her eye and result in her condition. *Id.*

Dr. Ying stated that tinnitus is the "conscious perception and reaction to sounds without any matching external acoustic stimulus", or a phantom perception. Ying Rep. at 14. Tinnitus is viewed as a symptom rather than a disease. *Id.* Somatosensory tinnitus is a prevalent subtype of tinnitus that can be modulated by touch or movement. *Id.*

Dr. Ying stated that there is a link between TMJ and tinnitus. Ying Rep. at 15. The temporomandibular joint is commonly believed to be involved in the ability to modulate tinnitus intensity. *Id.* The worsening of tinnitus is associated with the aggravation of temporomandibular disorder (TMD). *Id.* Studies show that treatment of TMD also helps control tinnitus. *Id.* Dr. Ying noted that Petitioner was diagnosed with TMJ on June 24, 2015 and was prescribed a night guard that she did not regularly wear. *Id.* Petitioner had OMT sessions with Dr. Kurisu after which she seemed to improve. *Id.* Petitioner also reported increased stress from work, which worsened her tinnitus. *Id.* Because the tinnitus was improved by OMT and PT, is it Dr. Ying's opinion that Petitioner suffers from somatosensory tinnitus due to TMD. *Id.* at 15, 16. She noted that a number of Petitioner's treating physicians believed she has somatic dysfunction, which predisposed her to somatosensory tinnitus. *Id.* at 15.

IV. Petitioner's Supplemental Declaration

Petitioner filed a declaration regarding her symptoms that responded to Dr. Ying's expert report. Petitioner stated that she was in relatively good health at the time of her vaccination. She had TMJ and neck pain from a prior accident and working on the computer. Ex. 143 at 2. Petitioner also stated she never had tinnitus prior to vaccination, and she has experienced nothing but issues since. *Id.* Petitioner stated that the tinnitus began in her right ear, progressively

got worse and spread to her left ear with hissing, clicking, and whooshing sounds within 24 hours of vaccination. *Id.*

Petitioner agreed with Dr. Ying, that she had TMD prior to vaccination, however she noted that she did not have tinnitus prior to the flu shot. Ex. 143 at 2. She stated that her TMD did get better with wearing a nightguard. *Id.*

Petitioner also added that Dr. Kurisu took several months to complete his visit notes which delayed her filing, thus she does not believe in the accuracy of these records. *Id.* Petitioner identified sections of Dr. Kurisu's medical records and Respondent's Rule 4(c) Report that do not line up with her recollection of events. Ex. 143 at 2-5.

Finally, Ms. Henry stated that any treatment she received helped her neck, jaw and back pain, but not her tinnitus. Ex. 143 at 6. Petitioner has only had relief from her tinnitus for a few hours at a time, but her symptoms would always return. *Id.* She stated, "The treatment helped the head, neck, jaw and back issue, not the tinnitus. At MOST, I received temporary relief for a couple hours." *Id.* Petitioner asserted that she does not have somatosensory tinnitus that can be modulated. *Id.*

V. Applicable Law

A. Petitioner's Burden

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); see § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); see also *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*. *Althen* requires that petitioner establish by preponderant evidence that the vaccinations he received caused her injury “by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). 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 a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec’y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015) (“[p]lausibility ... in many cases may be enough to satisfy *Althen* prong one” (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner’s ultimate burden to establish her overall entitlement to damages by preponderant evidence. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

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; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician’s views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is

nothing ... that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec’y of Health & Hum. Servs.*, No. 06-522V 2011 WL 1935813 at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without op.*, 475 Fed. App’x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff’d without op.*, 503 F. App’x 952 (Fed. Cir. 2013). *Koehn v. Sec’y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master’s discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they “contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions,” where “accuracy has an extra premium.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals;

(ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec’y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec’y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den’d*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec’y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475 at *19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent and compelling.” *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *LaLonde v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

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 or her claim. *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). See *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)). “The *Daubert* 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 play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec’y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) (“uniquely 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”). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. See, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner’s case. Where both sides offer expert testimony, a special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, 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*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). 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. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”); see also *Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

D. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the medical literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. *See 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 [s]he does not explicitly reference such evidence in h[er] decision.”); *Simanski v. Sec’y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) (“[A] Special Master is ‘not required to discuss every piece of evidence or testimony in her decision.’” (citation omitted)), *aff’d*, 601 F. App’x 982 (Fed. Cir. 2015).

VI. Analysis

Although in the petition, Ms. Henry alleged that she developed tinnitus as a result of her flu vaccine, Dr. Gershwin opined that Petitioner’s vaccination caused her to develop autoimmune inner ear disease (AIED) with tinnitus as one symptom of that disease. *See* First Gershwin Rep. at 4 (noting “Ms. Headding experienced the new onset of an autoimmune ear disorder slightly less than one day after receiving an influenza vaccine.”); Second Gershwin Rep. at 3-4 (where Dr. Gershwin concluded this report by stating, “I continue to submit that although rare, [Petitioner] would not have suffered from AIED were it not for her seasonal flu vaccination.”).

A. Autoimmune Inner Ear Disease (AIED)

AIED “has been defined as a condition of bilateral sensorineural hearing loss (SNHL), caused by an ‘uncontrolled’ immune system response.” Ciorba et al., *Autoimmune inner ear disease (AIED): A diagnostic challenge*, 32 INTERNATIONAL JOURNAL OF IMMUNOPATHOLOGY AND PHARMACOLOGY, 1-5 (2018) (filed as Ex. F, Tab 2) (hereinafter “Ciorba”). AIED is characterized by “rapidly progressive onset over weeks or months.” Ciorba at 3. AIED is a rare disease, and is thought to cause fewer than 1% of all cases of SNHL. Whitton Rep. at 3. Tinnitus and ear fullness can be present in 25-50% of cases. Ciorba at 3. “AIED is a diagnosis of exclusion, suspected in case of a documented progressive SNHL, when other etiologic causes have been ruled out.” Ying Rep. at 12.

B. Tinnitus

Tinnitus is defined as “the conscious perception and reaction to sounds without any matching external acoustic stimulus, [] commonly described as a phantom perception. It is considered a symptom rather than a disease per se. The prevalence of tinnitus ranges from 5.1% to 42.7% based on a recent meta-analysis and systematic review.” Ying Rep. at 13-14.

C. Factual Finding: Petitioner did not have a Viral Infection at the Time of Vaccination

Because the question of whether Petitioner had a viral infection at the time of vaccination is an integral part of her theory in this case, it is appropriate that I address this issue before conducting an *Althen* analysis.

Petitioner visited Lucia Millet, OD, at Carlsbad Optometry on December 11, 2014 with a chief complaint of “really red right eye.” Ex. 1 at 4. The HPI section of this record states that Petitioner “noticed her right eye is really red, right above her cornea. First noticed while driving this am, didn’t see it when reading earlier. Bent over to try and water the xmas tree, wonders if that[’]s what caused it.” *Id.* Petitioner reported “no pertinent illnesses or injuries since last visit.” *Id.* Dr. Millet’s impression was “Right Eye: Subconjunctival hemorrhage.”¹² *Id.* at 5. Under “treatment”, Dr. Millet stated, “pt educ on findings, first episode. RTC [return to clinic] if worsens after about 1 week, but warned it may start to look worse before it gets better due to spreading out. ... if begins to happen frequently, recommend visit with PCP.” *Id.* Dr. Millet did not prescribe any medication, but in a follow-up call, noted that Petitioner was using over-the-counter eye drops. *Id.*

Nothing in this medical record suggests that Petitioner was experiencing a viral infection that involved her eye. A subconjunctival hemorrhage is not an infection -- in fact, Petitioner attributed the redness in the white of her eye to bending over to water the Christmas tree. Dr. Whitton noted that “this is medically-plausible, because causes of [subconjunctival hemorrhage] include coughing, heavy lifting, and bending forward, all of which transiently increase blood pressure, increasing the risk of rupture of the delicate capillary blood vessels that lie under the conjunctival membrane.” Whitton Rep. at 8. The fact that Dr. Millet noted “if begins to happen frequently, recommend visit with PCP” further suggests no infection was present. Importantly, Dr. Millet did not prescribe any medication to treat Petitioner’s condition.

On December 30, 2014, Ms. Henry saw Allison Pierce, DO at Carlsbad Optometry for continued eye redness. Ex. 1 at 6-7. The HPI section of this record reads as follows:

RED EYE: Right eye: INFECTION: Reporting a continued red/bloody eye appearance. Vision seems unaffected. Superior/temporal white of the eye, moving downwards. Since 12/11. Appears to be improving, but slowly, little improvement over last few days. No discomfort/discharge/vision changes. Pt report history of probably heavy lifting while watering Christmas trees. Pt also has had cough/cold over the last week and has been coughing and sneezing regularly.

¹² Subconjunctival means “beneath the conjunctiva.” Dorland’s Online Med. Dictionary, *Subconjunctival*, www.dorlandsonline.com/dorland/definition?id=47627&searchterm=subconjunctival; the conjunctiva is “the delicate membrane that lines the eyelids and covers the exposed surface of the sclera.” Dorland’s Online Med. Dictionary, *Conjunctiva*, www.dorlandsonline.com/dorland/definition?id=10882&searchterm=conjunctiva; the sclera is “the tough white outer coat of the eyeball.” Dorland’s Online Med. Dictionary, *Sclera*, www.dorlandsonline.com/dorland/definition?id=44975&searchterm=sclera (last accessed April 14, 2022). A “[s]ubconjunctival hemorrhage is a benign disorder that is a common cause of acute ocular redness. The major risk factors include trauma and contact lens usage in younger patients, whereas among the elderly, systemic vascular diseases such as hypertension, diabetes, and arteriosclerosis are more common.” NIH, National Library of Medicine, National Center for Biotechnology Information, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3702240/> (last accessed April 14, 2022).

Id. at 6. Dr. Pierce's impression was "Right Eye: Subconjunctival hemorrhage. Resolving." *Id.* at 7. Under "plan", Dr. Pierce recommended as follows:

Rx, artificial tears, PRN [pro re nata, as the situation calls for it]. ... Pt reassurance, very dense hemorrhages will take longer to heal. Also, pt has a cold/cough and coughs/sneezing may be re-aggravating the original hemorrhage causing slower healing. Advised hemorrhage may take another 2 weeks to clear. ... This is patient's first conjunctival hemorrhage. If hemorrhages become more recurrent or hemorrhage does not clear in 2 weeks, consider CBC blood work with PCP to look for possible clotting problems.

Id. Dr. Pierce did not prescribe any medication.

Petitioner pointed to the word "infection" in her medical records as evidence that she had a viral infection that involved her eye. Pet'r's Brief at 3. Although the placement of the word is confusing, I do not find there is preponderant evidence that it refers to an infection that involved Petitioner's eye. I arrive at this determination after reviewing the entire optometry record, both before and after this appointment. First, in conducting her eye exam, Dr. Pierce did not describe that Petitioner had an infection of the eye. She noted in the medical record "epithelium, stroma and endothelium clear and healthy. Bulbar and palpebral conjunctiva are healthy and white. Chambers are deep and free of cells and flare. Iris appears healthy..." Ex. 1 at 7. Second, during this appointment, Dr. Pierce went on to note that Petitioner had a cold, which caused coughing and sneezing. Third, Dr. Pierce again did not prescribe Petitioner any medication to treat her condition. Finally, Dr. Pierce clearly documented that Petitioner's condition was a continuing problem from her last visit on December 11, 2014, noting "Right Eye: Subconjunctival hemorrhage. **Resolving.**" *Id.* (emphasis added). A subconjunctival hemorrhage is not an eye infection. Given these points, it is more likely than not that the use of the word "infection" referred to Petitioner's cold, and not an eye infection. Petitioner's optometry visit in July 2015 further supports this finding.

On July 8, 2015, Petitioner returned to Carlsbad Optometry reporting eye redness once again. Ex. 1 at 10-11. Petitioner reported she "woke up this am and felt like something was in her [r]ight eye, [which was] also a little blurry. rubbed it a bunch, seemed to feel better but looked in the mirror and it is really red superiorly (SAME PLACE AS LAST EPISODE). blur cleared up after about 1 hour." *Id.* at 10. Dr. Millet noted that Petitioner "has an array of chronic symptoms lately, seems to be since she had a flu shot last November: ears feel plugged, tinnitus, headaches, light sensitivity, rash post flu shot, etc." *Id.* Petitioner also noted that her subconjunctival hemorrhage took three months to clear up. *Id.* Dr. Millet's impression was "OD [right eye]: Subconjunctival hemorrhage. In same location as last episode (12/2014)." *Id.* at 11. Dr. Millet opined that the "likely cause of heme is dryness/foreign body that she then rubbed and caused heme," and "the likelihood that heme is related to other systemic symptoms (other than anemia) is low, but cannot be ruled out completely." *Id.* Dr. Millet instructed Petitioner to use eye drops as needed for relief. *Id.* Dr. Millet did not prescribe any medication.

This July 2015 visit supports my finding that Petitioner did not have a viral infection which involved her eye at the time of her prior eye appointment in December 2014. Dr. Millet again

diagnosed Petitioner with a subconjunctival hemorrhage that developed in the “SAME PLACE AS LAST EPISODE.” Ex. 1 at 10 (emphasis in original).

Dr. Phillips opined that there is no evidence that Petitioner had a concurrent infection at the time she developed tinnitus. First Phillips Rep. at 16. Dr. Whitton agreed. *See* Whitton Rep. at 8.

Dr. Gershwin noted that Petitioner “had a subconjunctival hemorrhage and this was a manifestation of a mild viral infection.” First Gershwin Rep. at 4. He also stated that Petitioner “developed skin rashes, light sensitivity, and had a subconjunctival hemorrhage. ... The most likely explanation for this constellation of events is a viral infection.” Fourth Gershwin Rep. at 2. Presumably, Dr. Gershwin based his opinion that Petitioner suffered from light sensitivity and a rash from the note in the July 8, 2015 optometry record stating, Petitioner “has an array of chronic symptoms lately, seems to be since she had a flu shot last November: ears feel plugged, tinnitus, headaches, light sensitivity, rash post flu shot, etc.” Ex. 1 at 10.

I note that none of Petitioner’s contemporaneous optometry records document that she experienced light sensitivity. *See* Ex. 1 at 4-5 (record from December 11, 2014); Ex. 1 at 6-7 (record from December 30, 2014). Presumably, if she had been experiencing light sensitivity at either of the December 2014 appointments, she would have mentioned this to her optometrist, and it would have been documented in her records. Because it is not, it stands to reason that Petitioner did not develop light sensitivity until after these two appointments. This places the onset of Petitioner’s light sensitivity to sometime between January and July 2015.

The medical record from January 2, 2015, documents that Petitioner complained of candida intertrigo¹³ under her breasts that she treated with a nystatin cream.¹⁴ Ex. 9 at 4-6. Dr. Gershwin seemingly ascribes significance to candida intertrigo which occurred between five and six weeks after vaccination. Dr. Gershwin did not elaborate on how purported light sensitivity, candida intertrigo (a fungal infection), or subconjunctival hemorrhage (a broken blood vessel in the eye) indicate the presence of a viral infection.

Furthermore, it is unclear how the presence of a purported viral infection manifesting with eye redness on December 11, 2014, with candida intertrigo around January 2, 2015, and with light

¹³ Candida is “a heterogeneous genus of anamorphic fungi of the order Saccharomycetales that grow as yeast cells.” *Candida*, Dorland’s Online Med. Dictionary, www.dorlandsonline.com/dorland/definition?id=7699&searchterm=Candida (last accessed April 26, 2022). Intertrigo is defined as “a superficial dermatitis occurring on apposed skin surfaces, such as in the axillae or groin, beneath pendulous breasts, or in skin furrows. It is caused by moisture, friction, warmth, and sweat retention, and obesity is a predisposing factor.” *Intertrigo*, Dorland’s Online Med. Dictionary, www.dorlandsonline.com/dorland/definition?id=25690&searchterm=intertrigo (last accessed April 26, 2022).

¹⁴ Nystatin is “a polyene antifungal agent produced by the growth of *Streptomyces noursei*, effective against *Candida albicans* and other *Candida* species; used in the treatment of vaginal, intestinal, oropharyngeal, and cutaneous candidal infections, administered orally and topically.” *Nystatin*, Dorland’s Med. Dictionary Online, www.dorlandsonline.com/dorland/definition?id=34567 (last accessed April 15, 2022).

sensitivity between January and July of 2015, had *any bearing* on Petitioner's development of tinnitus on November 21, 2014.

The medical records do indicate that Petitioner had an upper respiratory infection in December 2014. *See e.g.*, Ex. 1 at 7 (December 30, 2014 appointment with Dr. Pierce, noting Petitioner "also has had cough/cold over the last week."). However, Dr. Gershwin does not cite this evidence in support of his position that Ms. Henry had a viral infection around the time of her flu vaccine on November 20, 2014. He instead opined that Petitioner "developed skin rashes, light sensitivity, and had a subconjunctival hemorrhage. ... The most likely explanation for this constellation of events is a viral infection." Fourth Gershwin Rep. at 2. Indeed, Petitioner has presented no evidence that an upper respiratory infection can incubate for a period of several weeks before signs and symptoms manifest.

Based on the above, I find there is not preponderant evidence that Petitioner had a viral infection at the time she received her flu vaccine.

D. Diagnosis: Preponderant Evidence Supports the Determination that Petitioner's Correct Diagnosis is Somatosensory Tinnitus and not AIED

In *Broekelschen v. Sec'y of Health and Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test."

At the outset, I note that Dr. Ying is a trained otologist and neurotologist, and is board certified in both otolaryngology and neurotology. Ying Rep. at 1. While Dr. Gershwin is certainly qualified to opine on matters involving immunology, he does not possess Dr. Ying's specialized training and experience in the field at issue in this case. As such, I have afforded Dr. Ying's opinion more weight than the opinion of Dr. Gershwin regarding the evaluation and assessment of Petitioner's inner ear condition.

Dr. Ying opined that Petitioner did not have AIED. She based this opinion on several factors.

1. Petitioner did not have Progressive Hearing Loss

AIED is "a bilateral SNHL with a decline in at least one ear evolving in greater than 3 days but less than 90." Vambutas & Pathak, *AAO: Autoimmune and Autoinflammatory (Disease) in Otolaryngology: What is New in Immune-Mediated Hearing Loss*, LARYNGOSCOPE INVESTIGATIVE OTOLARYNGOLOGY 1, 110-15 (2016) (filed as Ex. F, Tab 1).

Dr. Ying opined that hearing loss is the primary clinic sign of AIED. Ying Rep. at 12. Dr. Ying noted that "the hallmark clinical features are [the] presence of a rapidly progressive, often fluctuating, bilateral and asymmetrical sensorineural hearing loss over a period of between 3 and 90 days." *Id.* Because the medical records do not demonstrate that Petitioner's hearing changed

between the dates of her audiograms, this suggests that AIED is not her correct diagnosis. *Id.* at 13. In fact, Petitioner did not complain of hearing loss to her medical providers. *Id.* at 12.

Petitioner had an audiogram on June 4, 2015. Ex. 19 at 9. Dr. Ying opined as follows:

While there is no baseline audiogram for comparison, her first available audiogram dated 6/4/2015 which is about 7 months later from vaccination date, obtained before initial otolaryngology consultation on 6/18/2015 in the department of Otolaryngology at UCSD, only showed bilateral normal sloping to mild mid frequency SNHL, improving to normal with excellent word recognition score (100%) for both ears.

Ying Rep. at 12.

Petitioner had a follow up audiogram approximately one year later, on June 15, 2016, which, according to Dr. Ying “showed no hearing loss progression or fluctuation.” Ying Rep. at 13 (referencing Ex. 17 at 8, 11). After comparing these studies, Dr. Ying opined: “Based on published literature and my clinical experience, there should be documented progressive sensorineural hearing loss or even hearing threshold fluctuations for [an] AEID diagnosis.” Ying Rep. at 13. Dr. Ying went on to note that “[Petitioner’s] audiogram remains essentially unchanged a year later which disprove[s] the possible AIED diagnosis.” *Id.*

Dr. Ying’s education, training, and clinical expertise make her opinion especially persuasive on this matter. The fact that Petitioner did not experience rapidly progressive hearing loss is a point that favors heavily in my ultimate conclusion that preponderant evidence does not support Dr. Gershwin’s opinion that Petitioner’s correct diagnosis is AIED.

2. Petitioner’s Laboratory Work is not Supportive of AIED

Although Petitioner’s ANA was positive, the remainder of her lab work was negative, suggesting that she did not have AIED. This included testing from January of 2016 which resulted in a negative value for anti-68 KD Ab; a negative value for anti-DSDNA; and a negative value for anti-nuclear antibody titer. Ex. 2 at 15-16. Furthermore, Petitioner’s erythrocyte sedimentation rate, measured on June 24, 2015, was normal. Ex. 19 at 4. Dr. Ying opined that these results were not supportive of an AIED diagnosis. Ying Rep. at 13.

3. Petitioner’s Treating Physicians Consistently Diagnosed her with a Somatic Condition

“Somatosensory tinnitus is a generally agreed subtype of tinnitus that is associated with activation of the somatosensory, somatomotor, and visual-motor systems. A key characteristic of somatosensory tinnitus is that [it] is modulated by physical contact or movement.” Haider et al., *Pathophysiology, Diagnosis and Treatment of Somatosensory Tinnitus: A Scoping Review*, 11 FRONTIERS IN NEUROSCIENCE 207, 1-11 (2017) (filed as Ex. F, Tab 3). Møller noted that “[t]innitus often occurs together with temporomandibular joint (TMJ) problems or neck problems. Correction of such pathologies can often reduce a person’s tinnitus.” Aage R. Møller, *Sensorineural Tinnitus:*

Its Pathology and Probable Therapies, INTERNATIONAL JOURNAL OF OTOLARYNGOLOGY, <http://dx.doi.org/10.1155/2016/2830157> 1-11, 6, (2016) (filed as Ex. F, Tab 4). Buergers et al. demonstrated a significant correlation between tinnitus and temporomandibular disorders (“TMD”), noting that “[p]revalence of tinnitus was found to be 8 times higher in participants with TMD.” Buergers et al., *Is There a Link between Tinnitus and Temporomandibular Disorders?*, 111 J PROSTHET DENT 222-27, 222 (2014) (filed as Ex. F, Tab 11).

Petitioner’s treating physicians consistently either diagnosed her with somatosensory tinnitus or concluded that her tinnitus had a somatic cause. *See* Ex. 19 at 2 (July 30, 2015 visit with Dr. Lebovits who concluded that “the most likely major contributors” to Petitioner’s tinnitus were her cervical musculoskeletal problems and associated neck ache, and her bruxism with TMJ dysfunction); Ex. 2 at 47 (August 21, 2015 medical appointment where Dr. Viirre assessed Petitioner with possible viral labyrinthitis, hearing change with secondary tinnitus, and somatosensory tinnitus); Ex. 2 at 62 (November 18, 2015 visit where Dr. Kurisu assessed Petitioner with somatic dysfunction); Ex. 21 at 12 (June 7, 2016 medical visit where Dr. Alexander noted Petitioner had “TMJ and augmentation of her tinnitus by musculoskeletal activity suggesting somatosensory tinnitus.”); Ex. 21 at 9 (June 14, 2016 visit where Petitioner reported significant improvement of her tinnitus after a deep tissue massage, which according to Dr. Alexander “supports the diagnosis of somatosensory tinnitus.”); Ex. 17 at 1 (November 29, 2016 visit with Dr. Bruce Reisman, who noted “a long history of fullness in the ears and tinnitus” that he believed was “secondary to TMJ.”).

Dr. Ying opined that Petitioner’s responsiveness to OMT and physical therapy further suggest that she suffers from somatosensory tinnitus. Ying Rep. at 15.

The only one of Petitioner’s treating physicians who mentioned AIED was Dr. Viirre. Dr. Viirre listed viral labyrinthitis versus AIED as differential diagnoses on January 25, 2016. Ex. 2 at 86. He ordered an autoimmune workup, presumably to test for autoimmune markers supportive of AIED. As discussed above, Petitioner’s lab work did not support a diagnosis of AIED, and Dr. Viirre never did diagnose her with that condition.

Dr. Ying noted the fact that none of Petitioner’s treating physicians referred her to a rheumatologist suggests that they did not believe she suffered from AIED. Dr. Ying stated that Petitioner “was seen by so many specialists, yet her PCP, neurologist or even Dr. E.S. Viirre (neurotologist) was not convinced to refer her to a rheumatologist for consultation based on her clinical history, and available data without knowing the pathogenesis of an uncontrolled immune system response.” Ying Rep. at 14.

The fact that Petitioner experienced an amelioration of tinnitus after osteopathic manipulative treatments (OMT) further supports her diagnosis with somatosensory tinnitus. In a letter dated March 3, 2018, Dr. Kurisu wrote that, although Petitioner has “tried and failed multiple medication regimens” to treat her tinnitus, she “does get relief from neurological electronic auditory reprogramming as well as Osteopathic manipulative treatments as well as her therapy appointments.” Ex. 84 at 7. Several other medical records support this statement by Dr. Kurisu. *See* Ex. 14 at 2 (Acupuncture record from February 11, 2016 noting “neck pain decreased for 24 hours after [treatment]. Tinnitus/pressure decreased for several hours.”); Ex. 14 at 1 (Acupuncture

record from February 18, 2016 which notes “neck pain/tinnitus decreased for several hours after [treatment]. Both came back raging by 2AM that night.”); Ex. 2 at 96 (Medical record from April 14, 2016 visit with Dr. Alexander, who diagnosed “[t]innitus with possible somatosensory component,” and noted that Petitioner was “responsive to [OMT] suggesting the somatosensory component.”); Ex. 2 at 102 (medical appointment with Dr. King where Petitioner reported “tinnitus and neck and jaw, constantly sore and TMJ problem. Only thing helping is OMT.”). Although in her supplemental declaration, Petitioner disputed that the OMT improved her tinnitus for more than a few hours and instead stated that it only reduced her neck and jaw pain, the medical records cited above belie this statement. “Written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.” *Reusser v. Sec’y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

For all these reasons, I find that Petitioner has not established Dr. Gershwin’s diagnosis of AIED by a preponderance of the evidence. Dr. Ying is persuasive that Petitioner’s correct diagnosis is Somatosensory Tinnitus. This opinion is consistent with the opinions of Dr. Alexander, Dr. Lebovits, Dr. Kurisu, and Dr. Reisman.

E. *Althen* Prong One

In the context of the Program, “to establish causation, the standard of proof is preponderance of evidence, not scientific certainty.” *Langland v. Sec’y of Health & Hum. Serv.*, 109 Fed. Cl. 421, 441 (2013). Petitioner’s burden under *Althen*’s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359.

I note at the outset that Petitioner’s causation theory is somewhat unclear. Dr. Gershwin has opined as follows:

The mechanism of action of this immunological reaction is most consistent with antibody response and, in particular, the initial production of an autoantibody which cross reacts with a component of her viral infection and a self antigen, in this case a component in the auditory nerve.

First Gershwin Rep. at 4. Dr. Gershwin maintained that “the continuation of her symptoms would eventually be that of an IgG response.” *Id.* He concluded, stating that

the autoantibody produced by Ms. Headding, in response to the breakage of tolerance to a self antigen, was a viral infection for whom loss of tolerance and cross reactivity was induced and perpetuated by the bystander cellular and cytokine response elicited by the influenza vaccine.

Id. Dr. Whitton remarked on this last statement, indicating that he “found this sentence difficult to understand (it appears to state that the autoantibody was a viral infection, which makes no sense to me).” Whitton Rep. at 9. Dr. Phillips wrote that the sentence was “uninterpretable and meaningless.” First Phillips Rep. at 11.

In distilling Dr. Gershwin's four reports, Petitioner's theory in this case appears to be that Petitioner's subclinical viral infection initiated an IgM antibody response causing cross-reactivity between the virus and the auditory nerve. First Gershwin Rep. at 4; Fourth Gershwin Rep. at 3. Petitioner's flu vaccination accelerated this immune response via bystander activation. Fourth Gershwin Rep. at 3. This understanding is in accord with that of Dr. Whitton, who wrote that Dr. Gershwin's theory involved "a speculative notion that a viral infection set up an environment that allowed the vaccine to induce bystander cells and cytokines that led to tinnitus." Whitton Rep. at 11.

Dr. Gershwin cited references discussing molecular mimicry. While these references do provide support for the concept of molecular mimicry, none supports the application of that theory to a case of hearing loss. The Nachamkin article discusses cross-reactivity between components of the flu vaccine and the anti-GM1 antibody in Guillain Barré syndrome. Nachamkin et al, *Anti-Ganglioside Antibody Induction by Swine (A/NJ/1976/H1N1) and Other Influenza Vaccines: Insights into Vaccine-Associated Guillain-Barré Syndrome*, 198 THE JOURNAL OF INFECTIOUS DISEASES, 226-33 (2008) (filed as Ex. 113). The Markovic-Plese study found that cloned human T-cells which reacted to an influenza virus hemagglutinin peptide also reacted to three peptides derived from human myelin proteins, and further, that significant homology existed between flu-hemagglutinin and those myelin proteins. Markovic-Plese, et al., *High level of cross-reactivity in influenza virus hemagglutinin-specific CD4+ T-cell response: Implications for the initiation of autoimmune response in multiple sclerosis*, 169 JOURNAL OF NEUROIMMUNOLOGY 31-38 (2005) (filed as Ex. 26) (hereinafter "Markovic-Plese"). The Markovic-Plese study involved multiple sclerosis. Petitioner did not offer any literature discussing the ability of the flu vaccine to cross-react with self-structures in the inner ear.

Although molecular mimicry may constitute a reliable causation theory involving the flu vaccine and various other injuries, that fact does not render it a persuasive theory when evaluating an entirely different disease. See *McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1541V, 2019 WL 4072113 at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) ("[M]erely chanting the magic 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 vaccine in question."). Because Dr. Gershwin did not connect the theory of molecular mimicry to AIED or tinnitus, I do not find it to be a persuasive theory in this context.

Furthermore, my finding that Petitioner did not have a subclinical viral infection eliminates a critical step in Dr. Gershwin's causation theory. If there was no viral infection, then there was no "initial production of an autoantibody which cross react[ed] with a component of her viral infection." (citing First Gershwin Rep. at 4). As Dr. Whitton noted in his report, "[i]f one accepts that there is no evidence that petitioner was suffering from a viral infection at the time of her flu vaccination, then it seems to me that Dr. Gershwin and I agree that the vaccine is exculpated." Whitton Rep. at 11.

Similarly, while Dr. Gershwin has provided medical literature supporting the general concept of bystander activation, this literature does not contemplate that vaccination causes disease of the inner ear via this process. See Fujinami, et al., *Molecular Mimicry, Bystander Activation, or Viral Persistence: Infections and Autoimmune Disease*, 19 CLINICAL MICROBIOLOGY REVIEWS 1,

80-94 (2006) (filed as Ex. 136). I also note that Dr. Gershwin did not explain how these bystander cells trafficked from the cite of purported infection to the inner ear.

Respondent filed the Baxter article, which was directly applicable to the issues raised in this case. Baxter et al. studied whether there was an association between vaccination and sudden sensorineural hearing loss. Baxter studied first time diagnoses of sudden sensorineural hearing loss from 2007 through 2013. During this time, more than 20 million vaccines were administered; this number included more than eight million trivalent inactivated flu vaccines (TIV). Baxter at 83. Baxter concluded: “We found no increased risk of prior TIV vaccination in patients with SSHL in any of the prespecified risk intervals.” *Id.*

Petitioner is not required to present medical literature or epidemiological evidence to establish the first *Althen* prong. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009). But epidemiology, when filed, is relevant to my determination concerning whether the flu vaccine can cause a particular disease, in this case, AIED. *Id.* The Baxter article constitutes persuasive evidence that there is no such association. The Federal Circuit noted in *Andreu*, that “a claimant’s theory of causation must be supported by a ‘reputable medical or scientific explanation.’” *Andreu*, 569 F.3d at 1379 (quoting *Althen*, 418 F.3d at 1278). Petitioner has not presented such a reputable explanation in this case; as such, she has failed to present preponderant evidence in support of *Althen* prong one.

F. *Althen* Prong Two

Under *Althen*’s second prong, Petitioner must “prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be “‘logical’ and legally probable, not medically or scientifically certain.” *Id.* Petitioner is not required to show “epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” *Id.* (omitting internal citations). *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong. *Isaac v. Sec’y of Health & Hum. Servs.*, No. 08-601V, 2012 U.S. Claims LEXIS 1023 at *75 (Fed. Cl. Spec. Mstr. July 30, 2012), *aff’d* 108 Fed. Cl. 743 (Fed. Cl. 2013).

Petitioner has provided scant evidence in support of the second *Althen* prong. Petitioner contends that because several treating physicians associated the flu vaccine with her condition, this satisfies her burden of proof. *See* Pet’r’s Brief at 29-31. While I have considered the opinions of Petitioner’s treating physicians, I do not find these opinions to be persuasive in this case.

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec’y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). However, the opinions of treating physicians are not sacrosanct. *Snyder v. Sec’y of Health*

& *Hum. Servs.*, 88 Fed.Cl. 706, 745 n.67 (2009). These opinions are only as trustworthy as the reasonableness of their suppositions or bases.

Petitioner cites to three providers in support of her position. Dr. Kurisu, Dr. Millet, and Nurse Lim. Pet'r's Brief at 29-31. I will address each in turn.

Michael Kurisu, DO is Petitioner's treating family medicine doctor. Dr. Kurisu submitted a letter on Petitioner's behalf dated February 1, 2017. The letter, in its entirety, reads as follows:

Darlene is a patient that is under my care. She has been suffering from somatosensory tinnitus since 2014 and has attributed her symptoms after receiving the influenza vaccination at that time. Her tinnitus has been debilitating and has caused a decrease in her quality of life. It would be to her benefit if she did not receive the vaccination in the future. Darlene is well aware of all the risks involved avoiding the vaccination.

Ex. 3 at 1. According to Petitioner, this statement by Dr. Kurisu indicates his belief that "the flu vaccine was the cause of the issues although he does not say it *explicitly* it is *implicit* in this statement." Pet'r's Brief at 30 (emphasis in original). The fact that Dr. Kurisu opined that it would benefit Petitioner not to receive the flu vaccine in the future is some evidence favorable to Petitioner. However, I do not find Dr. Kurisu's statement indicates his belief that the flu vaccine caused her condition. Dr. Kurisu noted that *Petitioner* has attributed her symptoms to vaccination. Further, he remarked that "it would be to her benefit" not to receive future flu vaccines. Dr. Kurisu did not offer an opinion as to whether the flu vaccine caused Petitioner's condition, or if it did, how it did so. Ultimately, while I have considered this statement, I do not find it is persuasive on the issue of causation.

I further note that during a visit on April 28, 2017, Dr. Kurisu's assessment included his opinion that Petitioner's complaints "may be attributed in part to underlying somatic dysfunction as described above." Ex. 53 at 5. Based on this impression, Dr. Kurisu applied Osteopathic Manipulative Treatment (OMT), which was immediately beneficial. *Id.* Dr. Kurisu did not indicate the flu vaccine was the cause of Petitioner's condition during this visit in April 2017. *See also, id.* at 6-11 (medical record from May 17, 2017 noting the same impression and treatment).

Petitioner also points to medical records from Dr. Millet as support for her position. On July 8, 2015, Petitioner visited Dr. Millet at Carlsbad Optometry. Dr. Millet made the following notes in Petitioner's medical records: "pt has an array of chronic symptoms lately. [S]eems to be since she had a flu shot last [N]ovember: ears feel plugged, tinnitus, headaches, light sensitivity, rash post flu shot, etc." Ex. 1 at 10. Petitioner argues that in making this notation, Dr. Millet indicated the vaccination was the cause of her issues. Pet'r's Brief at 29-30. Dr. Millet's notes are contained in the "history of present illness" section of the record. That section is often referred to as the subjective portion of the record; in other words, it is based on patient history. While Dr. Millet did record Petitioner's report that she experienced symptoms "since she had a flu shot", this notation simply documents a temporal association between these two events; it does not ascribe causality to the flu vaccine. While I have considered this record, I have not afforded it great weight on the issue of whether the flu vaccine "did cause" Petitioner's condition.

Finally, Petitioner points to a note authored by Nurse Elizabeth Lim. On November 21, 2014, Nurse Lim noted: “Ringing in the ears can possibly be one of the side effects of the vaccine. This usually begin[s] soon after the shot and last[s] 1 to 2 days.” Ex. 5 at 1. While Nurse Lim does ascribe causality to the vaccine, I have not afforded this notation great persuasive weight as it was not authored by a physician. *See Canuto v. Sec’y of Health & Hum. Servs.*, No. 04-1128V, 2015 WL 9854939, n.21 (Fed. Cl. Spec. Mstr. Dec. 18, 2015) (noting that “a nurse is generally not qualified to offer an opinion regarding the causation of medical conditions.”); *mot. rev. denied*, 2016 WL 2586510 (Fed. Cl. 2016); *aff’d*, 660 Fed. Appx. 955 (Fed. Cir. 2016); *cert. denied*, 137 S.Ct. 2221 (2017). In addition, Dr. Whitton disputed the accuracy of this statement, further undercutting its persuasive weight. *See* Whitton Rep. at 15.

I also note that one of Petitioner’s treating doctors specifically disavowed a connection between Petitioner’s vaccination and her development of tinnitus. In a visit on July 30, 2015, Dr. Marc Lebovits, an otolaryngologist, opined as follows:

Patient has multiple problems that can be associated with tinnitus. By history, her cervical musculoskeletal problems and associated neck ache, and her bruxism with TMJ dysfunction are the most likely major contributors. Other than time course, I cannot relate the tinnitus to her flu shot. Her rhinitis with eustachian tube dysfunction unilaterally and her very mild sensory hearing loss may also be contributing to her tinnitus.

Ex. 19 at 2. The fact that Dr. Lebovits is an otolaryngologist lends additional persuasive authority to his opinion that Petitioner’s flu vaccine was not the cause of her condition.

The court in *Capizzano* found medical opinion evidence to be probative with respect to the second *Althen* prong when it was coupled with both a showing that a vaccine can cause a specific injury and evidence demonstrating a close temporal relationship between the vaccine and the injury. *Capizzano*, 440 F.3d at 1326. This case differs from *Capizzano* in that I have not found Petitioner presented a sound and reliable *Althen* prong one theory. This fact, coupled with the limitations discussed above concerning the opinions of Dr. Kurisu, Dr. Millet, and Nurse Lim, and the contrary opinion of Dr. Lebovits, render Petitioner’s *Althen* prong two showing deficient.

For the reasons articulated above, I find that Petitioner has failed to preponderantly demonstrate that Petitioner’s flu vaccine “did cause” any of her medical problems and she has thus not established the second prong of *Althen*.

G. *Althen* Prong Three

The timing prong contains two parts. First, Petitioner must establish the “timeframe for which it is medically acceptable to infer causation” and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff’d without op.*, 503 Fed. App’x 952 (Fed. Cir. 2013).

In this case, Petitioner consistently reported an onset of symptoms 20 hours post-vaccination. She acknowledged that 20 hours is too short a period of time for an adaptive immune response. Dr. Gershwin stated, “It normally takes 24-48 hours to begin to see a significant IgM response.” First Gershwin Rep. at 4. However, Dr. Gershwin opined that Petitioner’s viral infection combined with the vaccination hastened the process.

I have already noted that she had a subconjunctival hemorrhage and this was a manifestation of a mild viral infection. I do not believe that the viral infection alone would have produced this magnitude and duration of clinical tinnitus. In fact, had her physicians been aware that she was developing a viral infection that was a potential prodrome of an autoimmune reaction, they would never have immunized her with influenza. Of course that would have required a crystal ball. The influenza vaccine includes recruitment of a variety of bystander cells based on the ability of the vaccine to elicit cytokine production and elicit an immune response. This process would amplify an immune response, including polyclonal B cell activation, which would accentuate and facilitate loss of tolerance including a viral induced self response. The concurrent vaccination would as part of the polyclonal activation facilitate the class switch from IgM to IgG and thus the perpetuation of the injury.

Id. Because I have found there is not preponderant evidence that Petitioner was suffering from a subclinical viral infection at the time of her vaccination, I also do not find that the onset of Petitioner’s tinnitus occurred in a timeframe for which it is medically acceptable to infer causation. In short, Petitioner’s onset of tinnitus 20 hours after vaccination is too short a period of time to inculcate the flu vaccine as causal. This finding is consistent with Dr. Gershwin’s statement that “[i]t normally takes 24-48 hours to begin to see a significant IgM response.” First Gershwin Rep. at 4. It is also consistent with Dr. Whitton’s opinion that “[T]here is no credible biological basis to the notion that flu vaccine can cause an IgM-mediated disease within 20 hours of injection.” *Id.* at 11. Finally, it is consistent with Dr. Ying’s report, where she opined that “time course of events (< 24 hours) appears medically inappropriate to infer vaccine causation for tinnitus.” Ying Rep. at 11.

Further, the medical literature filed in this case does not support an onset interval of 20 hours after vaccination. Nachamkin noted that it took at least seven days to see “[s]ignificant increases in both IgM and IgG antibodies to GM1 ganglioside.” Nachamkin at 229. Mantegazza et al. discussed the induction of experimental autoimmune Myasthenia gravis (EAMG) in Lewis rats via immunization. Mantegazza et al., *Animal models of myasthenia gravis: utility and Limitations*, INTERNATIONAL JOURNAL OF GENERAL MEDICINE, 53-64 (2016) (filed as Ex. D, Tab 3). The authors observed that it took seven days to produce sufficient IgM antibodies to cause disease. Mantegazza at 55.

In sum, I do not find that Petitioner has preponderantly established that 20 hours post vaccination is a medically acceptable onset interval to inculcate the flu vaccine. As a result, Petitioner has not met her burden to provide preponderant evidence with respect to *Althen* prong three.

VII. CONCLUSION

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits, and the experts reports and medical literature, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**¹⁵

IT IS SO ORDERED.

s/ Katherine E. Oler

Katherine E. Oler
Special Master

¹⁵ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.