In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: March 4, 2024

SALLY HERMS,	*	PUBLISHED
Petitioner,	*	No. 19-70V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal; Diphtheria Tetanus Toxoid Acellular Pertussis ("DTaP") Vaccine; Sensorineural Hearing Loss ("SNHL").
Respondent.	*	

John F. McHugh, Law Office of John McHugh, New York, NY, for Petitioner.
Mitchell Jones, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On January 15, 2019, Sally Herms ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018),[2] alleging that she sustained injuries "due to an adverse reaction to a [diphtheria tetanus toxoid acellular pertussis ("DTaP")] vaccination given to her on June 18, 2017, which resulted in her loss of hearing on her left side and constant loud tinnitus." Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating "this case is not

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) ("Vaccine Act" or "the Act"). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

appropriate for compensation under the terms of the Act." Respondent's Report ("Resp. Rept.") at 1 (ECF No. 38).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards, the undersigned finds Petitioner has failed to provide preponderant evidence that the DTaP vaccine she received caused her hearing loss and tinnitus. Thus, Petitioner has failed to satisfy her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, the petition must be dismissed.

I. ISSUES TO BE DECIDED

The parties stipulate that Petitioner received the DTaP vaccine on June 18, 2017. Joint Submission, filed Mar. 24, 2023, at 1 (ECF No. 132). They also stipulate that "[t]wo days later, she experienced fever, muscle aches[,] and a feeling of being in a tunnel. She awoke and found she was deaf in her left ear. The following morning, she had tinnitus in her left ear." Id.

The parties do not dispute the diagnosis of hearing loss and tinnitus. However, they dispute causation and state that the following issues require resolution: "Can DTaP cause an autoimmune attack on nerves? Is onset of [Petitioner's] condition within the time frame of an autoimmune reaction to the vaccination? Is [Petitioner's] record consistent with an autoimmune or other adverse reaction to the DTaP vaccination? Is there any other explanation for the onset of her conditions?" Joint Submission at 2.

Although the parties identify the issues above, the undersigned finds that the correct legal standards applicable here are those articulated in Althen. Althen, 418 F.3d at 1278 (indicating Petitioner must establish, by preponderant evidence, "(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").

II. BACKGROUND

A. Procedural History

Petitioner filed her petition on January 15, 2019. Petition. On April 29, 2019, Petitioner filed medical records,[3] and on August 19, Petitioner filed a declaration.[4] Petitioner's Exhibits ("Pet. Exs.") 1-8. On October 3, 2019, the case was reassigned to the undersigned. Notice of Reassignment dated Oct. 3, 2019 (ECF No. 22). On November 14, 2019, Petitioner filed an

[3] Petitioner continued to file medical records throughout the course of litigation.

[4] This exhibit is titled "Affidavit," but it is not notarized, and therefore the undersigned references it as a declaration. The same is true of a second declaration filed by Petitioner on July 31, 2021. ECF No. 93-1. Some of Petitioner's exhibits are not labeled. Therefore, the undersigned will refer to those exhibits by their ECF numbers.

expert report from Dr. Arthur E. Brawer. Pet. Ex. 10. Respondent filed his Rule 4(c) Report arguing against compensation on July 16, 2020. Resp. Rept. at 1.

On August 17, 2020, Petitioner filed a supplemental expert report from Dr. Brawer. Pet. Ex. 50. On September 14, 2020, Respondent filed an expert report from Dr. Ross M. Kedl. Resp. Ex. A.

On December 17, 2020, an order to show cause issued for Petitioner's failure to file medical records. Order to Show Cause dated Dec. 17, 2020 (ECF No. 66). In response, Petitioner filed a status report and medical records. See ECF No. 67.

At the request of the parties, the undersigned held a Rule 5 conference on July 27, 2021. Pet. Joint Status Rept., filed June 22, 2021 (ECF No. 90); Order dated July 27, 2021 (ECF No. 92). However, the undersigned was unable to give her preliminary findings and opinions due to an incomplete record. Order dated July 27, 2021, at 1. A second order to show cause issued on September 9, 2021. Order to Show Cause dated Sept. 9, 2021 (ECF No. 94). At a status conference on September 24, 2021, the undersigned indicated Petitioner did not need to respond to the order to show cause. Order dated Sept. 24, 2021, at 2 (ECF No. 97). Although Petitioner did not provide everything that was requested, the undersigned found the order to show cause satisfied. Id.

On April 27, 2022, Petitioner filed an expert report from Dr. Marcel Kinsbourne. Pet. Ex. 163. On October 25, 2022, Respondent filed a supplemental report from Dr. Kedl, and Petitioner filed a supplemental report from Dr. Kinsbourne on November 28, 2022. Resp. Ex. C; Pet. Ex. 164.

The parties agreed to resolve the issue of causation through a ruling on the record rather than an entitlement hearing. Pet. Status Rept., filed Jan. 3, 2023 (ECF No. 126); Resp. Joint Status Rept., filed Feb. 6, 2023 (ECF No. 129) (confirming the record is complete and indicating the parties previously discussed informal resolution but that Respondent intended to proceed on a litigation track).

On March 22, 2023, Petitioner filed her motion for a ruling on the record. Pet. Motion for Ruling on the Record ("Pet. Mot."), filed Mar. 22, 2023 (ECF No. 131). Respondent filed his response on June 21, 2023. Resp. Response to Pet. Mot. ("Resp. Response"), filed June 21, 2023 (ECF No. 138). On June 26, 2023, Petitioner filed a reply. Pet. Reply in Support of Pet. Mot. ("Pet. Reply"), filed June 26, 2023 (ECF No. 139).

This matter is now ripe for adjudication.

B. Factual History

1. Stipulated Facts

The parties agreed to the following stipulated facts as set forth in their Joint Submission. See Joint Submission at 1. Petitioner received the DTaP vaccine on June 18, 2017. Id. "Two

days later, she experienced fever, muscle aches[,] and a feeling of being in a tunnel. She awoke and found she was deaf in her left ear. The following morning, she had tinnitus in her left ear." Id.

2. Summary of Medical Records

In addition to the facts stipulated to by the parties, the following summary of medical records provides additional relevant information.

Petitioner's prior medical history was significant for hypertension. Pet. Ex. 1 at 1-3 (ECF No. 8-1).[5] Prior to receiving the vaccination at issue, Petitioner was seen at an urgent care facility on March 21, 2017, for complaints of "sinus infection, coughing, pressure, [and] eyes bright red and swollen for about three days." Pet. Ex. 45 at 1. Physical examination revealed bilateral conjunctivitis with redness but no drainage. Id. at 1-2. Her ear examination did not reveal any redness or swelling, and her hearing was "grossly intact." Id. at 1. She was diagnosed with bronchitis and conjunctivitis and given a prescription for Biaxin[6] and TobraDex[7] eye drops. Id. at 2.

Petitioner was fifty-eight years old at the time she received a DTaP vaccination on June 18, 2017 at a Walgreens pharmacy. Pet. Ex. 4 at 1.

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[5] Some of Petitioner's exhibits are mislabeled or duplicative. Therefore, to avoid confusion, the undersigned will refer cross-reference those exhibits with their ECF numbers.

[6] Biaxin is trademark for clarithromycin which is a "macrolide antibiotic effective against a wide spectrum of gram-positive and gram-negative bacteria, used in the treatment of respiratory tract infections and skin and soft tissue infections, and in conjunction with omeprazole in the treatment of duodenal ulcer associated with Helicobacter pylori infections." Clarithromycin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=9992 (last visited Feb. 20, 2024); Biaxin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=5990 (last visited Feb. 20, 2024).

[7] TobraDex is trademark for combinations of preparations of tobramycin and dexamethasone. TobraDex, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=50179 (last visited Feb. 20, 2024). Tobramycin is "an aminoglycoside antibiotic . . . effective against a wide range of aerobic gram-negative bacilli and some gram-positive bacteria . . . used topically in the treatment of external infections of the eye and its adnexa." Tobramycin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=50180 (last visited Feb. 20, 2024). Dexamethasone is "a synthetic glucocorticoid, 25 times as potent as cortisol; used topically on the skin and conjunctiva as an antiinflammatory and administered orally in replacement therapy for adrenocortical insufficiency, as an antiinflammatory and immunosuppressant in a wide variety of disorders, and as an antiemetic in cancer chemotherapy." Dexamethasone, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=13599 (last visited Feb. 20, 2024).

On June 20, 2017, Petitioner presented to her primary care physician ("PCP"), Dr. Nasseredin ("Nasser") Shariati, with complaints of stiffness, chills, ear congestion, hearing loss, and "feeling that she [was] in a tunnel," after receipt of the DTaP vaccine two days earlier. Pet. Ex. 1 at 1 (ECF No. 8-1). She also had body aches and a fever but was "somewhat better" at the time of the visit. Id. Dr. Shariati noted Petitioner was "obviously concerned about the possibility of side effect." Id. Physical examination revealed minimal amount of wax in her left ear, and "[a]udiometry a[t] 25 dB revealed marked hearing loss on left side." Id. Dr. Shariati's impression was "[p]robable side effects from receiving DTaP" and "wax buildup on the left ear." Id. He noted "one has to be concerned about the possibility of acoustic neuroma[8] as [Petitioner's] younger daughter suffered from acoustic neuroma on her left ear and [as] result[] of that[,] she lost her hearing on that side permanently." Id. Petitioner's list of current medications included Bactrim,[9] Cipro,[10] Lisinopril,[11] and Lo Loestrin Fe.[12] Id. at 2. Diagnosis

[8] An acoustic neuroma is "a progressively enlarging, benign tumor, usually within the internal auditory canal arising from Schwann cells of the vestibular division of the eighth cranial nerve." Acoustic Neuroma, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92588 (last visited Jan. 23, 2024).

[9] Bactrim is trademark for combination preparations of trimethoprim and sulfamethoxazole. Bactrim, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=5402 (last visited Feb. 20, 2024). Trimethoprim is "an antibacterial closely related to the antimalarial pyrimethamine, acting by inhibiting a step in bacterial folate biosynthesis and effective against various gram-negative and gram-positive bacteria; administered orally in the prophylaxis and treatment of urinary tract infections and the treatment of pneumocystis pneumonia." Trimethoprim, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=51090 (last visited Feb. 20, 2024). Sulfamethoxazole is "a sulfonamide used as an antibacterial active against various gram-negative and gram-positive organisms, especially for the treatment of acute urinary tract infections, and as an antiprotozoal." Sulfamethoxazole, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=47958 (last visited Feb. 20, 2024).

[10] Cirpro is trademark for preparations of ciprofloxacin hydrochloride which is "the monohydrated hydrochloride salt of ciprofloxacin, having the same actions as the parent compound and used to treat a wide variety of bacterial infections; administered orally, intravenously, and topically to the conjunctiva." Ciprofloxacin Hydrochloride, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=65257 (last visited Feb. 20, 2024); Cipro, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=9880 (last visited Feb. 20, 2024).

[11] Lisinopril is "the lysine derivative of the active form of enalapril; an angiotensin-converting enzyme inhibitor used in the treatment of hypertension (alone or in combination with a thiazide diuretic), congestive heart failure, and acute myocardial infarction; administered orally." Lisinopril, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=28515 (last visited Feb. 20, 2024)

was "[u]nspecified sensorineural hearing loss [("SNHL")]."[13] Id. Dr. Shariati's plan of treatment included "application of Debrox into her left ear" to clear out the wax, consideration of computed tomography ("CT") scan to rule out acoustic neuroma, and for Petitioner to resume taking her antihypertensive medication, which she had discontinued. Id. at 1.

On June 29, 2017, Petitioner presented to otolaryngologist Dr. Gregory Fleming. Pet. Ex. 1 at 3 (ECF No. 8-1). History notes indicated Petitioner had "sudden [SNHL] in the left ear which began on June 19, 2017. It began 24 hours after having a [DTaP] vaccine. She did have some arm discomfort and some generalized rigors but no fever. She awoke the next day with diminished hearing in the left ear." Id. at 4. Petitioner presented complaining of a "seashell type tinnitus[14] but no vertigo[15] or ear pain." Id. Petitioner denied barotrauma, a history of Lyme disease, sinus complaints, sore throat, difficulty swallowing, or a preceding upper respiratory infection. Id. Dr. Fleming also noted Petitioner's daughter had an acoustic neuroma but was "doing well following surgery." Id. On examination, Dr. Fleming noted Petitioner's cranial

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[12] Lo Loestrin Fe is trademark for combination preparations of norethindrone acetate, ethinyl estradiol, and iron. Lo Loestrin Fe, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=28707 (last visited Jan. 23, 2024). Norethindrone acetate is "used in the treatment of secondary amenorrhea, dysfunctional uterine bleeding, and endometriosis." Norethindrone Acetate, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=93416 (last visited Jan. 23, 2024). Ethinyl estradiol "a semisynthetic derivative of estradiol, one of the most potent estrogens. It is used in combination with a progestational agent in oral contraceptives and contraceptive patches, and administered orally in hormone replacement therapy." Ethinyl Estradiol, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=73904 (last visited Jan. 23, 2024).

[13] Sensorineural hearing loss or SNHL is "hearing loss due to a lesion in either the cochlea (sensory mechanism of the ear), the vestibulocochlear nerve, the central neural pathways, or a combination of these structures." Sensorineural Hearing Loss, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=80207 (last visited Jan. 23, 2024). It results from either damage to the cochlea or "disruption of the electrical conduction pathway from the inner ear to the brain. Thus, injury to hair cells, supporting cells, auditory neurons, or the central auditory pathway can cause [SNHL]." Anil K. Lalwani, Disorders of Hearing, in 1 Harrison's Principles of Internal Medicine 238, 240 (Joseph Loscalzo et al. eds., 21st ed. 2022). Damage to the hair cells may be caused by intense noise, viral infections, or aging. Id.

[14] Tinnitus is "a noise in the ears, such as ringing, buzzing, roaring, or clicking. It is usually subjective in type." Tinnitus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=50114 (last visited Jan. 23, 2024).

[15] Vertigo is "an illusory sense that either the environment or one's own body is revolving; it may result from diseases of the internal ear or may be due to disturbances of the vestibular centers or pathways in the central nervous system." Vertigo, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=52968 (last visited Jan. 23, 2024).

nerves II-XII were intact. Id. Petitioner's hearing test revealed a "moderate to severe [SNHL] in the left ear with no discernible speech discrimination. The tympanograms were normal. The right ear appeared normal." Id.; see also Pet. Ex. 52 at 10-11. The plan was to begin a prednisone taper (steroids), obtain magnetic resonance imaging ("MRI") to rule out an acoustic neuroma, and order a serology screening. Pet. Ex. 1 at 4 (ECF No. 8-1). "Antivirals were deferred in light of the 10 day[s] since onset of her hearing loss." Id. Intratympanic steroids were discussed but Petitioner declined. Id. Dr. Fleming's diagnosis was SNHL and tinnitus in the left ear. Id.

A brain MRI performed on July 14, 2017 was normal. Pet. Ex. 1 at 12 (ECF No. 8-1). There was no evidence of an acute infarction, mass effect, pathologic enhancement, or cerebellopontine angle mass. Id. at 12-13. Serology results showed negative Lyme immunoblot and negative C-reactive protein.[16] Id. at 9-11. Creatinine and blood urea nitrogen were normal. Id. at 10.

On July 25, 2017, Petitioner returned to Dr. Fleming for a follow-up visit following prednisone treatment. Pet. Ex. 1 at 18, 20 (ECF No. 8-1). Dr. Fleming informed Petitioner of her normal lab work and normal brain MRI. Id. at 20. Petitioner denied ear pain but expressed interest in pursuing all treatment possible "prior to possible initiation of a lawsuit regarding a possible vaccine side effect as the cause of her hearing loss." Id. Petitioner's hearing test, performed July 18, 2017 showed "good improvement of her speech discrimination but persist[ent] moderate [SNHL] on pure tone testing." Id. Petitioner requested a "neuro-otologic evaluation prior to initiating any invasive treatment," and planned to contact otolaryngologist Dr. Samuel Selesnick who had previously performed her daughter's acoustic neuroma surgery. Id. She was to follow-up with Dr. Fleming's office for her SNHL and discuss the possibility of intratympanic steroids. Id. "She [was] aware that time [was] of the essence regarding this type of treatment." Id. Petitioner refused a hearing aid in light of her improved speech discrimination. Id.

Petitioner saw otolaryngologist Dr. Jed Kwartler on July 27, 2017. Pet. Ex. 1 at 22 (ECF No. 8-1). She presented for an evaluation for "left sudden hearing loss" that occurred on "June 18 after a [DTaP] vaccine." Id. at 23. Petitioner also reported mild, low-level tinnitus. Id. No vertigo, head trauma, antecedent illnesses, prior hearing loss, or dizziness were noted. Id. Hypertension was documented as a significant comorbidity. Id. Dr. Kwartler reviewed Petitioner's most recent hearing test which showed "moderately severe left [SNHL] with 80% discrimination." Id. Because it had been approximately six weeks since onset, Dr. Kwartler explained that the likelihood of improvement with intratympanic steroid injections was decreased. Id. It was noted that they "spent time talking about the pathophysiology of idiopathic sudden [SNHL]." Id. Dr. Kwartler recommended a hearing aid as her next step, given "her reasonably good discrimination." Id.

[16] C-reactive protein is "a globulin that forms a precipitate with the somatic C-polysaccharide of the pneumococcus in vitro; it is the most predominant of the acute-phase proteins." C-Reactive Protein, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=100489 (last visited Feb. 20, 2024).

Petitioner presented for an updated hearing test on April 11, 2018. Pet. Ex. 52 at 4-7. Petitioner was going to a specialist in New York City the following day and the doctor requested an updated audiogram. Id. at 5. The notes stated "[history] of sudden hearing loss [] which [Petitioner] attribute[d] to [DTaP] vaccine, hearing loss happened [one and one half] days post vaccine." Id.; see also Pet. Ex. 1 at 24 (ECF No. 8-1).

The following day, on April 12, Petitioner saw Dr. Selesnick at Weill Cornell Otolaryngology Head and Neck Surgery. Pet. Ex. 1 at 26 (ECF No. 8-1). Notes indicated Petitioner received the DTaP vaccine in June 2017 and "[w]ithin 36 hours, [Petitioner] had a [three] hour episode of tremors and then awoke with sudden left-sided hearing loss and tinnitus." Id. Dr. Slesnick documented that Petitioner "was treated with oral steroids without benefit. [Petitioner] was offered intratympanic steroid in the past but was told that it would not likely be of help, since it was being suggested at an extended time after the event." Id. Petitioner denied "other inciting events such as loud noises, head trauma[,] or upper respiratory infections." Id. Dr. Selesnick noted a family history of ear disease in that Petitioner's daughter had an acoustic neuroma but that all other otologic history was negative. Id. at 27. Dr. Selesnick noted Petitioner's history of hypertension, and antihypertensive medication. Id. Cranial nerves II through VII were "grossly intact with the exception of the left VIII[] cranial nerve." Id.

On examination, Petitioner's "ability to communicate [was] limited by her hearing loss." Pet. Ex. 1 at 27 (ECF No. 8-1). There was no evidence of gaze nystagmus,[17] ataxia,[18] dysdiadochokinesia,[19] or tremor. Id. Dr. Selesnick noted Petitioner's brain MRI was normal. Id. A review of audiograms from June 29, 2017, July 18, 2017, and April 11, 2018, showed "stable low and mid frequency severe left sided [SNHL]." Id. Dr. Selesnick found the laboratory testing from July 2017 "noncontributory." Id. The impression was that Petitioner suffered "sudden left-sided [SNHL]." Id. Dr. Selesnick wrote that "[d]ue to the close time proximity of the administration of the vaccine, it is likely that the vaccine is at least in some way

[17] Gaze nystagmus is "nystagmus made apparent by looking to the right or to the left." Gaze Nystagmus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=94215 (last visited Feb. 20, 2024). Nystagmus is "an involuntary, rapid, rhythmic movement of the eyeball, which may be horizontal, vertical, rotatory, or mixed, i.e., of two varieties." Nystagmus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=34565 (last visited Feb. 20, 2024).

[18] Ataxia is "failure of muscular coordination; irregularity of muscular action." Ataxia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4630 (last visited Feb. 20, 2024).

[19] Dysdiadochokinesia is "a dyskinesia consisting of impaired ability to perform the rapid alternating movements of diadochokinesia." Dysdiadochokinesia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15173 (last visited Feb. 20, 2024). Diadochokinesia is "the function of arresting one motor impulse and substituting for it one that is diametrically opposite, to permit sequential alternating movements, as pronation and supination of the arm." Diadochokinesia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=13720 (last visited Feb. 20, 2024).

responsible for [Petitioner's] [SNHL]." Id. Dr. Selesnick concluded that Petitioner was a candidate for a hearing aid. Id.

Petitioner returned to her PCP, Dr. Shariati, on September 20, 2018 for a routine physical examination. Pet. Ex. 3 at 1. Dr. Shariati noted that "unfortunately, [Petitioner] stopped taking her blood pressure medication." Id. Review of symptoms noted Petitioner had no hearing on the left side and constant tinnitus. Id. Audiometry at 25 dB was normal on Petitioner's right ear but there was "no hearing on the left side." Id. at 2. The impression was "[s]ignificant hearing loss on the left side associated with tinnitus probably secondary to administration of vaccine [DTaP]." Id.

On April 16, 2019, Petitioner returned to Dr. Selesnick for a follow-up visit. Pet. Ex. 2 at 1. Petitioner reported ongoing complaints of tinnitus, which was having a significant effect on her ability to communicate and sleep. Id. at 2. Various treatment options were discussed. Id. Instead of medications and surgeries, which would unlikely suppress the tinnitus, Dr. Selesnick advised Petitioner that she was a candidate for a hearing aid that could suppress the tinnitus. Id. Tinnitus retraining therapy and cognitive behavioral therapy by an audiologist were also suggested. Id.

On May 20, 2019, Petitioner presented to Dr. Shariati complaining of "pounding headache, significant hearing loss, and significant ringing in her left ear." Pet. Ex. 1, ECF No. 67-5 at 2. Dr. Shariati documented that Petitioner "ha[d] major hearing loss in her left ear and ringing that was contributed from the [DTaP] vaccination that she received on [June 18, 2017]. . . . She was seen for a second opinion in New York City and nothing was identified." Id.

No other relevant medical records were filed.

3. Letters from Dr. Shariati

On April 13, 2018, Dr. Shariati authored a letter on behalf of Petitioner, stating that Petitioner presented to his office on June 20, 2017 and received the DTaP vaccination two days earlier. Pet. Ex. 1 at 29 (ECF No. 8-1). He stated Petitioner complained of "stiffness in her muscles, along with chills and congestion in her ears." Id. Petitioner indicated "that her fever and chills were somewhat better but she was concerned about the possibility of reaction to the vaccine." Id. "At the time of the examination, [Petitioner] was complaining of significant hearing loss and feeling as though she was in a tunnel." Id. Dr. Shariati concluded that "based on these observations, it is reasonable to assume that she in fact did have a reaction to the DTaP vaccination." Id.

On July 29, 2021, Dr. Shariati authored a second letter addressing the entry in his medical records stating that Petitioner's current medication included Bactrim and Cipro. See Pet. Ex. 62 at 2; Pet. Ex. 1 at 2 (ECF No. 8-1). In the letter, Dr. Shariati wrote that Petitioner "was not on antibiotics at the time she received the DTaP vaccine." Pet. Ex. 62 at 1.

4. Petitioner's Declarations

Petitioner filed two declarations dated January 7, 2018 and July 30, 2021. Pet. Ex. 6; ECF No. 93-1. Prior to June 18, 2017, Petitioner had no medical conditions besides hypertension. Pet. Ex. 6 at ¶ 1. On Sunday, June 18, 2017, Petitioner received a DTaP vaccination because she wanted to visit her newborn grandchild. ECF No. 93-1 at ¶ 3. At the time of vaccination, she was well; she did not have a cold, she did not have any signs of illness, and she was not on any antibiotics. Id. at ¶¶ 2-3.

"That evening, [Petitioner] noticed soreness at the injection site. The following night, about 1 A.M on June 19, 2017, [Petitioner] began to experience full body tremors, chills, aches[,] and stiffness which lasted approximately two and a half hours." Pet. Ex. 6 at ¶ 3. The next morning, Petitioner experienced "the loss of hearing in [her] left ear." Id. at ¶ 4. By the next day, June 20, "the loss of hearing in [her] left ear was nearly total and [she] began to experience tinnitus." Id. at ¶ 5.

On June 20, 2017, Petitioner presented to Dr. Shariati and explained "on the evening of the 19th/early morning hours of the 20th [she] experienced approximately [three] hours of full body tremors and awoke with noticeable loss of hearing on [her] left side." ECF No. 93-1 at ¶ 4. She recalled it initially sounded like she was "listening to a sea shell or wind tunnel but soon after, the noise became the loud roaring Tinnitus which continue[d]." Id. At this visit, Petitioner was advised that these conditions "were a reaction to the DTaP vaccination [she] had received, i.e. an adverse reaction to that DTaP vaccination." Pet. Ex. 6 at ¶ 6.

Petitioner wrote that she went to two additional specialists who confirmed her hearing loss "and one stated that the cause of [her] condition was a reaction to the vaccine. The other stated he could not determine any cause." Pet. Ex. 6 at ¶ 7. Petitioner concluded that she was advised by Dr. Shariati and Dr. Selsenick that her condition "is more likely than not the result of an adverse effect of the DTaP vaccination [she] received on June 18, 2017." Id. at ¶ 9.

On July 29, 2021, Petitioner spoke with Dr. Shariati about the notes from her visit with him on June 20, 2017. ECF No. 93-1 at ¶ 1. She asked about the antibiotics listed as her current medications at that visit. Id. Dr. Shariati informed Petitioner "that the 'current' list [was] of all the drugs [she] had been prescribed in the entire time [she] had been seeing him which was approximately 25 years. That particular note was not indicative of the medication [she] was taking at the time of the visit." Id.

Petitioner further declared that "there is no doubt in [her] mind that when [she] got the DTaP vaccination [she] had not had a cold or any other condition which would have called for the use of antibiotics." ECF No. 93-1 at ¶ 2. In late March of 2017, she was prescribed a ten-day course of an antibiotics from an urgent care for cold-like symptoms, which she took and finished by April 1 or April 2, 2017. Id. She "was not prescribed Bactrim, or Cipro, at any time within years of the vaccination." Id. at ¶ 5. Petitioner had "been on and off" her hypertension medication (lisinopril) "for some time," and the Lo Loestrin was prescribed for menopause symptoms but she "took it only for a few weeks apparently in 2012." Id.

C. Expert Reports

1. Petitioner's Expert, Dr. Arthur E. Brawer[20]

a. Background and Qualifications

Dr. Brawer is a rheumatologist, or "arthritis specialist," who received his M.D. from Boston University School of Medicine. Pet. Ex. 55 at 1. He is board-certified in internal medicine and rheumatology. Id. at 3. Since 1976, Dr. Brawer has maintained a rheumatology private practice and served as the Director of Rheumatology and Director of the Arthritis Clinic at Monmouth Medical Center, Long Branch, New Jersey. Id. at 1, 3. As of 2018, he was also an attending physician at Monmouth Medical Center. Id. at 3. Previously, he was also an Assistant Clinical Professor of Medicine at Robert Wood Johnson Medical School, New Brunswick, New Jersey, and an Associate Clinical Professor of Medicine at Drexel College of Medicine, Philadelphia, Pennsylvania. Id. at 1, 4. Dr. Brawer has authored or co-authored numerous publications. Id. at 4-7. His "research interests and peer reviewed publications encompass new arthritis conditions, new arthritis treatments, alternative medicine, . . . fibromyalgia, physical trauma and arthritis, [and] vaccine-induced autoimmunity." Id. at 1.

A review of his curriculum vitae does not indicate that Dr. Brawer has any training, education, or experience in the diagnosis or treatment of hearing loss or hearing disorders. Pet. Ex. 55. Additionally, there is no indication he has training, education, or experience in immunology. See id.

b. Opinion

Dr. Brawer opined Petitioner has "permanent [SNHL] in her left ear as a direct consequence of the [DTaP] vaccination she received on June 18, 2017." Pet. Ex. 10 at 2. He also opined the "unremitting, intractable tinnitus" Petitioner suffers is a direct result of the DTaP vaccination. Id.

i. Althen Prong One

Dr. Brawer did not offer a specific opinion about the mechanism or mechanisms by which the DTaP vaccination can cause SNHL. Instead, he provided a list of mechanisms generally associated with autoimmune disorders, focusing on the theory of molecular mimicry. Pet. Ex. 10 at 3-4.

In his first expert report, Dr. Brawer provided a paragraph with an overview of different mechanisms that have been described in the literature for how vaccinations generally can cause autoimmune disorders. Pet. Ex. 10 at 3-4. In part, these included molecular mimicry, polyclonal B cell activation, bystander activation, adjuvants (such as aluminum), "modification of surface antigens, induction of novel antigens, and exposure of sequestered antigens." Id. at 4-5. He suggested that research will continue to reveal the "relative contributions of each of these

[20] Petitioner filed two expert reports from Dr. Brawer. Pet. Exs. 10, 50.

mechanisms." Id. at 5. Other than molecular mimicry, Dr. Brawer did not describe the enumerated theories. And he did not appear to commit to any of the theories he identified as the mechanism whereby the DTaP vaccination can cause SNHL, although he spent more time discussing molecular mimicry than the others. See id. at 3-4.

Regarding molecular mimicry, he briefly summarized its history and stated "[i]t has been known for well over 20 years that there exists a cross reactivity between routinely used vaccine materials and self-antigens in the body." Pet. Ex. 10 at 3. He cited two examples of molecular mimicry from Kanduc and Shoenfeld,[21] related to hepatitis B virus antigens and human papilloma virus antigens that share amino acid sequences with human proteins. Id. (citing Pet. Ex. 21). However, the Kanduc and Shoenfeld study did not examine amino acids sequences in the DTaP vaccine or offer theories relative to SNHL caused by vaccines. Thus, while the paper generally supports the theory of molecular mimicry, it does not provide evidence that molecular mimicry plays a role in causing hearing loss after a DTaP vaccination.

Another paper cited by Dr. Brawer, Sutjita et al.,[22] showed cross-reactivity between epitopes in tetanus and diphtheria toxoid vaccines and self-antigens. Pet. Ex. 22 at 1, 7. Notably, the authors urged caution "in assessing the significance of the reactivities of monoclonal antibodies derived from humans" because this finding "do[es] not necessarily reflect on the propensity of an individual to develop autoimmune disease." Id. at 5-6. Further, they explained that antibodies from patients with autoimmune disease "may not be necessarily related to the pathogenic autoantibodies found [in] their serum." Id. at 5-6. Further, the study did not identify a mechanism by which the DTaP vaccine can cause an autoimmune disorder and SNHL was not discussed.

After generally identifying mechanisms implicated in autoimmune disorders, Dr. Brawer purported to cite publications "attesting to vaccination induced [SNHL]" caused by "damage . . . to the cochlear hair cells in the inner ear and/or damage to the hearing nerves themselves." Pet. Ex. 10 at 2-3. The first of these articles was by De Marco et al.,[23] who reported a case of a 33-year-old male who had sudden hearing loss after receiving tetanus and diphtheria and meningococcal vaccinations. Pet. Ex. 11 at 1. The patient improved following treatment with Bentelan (a steroid) and hearing testing at six months showed functional recovery on low and medium frequencies. Id. at 2. While the authors proposed that the temporal association to vaccination suggested an adverse reaction, they concluded that the "cause of [their] patient's [] hearing loss remain[ed] unknown" despite investigations by different specialties. Id. While they described possible explanations for how nerve damage could occur, they surmised that the hearing loss was possible due to "toxic-autoimmune damage of nerve cells" caused by "central

[21] Darja Kanduc & Yehuda Shoenfeld, From HBV to HPV: Designing Vaccines for Extensive and Intensive Vaccination Campaigns Worldwide, 15 Autoimmunity Revs. 1054 (2016).

[22] M. Sutjita et al., Polyspecific Human and Murine Antibodies to Diphtheria and Tetanus Toxoids and Phospholipids, 73 Clinical & Experimental Immunology 191 (1988).

[23] Federica De Marco et al., Post Vaccinal Temporary Sensorineural Hearing Loss, 15 Int'l J. Env't Rsch. & Pub. Health 1780 (2018).

nervous system sensitization, probably established during previous vaccinations." Id. at 3. Dr. Brawer did not offer the mechanism of prior sensitization here, and there are no facts presented to support such a mechanism.

The other case reports cited by Dr. Brawer do not involve the DTaP vaccine.[24] See, e.g., Pet. Ex. 14 (describing a 79-year-old woman who developed bilateral deafness two days after a flu vaccine and hearing loss did not improve with steroids);[25] Pet. Ex. 15 (describing a 42-year-old man who developed unilateral SNHL and tinnitus after a series of hepatitis B vaccinations, and who had no improvement with steroids, but had gradual improvement over time);[26] Pet. Ex. 16 (describing a 27-year-old woman who developed bilateral hearing loss 22 days after a measles-rubella vaccine, and a trial of steroids did not improve hearing);[27] Pet. Ex. 17 (describing a 17-year-old girl who developed bilateral hearing loss 14 hours after H1N1 vaccination, where hearing improved after steroid therapy).[28] Although causal mechanisms were discussed in several of these case reports, none of them identified molecular mimicry as an accepted theory. And steroid therapy was only successful in one case, suggesting that autoinflammatory or immune-mediated mechanisms may not have been at play in the other cases. See Pet. Ex. 17 at 1. Further, Dr. Brawer did not explain why case reports involving other vaccines would be relevant or persuasive evidence of vaccine causation as it relates to any of his proffered mechanisms, including molecular mimicry.

Other articles cited by Dr. Brawer do not support vaccine causation. For example, he cited a paper by Karussis and Petrou[29] about post-vaccination central nervous system demyelinating syndromes such as optic neuritis[30] and acute demyelinating encephalomyelitis

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[24] Petitioner's other expert, Dr. Kinsbourne, also discussed some of these reports, and if so, the cases are discussed below in Dr. Kinsbourne's section.

[25] Claudia Kolarov et al., Bilateral Deafness Two Days Following Influenza Vaccination: A Case Report, 15 Hum. Vaccines & Immunotherapeutics 107 (2018).

[26] B. Biacabe et al., A Case Report of Fluctuant Sensorineural Hearing Loss After Hepatitis B Vaccination, 24 Auris Nasus Larynx 357 (1997).

[27] Tim. V. Hulbert et al., Bilateral Hearing Loss After Measles and Rubella Vaccination in an Adult, 325 New Eng. J. Med. 134 (1991).

[28] Hsueh-Hsin Huang et al., Bilateral Sudden Deafness Following H1N1 Vaccination, 143 Otolaryngology Head & Neck Surgery 849 (2010).

[29] Dimitrios Karussis & Panayiota Petrou, The Spectrum of Post-Vaccination Inflammatory CNS Demyelinating Syndromes, 13 Autoimmunity Revs. 215 (2014).

[30] Optic neuritis is "inflammation of the optic nerve; it is classified as either [] affecting the part of the nerve within the eyeball . . . or [] affecting the portion behind the eyeball." Optic Neuritis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92519 (last visited Jan. 23, 2024).

("ADEM"). Pet. Ex. 35 at 1. However, Dr. Brawer offered no evidence that SNHL is a demyelinating disorder of the central nervous system following the DTaP vaccination. Dr. Brawer also cited Cabrera-Maqueda et al.,[31] which discussed two case reports of pregnant women who developed unilateral optic neuritis three weeks after tetanus-diphtheria-acellular pertussis ("Tdap") vaccination. Pet. Ex. 20 at 1. Both women had a complete recovery. Id. However, the authors assessed the causal association as "indeterminate" because there was no laboratory test that implicated vaccine causation.[32] Id. at 2. Moreover, the article did not discuss hearing loss or tinnitus and Dr. Brawer did not explain its relevance.

Dr. Brawer also cited articles about optic neuritis, Guillain-Barré syndrome ("GBS"), acute hemolytic anemia, rheumatoid arthritis, systemic lupus erythematosus, connective tissue disease, fatigue syndromes, channelopathies, breast implants, and rheumatologic disorders. Pet. Ex. 10 at 4. But these disorders are not at issue and Dr. Brawer did not explain why papers about other disorders, many of which have been proven to be autoimmune in nature, provide persuasive evidence of causation here. See, e.g., Pet. Ex. 32 (describing a seven-month-old who developed acute transverse myelitis ("TM") after diphtheria-tetanus-pertussis immunization);[33] Pet. Ex. 33 (describing three patients who developed systemic lupus erythematosus ("SLE"), polymyalgia rheumatica ("PMR"), and rheumatoid arthritis following flu vaccinations);[34] Pet. Ex. 34a (describing two women who developed optic neuritis after varicella zoster vaccinations and both completely recovered after treatment with steroids);[35] Pet. Ex. 37 (describing a patient who developed GBS after vaccination with tetanus toxoid);[36] Pet. Ex. 41 at 1 (describing two females who developed rheumatoid arthritis and one female who developed SLE "in close proximity" to flu vaccinations);[37] Pet. Ex. 42 (finding that vaccinations are associated with an

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[31] Jose M. Cabrera-Maqueda et al., Optic Neuritis in Pregnancy After Tdap Vaccination: Report of Two Cases, 160 Clinical Neurology & Neurosurgery 116 (2017).

[32] In Cabrera-Maqueda et al., the authors used the Halsey et al. algorithm to assess causation. Pet. Ex. 20 at 2 (citing Neal A. Halsey et al., Algorithm to Assess Causality After Individual Adverse Events Following Immunizations, 30 Vaccine 5791 (2016)). This article was not filed.

[33] RMS Riel-Romero, Acute Transverse Myelitis in a 7-Month-Old Boy After Diphtheria-Tetanus-Pertussis Immunization, 44 Spinal Cord 688 (2006).

[34] M.A. Brown & J.V. Bertouch, Rheumatic Complications of Influenza Vaccination, 24 Austl. N.Z. J. Med. 572 (1994).

[35] Sang Beom Han et al., Optic Neuritis Following Varicella Zoster Vaccination: Report of Two Cases, 32 Vaccine 4881 (2014).

[36] Norris Newton, Jr. & Abdorassol Janati, Guillain-Barré Syndrome After Vaccination with Purified Tetanus Toxoid, 80 S. Med. J. 1053 (1987).

[37] Arthur E. Brawer & Sai Koyoda, The Onset of Rheumatoid Arthritis and Systemic Lupus Erythematosus Following Influenza Vaccination: Reports of Three Cases, 4 Clinical Microbiology & Infectious Diseases (2019). This is also cited as Pet. Ex. 54.

increased risk of SLE and rheumatoid arthritis);[38] Pet. Ex. 43 (finding a temporal association between the hepatitis B vaccine and 10 cases of SLE);[39] Pet. Ex. 44 at 1 (reviewing five patients who developed SLE after immunization and finding it "immunologically plausible" that vaccination can trigger autoimmunity in rare cases);[40] Pet. Ex. 51 (discussing novel mechanisms for vaccine-induced diseases);[41] Pet. Ex. 52a (discussing the diversity of rheumatologic diseases that may arise following vaccination);[42] Pet. Ex. 53 (describing a 21-year-old female who developed a "multisystem illness" or "[human papillomavirus ("HPV")] vaccine-induced illness" after receiving the HPV vaccines and discussing the components of the vaccine).[43]

He also cited research papers and papers about specific theories, tetanus toxoid, or other matters, but the subject matter results of the studies discussed are either collateral to the issues here or irrelevant, and again, Dr. Brawer did not explain their relevance.[44] See, e.g., Pet. Ex. 24 (describing the induced immune response from tetanus toxoid and cross-reactivity with self-

[38] Bin Wang et al., Vaccinations and Risk of Systemic Lupus Erythematosus and Rheumatoid Arthritis: A Systematic Review and Meta-Analysis, 16 Autoimmunity Revs. 756 (2017).

[39] N. Agmon-Levin et al., Ten Cases of Systemic Lupus Erythematosus Related to Hepatitis B Vaccine, 18 Lupus 1192 (2009).

[40] Steven A. Older et al., Can Immunization Precipitate Connective Tissue Disease? Report of Five Cases of Systemic Lupus Erythematosus and Review of the Literature, 29 Seminars Arthritis & Rheumatism 131 (1999).

[41] Arthur E. Brawer, Vaccination Induced Disease and Their Relationship to Neurologic Fatiguing Syndromes, Channelopathies, Breast Implant Illness, and Autoimmunity via Molecular Mimicry, 4 Int'l J. Vaccines & Immunization (2020).

[42] Arthur E. Brawer, Why Are Vaccination Induced Rheumatologic Disorders So Diverse?, 4 J. Med. Clinical Rsch. & Revs. (2020).

[43] Arthur E. Brawer, Hidden Toxicity of Human Papillomavirus Vaccine Ingredients, 5 J. Rheumatic Diseases & Treatment (2019).

[44] Dr. Brewer also referenced case numbers for two other Vaccine Program hearing loss cases: Case Number 14-916V, involving the flu vaccine where Petitioner also sustained ADEM, and Case Number 13-916V, involving the MMR vaccine. Pet. Ex. 10 at 2; see Haworth v. Sec'y of Health & Hum. Servs., No. 14-916V, 2015 WL 10436103 (Fed. Cl. Spec. Mstr. Oct. 15, 2015); Bosco v. Sec'y of Health & Hum. Servs., No. 13-916V, 2014 WL 6606561 (Fed. Cl. Spec. Mstr. Oct. 22, 2014). Neither case involved the DTaP vaccination, and Dr. Brawer did not explain their relevance. Further, there is no reasoned decision in either case as both of these matters resolved by stipulation and there was no finding as to whether those Petitioners proved vaccine causation by preponderant evidence.

antigens);[45] Pet. Ex. 25 (testing bystander activation of non-vaccine specific $CD4^{+}$T cells);[46] Pet. Ex. 28 (arguing to teach physicians to use a mix of methodologic and biologic reasoning in medicine);[47] Pet. Ex. 29 (editorial discussing problems with the application of evidence based medicine in rheumatology).[48]

ii. Althen Prongs Two and Three

Dr. Brawer opined "based on a reasonable degree of medical certainty, that the [DTaP] vaccination received by [Petitioner] on June 18, 2017 was the direct cause of her [SNHL] and chronic tinnitus." Pet. Ex. 10 at 3. He offered three reasons for his opinion.

First, Dr. Brawer opined Petitioner did not "manifest any chronic nor recurrent hearing impairment," nor "suffer from any systemic neurological, rheumatological, or otolaryngological condition prior to the administration of the [DTaP] vaccination on June 18, 2017." Pet. Ex. 10 at 3, 5. He stated Petitioner was in "her usual state of good health" until the date of vaccination and there were "no prior ear problems of any kind." Id. at 1-2.

Second, he explained that based on the medical records, Petitioner's condition began within 36 to 48 hours following the DTaP vaccination on June 18, 2017. Pet. Ex. 10 at 5. On that date, Petitioner received the DTaP vaccine and within 36 hours, Petitioner "developed transient self-limited myalgias and chills, followed nearly immediately (within hours) by sudden hearing loss in her left ear, accompanied by tinnitus." Id. at 1. Accordingly, Dr. Brawer opined there is a temporal relationship connecting Petitioner's DTaP vaccination to her development of SNHL and tinnitus. Id.

And third, Dr. Brawer asserted that Petitioner's SNHL and tinnitus "cannot be attributed to any other well-defined and well-known causes that can trigger such phenomena." Pet. Ex. 10 at 5; see also Pet. Ex. 50 at 1 (opining the DTaP vaccine "is the only substantial factor that brought about [Petitioner's] injury" and "there is no other 'agent' that was the actual cause of her injury"). Petitioner underwent "comprehensive evaluations" and was examined by Dr. Brawer on October 23, 2019. Pet. Ex. 10 at 1. Dr. Brawer opined the assessments "clearly excluded a multiple of other potential causes for [Petitioner's] hearing loss." Id. at 1-2. Dr. Brawer listed some of the potential causes that were excluded including autoimmune disease, physical trauma

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[45] Marijana Stojanovic et al., Role of Molecular Mimicry and Polyclonal Cell Activation in the Induction of Pathogenic β2-Glycoprotein I-Directed Immune Response in Balb/c Mice upon Hyperimmunization with Tetanus Toxoid, 56 Immunologic Rsch. 20 (2013).

[46] Susan van Aalst et al., Bystander Activation of Irrelevant $CD4^{+}$T Cells Following Antigen-Specific Vaccination Occurs in the Presence and Absence of Adjuvant, 12 PLoS ONE e0177365 (2017).

[47] Jan P. Vandenbroucke, Observational Research and Evidence-Based Medicine: What Should We Teach Young Physicians?, 51 J. Clinical Epidemiology 467 (1998).

[48] Paul Dieppe & Béla Szebenyi, Evidence Based Rheumatology, 27 J. Rheumatology 4 (2000).

or rupture to the ear, vascular disease, aging, excessive noise, medications, and upper or lower respiratory infections. Id. at 2.

Although Dr. Brewer opined generally that medications were not an alternative cause of Petitioner's hearing loss, he did not address the fact that the medical records documented that Petitioner was taking antibiotics on the date of vaccination. Pet. Ex. 10 at 1-2, 5; see also Pet. Ex. 50 at 1.

In conclusion, Dr. Brawer opined "were it not for the [DTaP] vaccination of June 18, 2017, [Petitioner] would not now be suffering from [SNHL] and tinnitus." Pet. Ex. 10 at 5.

2. Petitioner's Expert, Dr. Marcel Kinsbourne[49]

a. Background and Qualifications

Dr. Kinsbourne's prior career focused on pediatric neurology. See Pet. Ex. 170. There is no indication that Dr. Kinsbourne specializes in otolaryngology. And he agreed that he is not an immunologist and he specifically deferred to Dr. Brawer "on technical issues in immunology." Pet. Ex. 163 at 1.

In 1955, Dr. Kinsbourne obtained his B.M., B.Ch. from Oxford University Medical School, and he completed postdoctoral training through 1964 in the United Kingdom. Pet. Ex. 170 at 1. Thereafter, he obtained board certification and licensing in the United States and Canada and worked as a professor at various teaching institutions. Id. at 2-3. Dr. Kinsbourne has served and is currently serving on a number of editorial boards. Id. at 4-5. He has authored or co-authored more than 400 publications. Id. at 6-39.

Dr. Kinsbourne is no longer a practicing physician. Pet. Ex. 170 at 2-3. He has not treated patients in a clinical setting since the 1990s. Id. at 3.

b. Opinion

i. Althen Prong One

At the outset, Dr. Kinsbourne explained that there are many causes of SNHL. Pet. Ex. 163 at 2. "[V]iral infections, genetic mutations, trauma, toxic agents, neoplastic diseases, vascular damage, and immune mechanisms" can cause damage to the inner ear and can be "responsible for sudden [SNHL]." Pet. Ex. 163 at 2. But he also noted that sudden SNHL is sometimes considered to be autoimmune. Id. at 3, 5 (citing Pet. Ex. 163-7).[50]

[49] Petitioner filed two expert reports from Dr. Kinsbourne. Pet. Exs. 163-64.

[50] Bruno Almeida Antunes Rossini et al., Sudden Sensorineural Hearing Loss and Autoimmune Systemic Diseases, 21 Int'l Archives Otorhinolaryngology 213 (2017).

Dr. Kinsbourne stated he was not an immunologist and he deferred to Dr. Brawer "on technical issues of immunology." Pet. Ex. 164 at 1. He did not offer an opinion as to a mechanism whereby the DTaP vaccine could cause SNHL. However, he cited several articles about autoimmunity and hearing loss.

Li et al.[51] explained that the "inner ear and brain" were "traditionally viewed as being immune privileged" due to the "blood-labyrinthine barrier," which like the "blood-brain barrier," is generally thought to be protective against autoimmune disorders. Pet. Ex. 163-4 at 1. According to the authors, the idea of autoimmune hearing loss emerged in 1979 when research by McCabe showed that some patients with hearing loss responded well to steroids. Id. The inner ear immune response described in Li et al. is quite complex and well beyond the scope of this Decision. As explained by Li et al., "the exact mechanism of pathogenesis" of SNHL "is not yet fully understood"[52] and the pathogenesis of "the injury process remains unclear." Id. at 3-4. An additional challenge is that the diagnosis of autoimmune hearing loss is difficult to make but immunosuppressive therapy generally results in a positive response, and thus, glucocorticoids are the first line of treatment for autoimmune disorders of the inner ear. Id. at 6. Notably, Li et al. did not discuss vaccinations as a possible cause for autoimmune hearing loss or identify any mechanism by which vaccinations could cause SNHL.

Greco et al.[53] also acknowledged that the "[]etiology and pathogenesis" of SNHL "remain unknown." Pet. Ex. 163 at 2 (citing Pet. Ex. 163-3). The authors described several theories of causation, including "viral infections, vascular occlusion[,] and immune system-mediated mechanisms." Pet. Ex. 163-3 at 1. They discussed the idea that systemic or distant viral infections may play a causal role, but concluded that further studies are necessary to "clarify the immunologic role of antibodies found in SNHL patients." Id. at 4. The authors did not identify vaccines as a cause of immune mediated hearing loss or hypothesize that vaccines could serve as agents that trigger such an immune response.

Regarding the mechanisms of systemic or distant infections discussed by Greco et al. according to Dr. Kinsbourne, it is rare to find evidence of such infection. Pet. Ex. 163 at 2. Thus, Dr. Kinsbourne appears to suggest that autoimmune reactions to these types of infections may be more likely. Id. (citing Pet. Ex. 163-3 at 2-4). He argued that vaccines are like infections in that they can invoke an immune response. Id. (citing Pet. Ex. 163-2 (describing

[51] Guangfei Li et al., The Role of Autoimmunity in the Pathogenesis of Sudden Sensorineural Hearing Loss, 2018 Neural Plasticity 7691473.

[52] For a more complete discussion of the various mechanisms of autoimmune SNHL that have been identified, see Pet. Ex. 163-4.

[53] A. Greco et al., Sudden Sensorineural Hearing Loss: An Autoimmune Disease?, 10 Autoimmunity Revs. 756 (2011).

proinflammatory cytokine response after flu vaccination));[54] see also Pet. Ex. 36 (describing how peripheral cytokines expressed after vaccination can cause neuroinflammation).[55]

Specific to vaccine-induced injury, Dr. Kinsbourne first noted that it is "well known that the [DTaP] vaccination can trigger immune overreactions, resulting in autoimmune syndromes, notably [GBS]." Pet. Ex. 163 at 5. But he did not explain how SNHL is like GBS. And he failed to show that SNHL is a demyelinating disease of the peripheral nerves like GBS.

Next, Dr. Kinsbourne cited several case reports of vaccinations triggering SNHL. Okhovat et al.[56] reported the case of a 33-year-old man who developed "profound sudden onset right-sided hearing loss with tinnitus and vertigo" within 24 hours of a rabies vaccination. Pet. Ex. 13 at 1. After two months, the tinnitus resolved and the patient's hearing slightly improved. Id. at 2. The authors postulated a hypersensitivity reaction as the mechanism, not molecular mimicry. Id. at 1. They concluded that the mechanism for sudden SNHL after immunization remained unclear. Id.

Stewart and Prabhu[57] reported six children with SNHL after measles, mumps, and rubella ("MMR") vaccinations in which the cause was unknown, but MMR remained a "possible" etiology. Pet. Ex. 12 at 1. Four of the six children had unilateral hearing loss. Id. at 1 tbl.1. The authors concluded that the risk of hearing loss after MMR vaccination was low and that the risk should be weighed against the risks of natural infection. Id. at 2. Like Dr. Brawer, Dr. Kinsbourne also cited De Marco et al. See Pet. Ex. 163 at 3; Pet. Ex. 11. The DTaP vaccine was not at issue in these case reports.

Finally, Dr. Kinsbourne cited the Baxter et al.[58] study, a large case-centered analysis using Kaiser Permanente North California databases of over 3.5 million patients to research the association between vaccinations and sudden SNHL. Pet. Ex. 163 at 3 (citing Pet. Ex. 163-1);

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[54] Lisa M. Christian, Proinflammatory Cytokine Responses Correspond with Subjective Side Effects after Influenza Virus Vaccination, 33 Vaccine 3360 (2015).

[55] G. Giannotta & N. Giannotta, Vaccines and Neuroinflammation, 3 Int. J Public Health & Safety 163 (2018).

[56] Saleh Okhovat et al., Sudden Onset Unilateral Sensorineural Hearing Loss After Rabies Vaccination, 2015 BMJ Case Reps. 1.

[57] Barbara J.A. Stewart & P. Umesh Prabhu, Reports of Sensorineural Deafness After Measles, Mumps, and Rubella Immunisation, 69 Archives Disease Childhood 153 (1993).

[58] Roger Baxter et al., Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis, 155 Otolaryngology Head & Neck Surgery 81 (2016).

see also Pet. Ex. 163-5 at 7 (discussing the Baxter et al. study).[59] The study found no "statistically significant" association between the DTaP vaccine, or any vaccine, and the onset of sudden SNHL. Pet. Ex. 163 at 4 (citing Pet. Ex. 163-1 at 1, 5). Dr. Kinsbourne acknowledged the results of the Baxter et al. study but asserted that epidemiological studies "are rarely powerful [enough] to detect rare events." Pet. Ex. 164 at 3-4.

ii. Althen Prongs Two and Three

Dr. Kinsbourne opined that "the [DTaP] vaccination triggered an immune attack on [Petitioner's] left inner ear, resulting in . . . abrupt onset of unilateral sudden hearing loss two days after [] [DTaP] vaccination." Pet. Ex. 163 at 5.

Dr. Kinsbourne assumed that Petitioner's hearing loss was due to autoimmunity because he asserted there was no evidence of another cause to explain her hearing loss, "other than the close temporal relationship to the [DTaP] vaccination, which suggests an immune mechanism." Pet. Ex. 163 at 2. Dr. Kinsbourne opined "[w]hich of the several known mechanisms of autoimmunity is operative in an individual case is of no clinical significance because the same treatments apply to them all. . . . The key clinical issue for treatment is whether the injury was immune or not." Pet. Ex. 164 at 2.

Specifically, Dr. Kinsbourne reasoned that "[i]n the absence of associated syndromes . . . or evidence of structural damage, it is very likely [Petitioner] was a victim of an isolated autoimmune attack." Pet. Ex. 163 at 2. He stated Petitioner was "in good health" on June 18, 2017, when she received the DTaP vaccination. Id. at 1. "Thirty-six hours after the [DTaP] vaccination[,] [Petitioner] began to have muscle pains, chills, and a feeling of congestion in her left ear." Id. Dr. Kinsbourne attributed these symptoms to "a robust flow of proinflammatory cytokines post vaccination." Id. at 4. He did not offer any explanation or discuss any causal role related to the post vaccination "proinflammatory cytokines."

Dr. Kinsbourne noted Petitioner's laboratory testing was unrevealing and there was no evidence of infection. Pet. Ex. 163 at 1-2. However, he conceded that the "presence of antibodies was not investigated" which might support one of the mechanisms of causation discussed in the literature cited. Id. at 2.

Next, Dr. Kinsbourne relied on Petitioner's treatment with steroids to further support his position. He stated that "the treating physician attempted the use of an oral steroid at the onset, implying that he regarded [Petitioner's] hearing loss as autoimmune-mediated." Pet. Ex. 163 at 2. According to Dr. Kinsbourne, "[t]he clinician would not have ventured to use a steroid if there was any chance that the left inner ear had been invaded by an infectious organism, in which case the use of steroids is contraindicated." Id. at 4. In contrast, Dr. Kinsbourne offered that "treatment with steroids would be appropriate if the mechanism of injury were autoimmune." Id.

[59] Yi-Chun Carol Liu et al., Sensorineural Hearing Loss (SNHL) as an Adverse Event Following Immunization (AEFI): Case Definition & Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data, 38 Vaccine 4717 (2020).

at 5. However, Dr. Kinsbourne acknowledged "[o]ral steroids conveyed no benefit" to Petitioner here. Id. at 1-2.

Lastly, Dr. Kinsbourne opined there were no known risk factors of SNHL or other potential alternate causes for Petitioner's hearing loss in the evidence. Pet. Ex. 163 at 5. Dr. Kinsbourne disagreed that the antibiotics, specifically Cipro and Bactrim, caused Petitioner's hearing loss, because he argued that the effect would have been gradual and not sudden. Id. at 4. Moreover, he noted that Petitioner's PCP explained that Petitioner was not taking these medications at the time of vaccination. Id.

In summary, Dr. Kinsbourne opined Petitioner's sudden onset of unilateral hearing loss was "more likely than not" caused by the DTaP vaccination because (1) she had no known risk factors, (2) SNHL is "sometimes . . . autoimmune," (3) "[a]utoimmune [sudden SNHL] is indistinguishable from [sudden SNHL] that occurs in isolation," and (4) it "occurred within two days of a [DTaP] vaccination." Pet. Ex. 163 at 5.

3. Respondent's Expert, Dr. Ross M. Kedl, Ph.D.[60]

a. Background and Qualifications

Dr. Kedl is a Professor of Immunology in the Department of Immunology and Microbiology at the University of Colorado Denver. Resp. Ex. A at 1; Resp. Ex. B at 1. He received his Ph.D. in Pathobiology from the University of Minnesota. Resp. Ex. B at 1. Thereafter, he completed a postdoctoral fellowship at the National Jewish Medical and Research Center in Denver, Colorado, then spent three years as a senior immunologist at 3M Pharmaceuticals in their Immune Response Modifier Program. Resp. Ex. A at 1; Resp. Ex. B at 2. Since joining the University of Colorado in 2004, Dr. Kedl has maintained a National Institutes of Health ("NIH") funded research program "centered on the biology of vaccine adjuvants and their capacity to induce robust and enduring cellular immunity." Resp. Ex. A at 1. Dr. Kedl has authored or co-authored numerous publications in areas "focused on vaccine adjuvants and the mechanisms by which they induce adaptive (T and B cell) immunity." Id.; see Resp. Ex. B at 12-20.

Dr. Kedl is not a medical doctor and there is no indication he has specialized experience in otolaryngology.

b. Opinion

i. Althen Prong One

Dr. Kedl opined that neither Dr. Brawer nor Dr. Kinsbourne provided evidence to support "a valid theory of causation." Resp. Ex. C at 2. He referenced a paper by Mascola and Haynes[61] that illustrates the complexity of immune pathways in disease development. Resp. Ex. A-5.

[60] Respondent filed two expert reports from Dr. Kedl. Resp. Exs. A, C.

Regarding the focus on molecular mimicry, Dr. Kedl offered several observations[62] to illustrate his point that a simple assertion of molecular mimicry as a causal theory, without consideration of the complexities involved, is insufficient to establish causation. See Resp. Ex. A at 4-5; Resp. Ex. C at 4-6. First, he explained that short sequence similarity between proteins is very common. Resp. Ex. A at 5. The finding of short sequences that are similar without more does not provide support for the mechanism. Id. He cited a study by Silvanovich et al.[63] which showed that "short amino acid sequence matches of eight amino acids or fewer to identify proteins as potential cross-reactive allergens is a product of chance and adds little value to [] assessments for newly expressed proteins." Resp. Ex. A-7 at 1.

Even if short sequence similarity alone was proof of a causal theory, Dr. Kedl opined that Petitioner has not provided evidence of a "putative ear specific antigen" with "similarity to any of the antigens contained within the [DTaP] vaccine formulation." Resp. Ex. C at 4; see also Resp. Ex. A at 4-5. Moreover, Petitioner has not gone the next step to show a "plausible path from a vaccine-specific antigen to its self-antigen 'mimic.'" Resp. Ex. A at 5; Resp. Ex. C at 4.

Further, Dr. Kedl opined that "detection of autoantigen cross reactivity" does not prove "autoimmune pathology." Resp. Ex. A at 7. In support of this aspect of his opinion, Dr. Kedl cited several papers. Hurez et al.[64] found "natural autoantibodies directed against a wide range of self-antigens [including tetanus toxoid] present in the serum of healthy individuals." Resp. Ex. A-2 at 1. The authors suggested that autoantibodies are not necessarily indicators of disease, but instead may be a factor of the aging process. Id. at 1, 6; see also Resp. Ex. A-3 at 1 (finding autoreactive antibodies and B cells, as well as autoreactive T cells, "present in healthy individuals").[65] Moreover, "the stability of self-reactive antibody repertoires" were found in a study of five adult males over a period of 25 years. Resp. Ex. A-4 at 1.[66]

And a recent study cited by Dr. Kedl suggested that "cross reactivity with self-antigens may have more to do with intrinsic biochemical features of the [B cell receptors] [] rather than

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[61] John R. Mascola & Barton F. Haynes, HIV-1 Neutralizing Antibodies: Understanding Nature's Pathways, 254 Immunological Revs. 225 (2013).

[62] For Dr. Kedl's full discussion of the reasons that Petitioner's theory based on molecular mimicry fails, see Resp. Ex. A at 4-8.

[63] Andre Silvanovich et al., The Value of Short Amino Acid Sequence Matches for Prediction of Protein Allergenicity, 90 Toxicological Scis. 252 (2006).

[64] Vincent Hurez et al., Expression and Control of the Natural Autoreactive IgG Repertoire in Normal Human Serum, 23 Eur. J. Immunology 783 (1993).

[65] Sébastien Lacroix-Desmazes et al., Self-Reactive Antibodies (Natural Autoantibodies) in Healthy Individuals, 216 J. Immunological Methods 117 (2016).

[66] Sébastien Lacroix-Desmazes et al., Stability of Natural Self-Reactive Antibody Repertoires During Aging, 19 J. Clinical Immunology 26 (1999).

similarity between the self and foreign [antigens]." Resp. Ex. A-9 at 9.[67] Overall, according to Dr. Kedl, the current knowledge about molecular mimicry establishes that "the simple detection of autoantigen cross reactivity is not an indication of autoimmune pathology." Resp. Ex. A at 7.

Next, Dr. Kedl explained the problems with using case studies over "research designed to investigate the actual causality of vaccine-related adverse events." Resp. Ex. A at 3-4; see also Resp. Ex. C at 1-2. He opined that case studies are "not [] designed to investigate [] causality of vaccine-related adverse events," and thus, they are less reliable than epidemiology studies designed to study the side effects of the DTaP vaccination. Resp. Ex. A at 3-4. Dr. Kedl observed that Petitioner did not provide "any scientifically reliable literature supporting a linkage between the [DTaP] vaccine and [] hearing loss." Id. at 4.

In summary, Dr. Kedl opined that Petitioner failed to offer evidence of a valid theory of causation, and regarding the focus on molecular mimicry, Petitioner "failed to lay out any logical course of events connecting [DTaP] antigens to ear-related antigens." Resp. Ex. A at 8.

ii. Althen Prongs Two and Three

Dr. Kedl opined that Petitioner failed to provide evidence that her hearing loss was consistent with "an inflammatory or immune-related" event. Resp. Ex. C at 4.

In support of his position that Petitioner's hearing loss was not immune-mediated, Dr. Kedl noted that the Petitioner did not have a positive response to steroids. Resp. Ex. C at 4. According to Dr. Kedl, the "presupposition of an immune based mechanism is actively contradicted by [Petitioner's] failure to respond to a treatment specifically used as a tool for the differential diagnosis of immune-mediated mechanisms of disease." Id. More simply put, Petitioner's failure to respond to steroids is evidence against an immune-mediated form of hearing loss.

Next, Dr. Kedl opined that the records show that Petitioner was taking antibiotics, Cipro and Bactrim, when she received her vaccination, and one of those, Cipro, is in the Quinolone class of medicines known to cause ototoxicity and hearing loss. Resp. Ex. A at 3. Further, he noted that the combination of antibiotics reflected in Petitioner's medical records, Cipro and Bactrim, are often given for otitis media, or ear infection, which could also be relevant. Id.

Dr. Kedl criticized Petitioner's experts' approach of arguing that there was no evidence of any other cause, other than vaccination, for her hearing loss. Resp. Ex. C at 2. And he disagreed that this position fails to advance a valid theory to explain causation, particularly a standard of "more likely than not." Id. Dr. Kedl explained that a scientifically valid theory is important to eliminate claims based on coincidence due to a temporal association with vaccination. Id.

[67] Holly R. Steach et al., Cross-Reactivity with Self-Antigen Tunes the Functional Potential of Naïve B Cells Specific for Foreign Antigens, 204 J. Immunology 498 (2020).

Lastly, Dr. Kedl opined that Petitioner's hearing loss after vaccination was "coincidental and not related to her vaccination." Resp. Ex. C at 6. He explained that an onset of complete hearing loss in two days after vaccination does not support an immune response to vaccination, particularly in "the absence of any clinical signs of a local destructive inflammatory response." Id. at 4.

In summary, while Dr. Kedl agreed that Petitioner suffered hearing loss in her left ear, he opined that "the preponderance of evidence does not support a vaccine-related cause for [her] hearing loss." Resp. Ex. C at 6; Resp. Ex. A at 8.

III. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove 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, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157,

162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received actually caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(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." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The special master must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioners' favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and

noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

IV. ANALYSIS

A. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009); Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 257 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds Petitioner failed to provide preponderant evidence of a sound and reliable theory to explain how the DTaP vaccine can cause SNHL and tinnitus. There are several reasons for this finding.

First, the undersigned finds that Dr. Brawer's opinions as to Althen prong one are not developed and are conclusory in nature.[68] When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot.

[68] Dr. Brawer's opinions in other cases have also been criticized as underdeveloped and/or conclusory. See, e.g., McDonald v. Sec'y of Health & Hum. Servs., No. 15-612V, 2023 WL 2387844, at *5-8, *23 (Fed. Cl. Spec. Mstr. Mar. 7, 2023); Hughes v. Sec'y of Health & Hum. Servs., No. 20-1548V, 2023 WL 8432849, at *3-4, *12-13 (Fed. Cl. Spec. Mstr. Nov. 7, 2023); Whelan v. Sec'y of Health & Hum. Servs., No. 16-1174V, 2019 WL 1061473, at *3-4, *13-15 (Fed. Cl. Spec. Mstr. Jan. 28, 2019); Clark v. Sec'y of Health & Hum. Servs., No. 17-1553V, 2023 WL 4897284, *27, *29 (Fed. Cl. Spec. Mstr. June 16, 2023).

for rev. den'd, decision aff'd, 141 Fed. Cl. 138, aff'd, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Moberly, 592 F.3d at 1315. Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. See id.

In his initial report, Dr. Brawer provides a paragraph listing potential causes of hearing loss and then, without analysis, concludes that Petitioner has SNHL due to vaccination. He does not explain SNHL, the pathogenesis of the illness, or provide evidence for his conclusions that it can be caused by vaccination.

Regarding Dr. Brawer's focus on molecular mimicry, he provides a brief history and overview of the theory. But he does not explain how molecular mimicry explains hearing loss due to the DTaP vaccination. He does not explain how antigens from the DTaP vaccination activate the immune system of the inner ear. He does not offer insight into what antigens are involved. He does not describe any target of the antigens in the inner ear. He does not cite any literature that explains how the DTaP vaccine, or any component of the vaccine, could trigger the immune system of the inner ear so as to cause hearing loss.

Then Dr. Brawer provides another long list of other mechanisms for autoimmune conditions. But he does not explain why this list is relevant or describe how any of the mechanisms can cause hearing loss after vaccination. And he cites articles without explaining why they are relevant, or how they provide evidence that the DTaP vaccine can cause SNHL. Regarding the case reports cited, many relate to other vaccines, and Dr. Brawer does not explain if or why they are relevant.

Dr. Kinsbourne takes a broader approach as to the mechanism and discusses an immune-mediated theory with an emphasis on autoimmunity. Dr. Kinsbourne does not disagree with Dr. Brawer on the legitimacy of molecular mimicry, but states that there are several mechanisms of autoimmunity, including molecular mimicry, and does not opine as to one in particular for this case.

Dr. Kinsbourne cites literature discussing viral infection as a trigger for immune-mediated hearing loss, but this literature does not contemplate vaccination as a trigger via the same process. Further, neither Greco et al. nor Li et al. discuss vaccination. Dr. Kinsbourne explains that "[v]accines are designed to elicit an immune reaction against the relevant antigen, like the immune reaction to the corresponding infection." Pet. Ex. 163 at 2. But he does not discuss the corresponding infection here.

Respondent's expert, Dr. Kedl, rejects molecular mimicry as a viable theory here. In addition to opining that molecular mimicry is "highly questionable as a relevant mechanism of pathology," Dr. Kedl states that Dr. Brawer fails to provide "evidence that any putative ear specific antigen has any similarity to any of the antigens contained within the [DTaP] vaccine formulation." Resp. Ex. A at 4; Resp. Ex. C at 4.

The undersigned agrees with Dr. Kedl's interpretation of Dr. Brawer's opinions. Based on the current understanding of immune-mediated hearing loss as described in the literature filed

herein, Petitioner's proposed mechanisms fall short of sound and reliable, are conclusory in nature, and vague.

Petitioner need not make a specific type of evidentiary showing or require identification of a specific antigenic trigger for an immune-mediated pathology to prove that a theory is sound and reliable by preponderant evidence. Given the state of current scientific knowledge, there is no way that a petitioner could satisfy such a requirement. Requiring proof of the identify of a specific antigen to prove causation would require scientific certainty, which is a bar too high. See Knudsen, 35 F.3d at 549 (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program").

As the medical literature filed herein shows, the causal mechanism of immune-mediated SNHL is unknown. See, e.g., Pet. Ex. 163-3 at 1-2 (explaining the etiology and pathogenesis of SNHL remains unknown, making SNHL "one of the most controversial and challenging issues in otology"); Pet. Ex. 163-4 at 4 (stating the "exact mechanism behind the injury process remains unclear"); Pet. Ex. 13 (noting 90% of sudden SNHL cases are idiopathic and the mechanism responsible for cases of sudden SNHL after immunization remains unclear); Pet. Ex. 163-7 at 2 (noting that the "pathophysiology of immune-mediated SNHL remains unknown"); Pet. Ex. 11 at 2 (noting that sudden SNHL is usually idiopathic).

Further, although molecular mimicry is an accepted scientific mechanism, generally opining that molecular mimicry is a causal theory, without more, is insufficient. See, e.g., Loyd ex rel. v. Sec'y of Health & Hum. Servs., No. 16-811V, 2021 WL 2708941, at *31 (Fed. Cl. Spec. Mstr. May 20, 2021) ("[T]hough molecular mimicry is a generally accepted scientific concept, and is frequently invoked in Program cases, the mere mention of it does not constitute satisfaction of the preponderant evidentiary standard. Rather, it must be shown that the mechanism likely does link the vaccine in question to the relevant injury." (internal citations omitted)); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (explaining that "merely 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" (emphasis omitted)); Sheets v. Sec'y of Health & Hum. Servs., No. 16-1173V, 2019 WL 2296212, at *17 (Fed. Cl. Spec. Mstr. Apr. 30, 2019) (determining Petitioner had not satisfied Althen prong one when he did not relate molecular mimicry "to either the vaccines in question or Petitioner's own specific condition").

Moreover, only one of Petitioner's case reports of hearing loss associated with vaccination involved Tdap. Therefore, the relevance of the remaining case reports is unclear as case reports about one vaccine cannot automatically be imputed to a different vaccine, particularly when the mechanisms offered have not been suggested as to the vaccine at issue. "An expert may 'extrapolate from existing data,' and use 'circumstantial evidence,' [b]ut the reasons for the extrapolation should be transparent and persuasive." K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *12 (Fed. Cl. Spec. Mstr. July 7, 2016) (internal citations omitted) (first quoting Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 743 (2009); and then quoting Althen, 418 F.3d at 1280).

Here, Petitioner does not explain how data from other unrelated vaccines could be extrapolated to the vaccines at issue here and accordingly, the data is not persuasive. See K.O., 2016 WL 7634491, at *12 (finding the case reports offered by Petitioner as having even less value than case reports do generally because they reported a sequence in which a vaccine, but not the vaccine at issue, preceded the onset of the injury at issue (citing Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011))); Crosby v. Sec'y of Health & Hum. Servs., No. 18-1478V, 2021 WL 3464125, at *9 (Fed. Cl. Spec. Mstr. July 22, 2021) (declining to give substantial weight to an article because it was on a different vaccine than the one at issue making reasoning difficult); see also Deshler v. Sec'y of Health & Hum. Servs., No. 16-1070V, 2020 WL 4593162, at *19-21 (Fed. Cl. Spec. Mstr. July 1, 2020) (declining to attribute case reports on the flu vaccine to pneumococcal vaccines); McDonald v. Sec'y of Health & Hum. Servs., No. 15-612V, 2023 WL 2387844, at *23 (Fed. Cl. Spec. Mstr. Mar. 7, 2023).

And the one epidemiological study of vaccination as a cause/trigger of sudden SNHL cited by Dr. Kinsbourne does not support Petitioner's position. Baxter et al. found no increased risk or association between SNHL and the DTaP vaccine or any other vaccine. While Dr. Kinsbourne explains that DTaP-related SNHL has "little to no chance of generating a signal in this study" because it is a rare event difficult to detect with epidemiological studies, that observation will not carry the day. Pet. Ex. 163 at 4. As De Marco et al. noted two years after the Baxter et al. study, "to date, there is not sufficient scientific evidence indicating sudden [hearing loss] [is] an adverse event to vaccination." Pet. Ex. 11 at 3.

Although a petitioner need not make a specific type of evidential showing (i.e., epidemiologic studies) to satisfy his burden, special masters shall still consider and weigh the evidence in the record, including the epidemiological studies filed. See § 13(b)(1) (indicating the special master shall consider all materials in the record); Capizzano, 440 F.3d at 1325-26; Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1149 (Fed. Cir. 1992) (finding "epidemiological studies are probative medical evidence relevant to causation" and "considerable weight [is] due to epidemiological studies in the absence of direct evidence of actual causation"). And after weighing the submitted evidence, the undersigned finds the evidence does not weigh in Petitioner's favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."). The undersigned finds the totality of the evidence presented fails to demonstrate by preponderance evidence that the DTaP vaccine can cause SNHL.

Lastly, there are several other Vaccine Program cases with reasoned decisions regarding numerous causation theories for hearing loss, and the special masters in those cases often denied entitlement. None of these cases involved the DTaP vaccination; instead, they relate to the flu vaccine. Regardless, SNHL has been rejected as a vaccine-related injury due to insufficient evidence to support causation. Although decisions of other special masters are not binding, the undersigned generally agrees with the reasoning of her colleagues in these cases. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

The Petitioner in Inamdar alleged the flu vaccine caused his bilateral SNHL. Inamdar v. Sec'y of Health & Hum. Servs., No. 15-1173V, 2019 WL 1160341, at *1 (Fed. Cl. Spec. Mstr. Feb. 8, 2019). Petitioner proposed the flu vaccine "could cause the production of proinflammatory cytokines immediately upon vaccine administration," and alternatively, that specific components of the vaccine "were structurally homologous with ganglioside receptors on the neuronal myelin contained in the inner ear tissue, and that antibodies generated in response to the vaccine could also cross-react with the self-myelin, resulting in tissue damage." Id. at *5-6. The special master found the first theory relied too heavily on what was known about the wild virus rather than the vaccine, and further found that both theories were unsupported by the literature. Id. at *17-18. Additionally, the Inamdar Petitioner "did not adequately substantiate the how (i.e. the mechanistic process) portion of his theory—the manner in which the rapid upregulation of cytokines would cause tissue damage in the ear resulting in hearing loss." Id. at *18.

Similarly, in Doe/16, Petitioner's expert proposed an autoimmune hypersensitivity reaction theory for how the flu vaccine can cause unilateral sudden SNHL. Doe/16 v. Sec'y of Health & Hum. Servs., No. 06-670V, 2008 WL 2390064, at *5 (Fed. Cl. Spec. Mstr. June 2, 2008). Petitioner's expert "did not believe the killed virus in the vaccine could directly provoke an illness," rather that the flu vaccine "triggered an antigen reaction, which caused inflammation" in the endolymphatic sac. Id. The special master found the medical literature lacked support for the autoimmune hypersensitivity reaction. Id. at *12-14.

In Kelly, the Petitioner alleged the flu vaccine caused his unilateral SNHL. Kelly v. Sec'y of Health & Hum. Servs., No. 16-878V, 2021 WL 5276373, at *1 (Fed. Cl. Spec. Mstr. Oct. 18, 2021), mot. for rev. den'd, 160 Fed. Cl. 316 (2022). Petitioner proposed a Type I sensitivity reaction and alternatively, an autoimmune response. Id. at *25-26. The Chief Special Master found limited support for the primary theory and found the autoimmune theory inconsistent with the facts presented, including the fact that Petitioner's hearing loss was unilateral, and the onset was two hours. Id. at *24-26.

Recently, the undersigned denied entitlement where Petitioner alleged the flu and Prevnar 13 vaccines caused his hearing loss. Alsaadeh v. Sec'y of Health & Hum. Servs., No. 19-1097V, 2024 WL 694072 (Fed. Cl. Spec. Mstr. Jan. 23, 2024). The undersigned found Petitioner's immune-mediated theory was not sound or reliable in part because the causal mechanism of immune-mediated hearing loss is unknown. Id. at *31-34.

While there is one reasoned decision where entitlement was granted to a petitioner who alleged the flu vaccine caused sudden SNHL, the undersigned notes that the facts and theory here are different. Madigan v. Sec'y of Health & Hum. Servs., No. 14-1187V, 2021 WL 3046614, at *1 (Fed. Cl. Spec. Mstr. June 25, 2021). In Madigan, the Petitioner proposed a stress response theory which "suggests that stress leaves people susceptible to immune disruption both by reducing natural killer ('NK') cells, which help resist viral and bacterial infection, and by promoting production of proinflammatory cytokines IL-1 and IL-6." Id. at *12. The special master distinguished Madigan from Doe/16 and Inamdar because those cases relied on "the presence of post-vaccination inflammation seemingly without an explanation (such as the stress response theory) for how they could affect the inner ear and/or be injurious." Id. at *17.

In summary, Petitioner has failed to offer a sound and reliable medical theory in support of her claim. Thus, the undersigned finds Petitioner has failed to provide preponderant evidence with respect to the first Althen prong.

B. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical 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 trustworthy evidence since they are created contemporaneously with the treatment of the vaccinee. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the "diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court").

Since Petitioner failed to prove Althen prong one, it follows that she cannot prove Althen prong two. In addition, Petitioner has failed to show by preponderant evidence that there is a logical sequence of cause and effect showing Petitioner's DTaP vaccine caused her hearing loss because she has failed to establish that her hearing loss was autoimmune in nature. Although no antibody testing[69] was done which would have been helpful to prove or disprove an autoimmune etiology, here Petitioner failed to have a significant response to steroid therapy. If her condition had been autoimmune in origin, an improvement would be expected.

The medical literature cited by the parties establishes that SNHL thought to be autoimmune is treated with corticosteroids. See, e.g., Pet. Ex. 163-7 at 2 (stating that recovery of hearing after immunosuppressive therapy helps reinforce the existence of an immune-mediated mechanism of hearing loss); Pet. Ex. 163-4 at 1 (same); Pet. Ex. 163-3 at 4 (recommending patients with SNHL treating with steroids or immunosuppressants). But see Pet. Ex. 163-7 at 12 (the Brighton Collaboration SNHL Working Group deciding against using "treatment or treatment response towards the fulfilment of the SNHL case definition" because a "standard treatment is not established, and a treatment response or its failure is not in itself diagnostic of SNHL").

[69] Petitioner's C-reactive protein, an indicator of inflammation, was not elevated. Pet. Ex. 1 at 10 (ECF No. 8-1).

However, the experts agree that Petitioner did not have any significant response to the steroids. Pet. Ex. 163 at 1 (Dr. Kinsbourne acknowledging "[o]ral steroids conveyed no benefit" to Petitioner); Resp. Ex. C at 4 (Dr. Kedl opining "oral steroids had absolutely no benefit to [Petitioner's] condition"); Pet. Ex. 10 at 1 (Dr. Brawer indicating that Petitioner's hearing loss is "fixed and permanent").

Dr. Kedl opines that Petitioner's failure to respond to steroid treatment is evidence that she did not have an autoimmune disorder. Thus, Petitioner's clinical course is not consistent with an autoimmune reaction.

Next, although some of Petitioner's treating physicians documented her reports of symptoms and/or their temporal association with vaccination, the undersigned does not find their statements provide persuasive evidence of causation.

Generally, treating physician statements are typically "favored" 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.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280). However, no treating physician's views bind the special master, per se; rather, their views are carefully considered and evaluated. § 13(b)(1); Snyder, 88 Fed. Cl. at 746 n.67. "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." Welch v. Sec'y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at *8 (Fed. Cl. Spec. Mstr. July 2, 2019).

Dr. Shariati was Petitioner's primary care provider. His records show that he is an internist, not an otolaryngologist or immunologist. He documented several statements attributing Petitioner's hearing loss to vaccination. See, e.g., Pet. Ex. 1 at 1 (ECF No. 8-1) (assessing Petitioner's hearing loss as "[p]robable side effect[] from receiving DTaP"); Pet. Ex. 3 at 2 (assessing Petitioner's hearing loss with tinnitus as "probably secondary to administration of vaccine"); Pet. Ex. 1, ECF No. 67-5 at 2 (noting Petitioner's hearing loss and ringing in her left ear "was contributed from the [DTaP] vaccination").

Although Dr. Shariati consistently documented his opinion that Petitioner's hearing loss was caused by vaccination, he did not provide any explanation for his opinion. "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." Welch v. Sec'y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at *8 (Fed. Cl. Spec. Mstr. July 2, 2019). An opinion by a treating physician that is not supported by a factual basis or other evidence is conclusory in nature. See Robertson v. Sec'y of Health & Hum. Servs., No. 18-554V, 2022 WL 17484980, at *17 (Fed. Cl. Spec. Mstr. Dec. 7, 2022) (finding treating physicians' statements of mere suspicion fall short of an opinion supporting vaccine causation); Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1347 (Fed. Cir. 2010) (concluding the special master did not err in affording little weight to the opinions of Petitioner's treating physicians where "none of the treating physicians concluded that the [] vaccine caused [Petitioner's] [condition]").

The balance of the records by Petitioner's treating physicians appear to be based on the temporal association between vaccination and hearing loss. For example, otolaryngologist Dr. Selesnick wrote that "[d]ue to the close time proximity of the administration of the vaccine, it is likely that the vaccine is at least in some way responsible for [Petitioner's] [SNHL]." Pet. Ex. 1 at 27 (ECF No. 8-1); see also Pet. Ex. 1 at 4 (ECF No. 8-1) (Dr. Flemming indicating Petitioner had sudden SNHL in the left ear and that it "began 24 hours after having a [DTaP] vaccine"); 22 (Dr. Kwartler noting Petitioner's hearing loss occurred after DTaP vaccine).

A "treating physician's recognition of a temporal relationship does not advance the analysis of causation." Isaac v. Sec'y of Health & Hum. Servs., No. 08-601V, 2012 WL 3609993, at *26 (Fed. Cl. Spec. Mstr. July 30, 2012). And a temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer, 100 Fed. Cl. at 356 (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury").

Lastly, Respondent's expert offers an opinion as to alternate cause for Petitioner's hearing loss, namely the antibiotic Cipro documented in her medical records. Dr. Kedl opines the medical records show that Petitioner was taking antibiotics when she received her vaccination, and that one of the antibiotics is known to cause ototoxicity and hearing loss. Dr. Kinsbourne disagrees that the antibiotics caused Petitioner's hearing loss, because he argues that the effect would have been gradual and not sudden. Moreover, he notes that Petitioner's PCP explained that Petitioner was not taking these medications at the time of vaccination.

When Petitioner first presented to her PCP, Dr. Shariati, with complaints of hearing loss on June 20, 2017, antibiotics (Bactrim and Cipro) were listed as current medications. Petitioner later asked Dr. Shariati about the antibiotics listed as her current medications from that visit and Dr. Shariati informed her "that the 'current' list [was] of all the drugs [she] had been prescribed in the entire time [she] had been seeing him" and "[t]hat particular note was not indicative of the medication [she] was taking at the time of the visit." ECF No. 93-1 at ¶ 1. Petitioner further declared she was not on antibiotics at that time. Dr. Shariati also submitted a letter addressing this entry writing that Petitioner "was not on antibiotics at the time she received the DTaP vaccine." Pet. Ex. 62 at 1.

The undersigned acknowledges that Petitioner is not required to eliminate other potential causes in order to be entitled to compensation. See Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1149-52 (Fed. Cir. 2007) (finding a petitioner does not bear the burden of eliminating alternative independent potential causes). However, it is reasonable to consider "evidence of other possible sources of injury" to determine "whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question." Stone, 676 F.3d at 1379; see also Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th 958, 963 (Fed. Cir. 2023) (finding the special master's "contemplation of a potential causative agent when evaluating whether or not a petitioner has established a prima facie case is in accordance with the law").

However, after consideration of all of the evidence, the undersigned finds that while the records document that Petitioner was on antibiotics at the time that she received her vaccination, she has filed evidence to show that the record was incorrect. The undersigned finds that Petitioner provided preponderant evidence to show that she was not taking antibiotics at the time of vaccination. Therefore, the antibiotics do not constitute an alternative cause for her hearing loss and there is no evidence of an alternative cause. Regardless of this finding, the undersigned finds that Petitioner has failed to show that her condition was autoimmune.

Moreover, in essence, Dr. Brawer opines that because Petitioner did not have any hearing impairment or systemic neurological or otolaryngological condition prior to her DTaP vaccine, Petitioner's condition began within 36 to 48 hours following the DTaP vaccination, and Petitioner's SNHL and tinnitus "cannot be attributed to any other well-defined and well-known causes that can trigger such phenomena," that the DTaP vaccine did cause Petitioner's SNHL and tinnitus. Pet. Ex. 10 at 5. The Federal Circuit in Capizzano noted that "[t]he second prong of the Althen . . . test is not without meaning." Capizzano, 440 F.3d at 1327. Indeed, in Althen, the Court stated: "Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." Althen, 418 F.3d at 1278.

Therefore, Petitioner has failed to provide preponderant evidence of a logical sequence of cause and effect.

C. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a "medically acceptable temporal relationship." Id. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352.

The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen prong one). de Bazan, 539 F.3d at 1352; see also Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243-44 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542. Thus, prong three 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, 101 Fed. Cl. at 542-43. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer, 100 Fed. Cl. at 356 (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury").

Because Althen prong three coincides with Althen prong one, Petitioner's inability to meet his burden demonstrating how the DTaP vaccine can cause hearing loss effectively

precludes him from being able to meet his burden under the third Althen prong. Thus, because the undersigned found that Petitioner did not offer a sound and reliable theory of causation, he cannot demonstrate that his condition arose in a medically acceptable timeframe pursuant to that theory. Even assuming that Petitioner satisfied Althen prong three, that alone would not satisfy Petitioner's overall burden of proof. Veryzer, 100 Fed. Cl. at 356 (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury."). However, Petitioner's showing with respect to the third Althen prong is deficient.

The parties stipulated that Petitioner's hearing loss began approximately two days after receiving the DTaP vaccine. Joint Submission at 1.

Dr. Brawer opines there is a temporal relationship because Petitioner's development of SNHL and tinnitus began within 36 to 48 hours of her DTaP vaccination. But he does not explain how this is a medically acceptable timeframe pursuant to the mechanisms discussed. Similarly, Dr. Kinsbourne opines Petitioner developed sudden hearing loss two days after the DTaP vaccination but does not provide any explanation of how this is consistent with autoimmunity induced hearing loss. Dr. Kedl explains that an onset of hearing loss two days after vaccination is not supportive of an immune response to vaccination but does not explain why. As explained above, there is insufficient evidence of a mechanistic theory and while there are opinions stated as to onset, the opinions are not developed within the context of a supportive theory of causation.

Accordingly, the undersigned finds Petitioner failed to provide preponderant evidence of Althen prong three.

V. CONCLUSION

The undersigned extends her sympathy to Petitioner for her hearing loss and tinnitus. The undersigned's Decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

For the reasons discussed above, the undersigned finds that Petitioner has failed to establish by preponderant evidence that DTaP vaccination she received caused her hearing loss and tinnitus. Therefore, Petitioner is not entitled to compensation and the petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master