In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 23, 2025

ROBERTA JOHNSON,	*	PUBLISHED
Petitioner,	*	No. 22-107V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Measles-Mumps-Rubella ("MMR") Vaccine; Sudden Onset Sensorineural Hearing Loss ("SSNHL"); Autoimmune Inner Ear Disease ("AIED").
Respondent.	*	

Ronald Craig Homer, Conway, Homer, PC, Boston, MA, for Petitioner.
James Vincent Lopez, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On February 2, 2022, Roberta Johnson ("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 a measles-mumps-rubella ("MMR") vaccine administered on April 19, 2019, caused her to develop bilateral sudden onset sensorineural

[1] Because this Ruling 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 Ruling 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 Ruling to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

hearing loss ("SSNHL") and autoimmune inner ear disease ("AIED").[3] Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating "this case is not appropriate for compensation under the Vaccine Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 22).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards,[4] the undersigned finds Petitioner has provided preponderant evidence that the MMR vaccine she received on April 19, 2019 caused her to develop AIED, satisfying Petitioner's burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

I. ISSUES TO BE DECIDED

The parties agree on Petitioner's diagnosis of AIED. Joint Submission at 1.

The parties dispute all three Althen prongs. Joint Submission at 2. Specifically, Respondent disputes that Petitioner has shown that "administration of an MMR can cause the injuries alleged;" disputes that there is a "logical sequence of cause and effect between [Petitioner's] April 19, 2019 MMR vaccination and her subsequent injuries;" and disputes that there is "an appropriate temporal relationship between [Petitioner's] April 19, 2019 MMR vaccination and the onset of her injuries." Id.

II. BACKGROUND

A. Procedural History

On February 2, 2022, Petitioner filed a petition requesting compensation followed by medical records and affidavits.[5] Petitioner's Exhibits ("Pet. Exs.") 1-7. The case was then assigned to the undersigned. Notice of Assignment dated Apr. 26, 2022 (ECF No. 12). Respondent filed a Rule 4(c) report on November 15, 2022, arguing against compensation. Resp. Rept. at 1.

[3] While the petition only alleges Petitioner developed SSNHL, subsequent filings specify that Petitioner developed AIED. See, e.g., Joint Submission, filed Sept. 30, 2024, at 1 (ECF No. 70).

[4] While the undersigned has reviewed all of the information filed in this case, only those filings and records that are most relevant will be discussed. See Moriarty v. Sec'y of Health & Hum. Servs., 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision."); see also Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

[5] Petitioner continued to file medical records throughout litigation.

On June 29, 2023, Petitioner filed an expert report from Dr. Edwin M. Monsell. Pet. Ex. 11. On December 27, 2023 and January 26, 2024, Respondent filed expert reports from Dr. Herman F. Staats and Dr. Yu-Lan Mary Ying. Resp. Exs. A, C.

The undersigned held a Rule 5 conference on March 21, 2024. Order dated Mar. 21, 2024 (ECF No. 55). She advised that parties that she had "adjudicated several SNHL cases and has previously found it difficult for petitioners to show the hearing loss was autoimmune and that it was caused by a vaccine." Id. at 2. However, she explained the present case was "different from past cases because the experts agreed Petitioner's diagnosis is an autoimmune hearing loss (AIED) and agreed as to Althen prong three." Id. The undersigned noted the "case merits consideration for settlement given that there is risk for both parties" and noted the case could be resolved without an entitlement hearing. Id.

On July 24, 2024, Respondent filed a joint status report advising that he was not amenable to settlement discussion in this case. Joint Status Rept., filed July 24, 2024 (ECF No. 66). The parties requested the undersigned set a briefing schedule for a ruling on the record. Id.

Petitioner filed his motion for a ruling on the record on September 30, 2024. Pet. Motion for a Ruling on the Record ("Pet. Mot."), filed Sept. 30, 2024 (ECF No. 73). Respondent filed his responsive brief on January 21, 2025, and Petitioner filed a reply on March 5, 2025. Resp. Response to Pet. Mot ("Resp. Response"), filed Jan. 21, 2025 (ECF No. 80); Pet. Reply to Resp. Response ("Pet. Reply"), filed Mar. 5, 2025 (ECF No. 81).

This matter is now ripe for adjudication.

B. Medical Terminology

1. Autoimmune Inner Ear Disease

AIED is "a condition of a bilateral sensorineural hearing loss [("SNHL")], caused by an 'uncontrolled' immune system response." Resp. Ex. C, Tab 18 at 1;[6] see also Resp. Ex. C, Tab 19 at 13 tbl.7, 16.[7] "AIED is considered to be responsible for [less than] 1% of all SNHL cases." Resp. Ex. C, Tab 18 at 1.

"The clinical expression of AIED is a progressive bilateral and not always symmetric SNHL, progressively developing between [three] and 90 days, which typically benefits from [] steroid and immunosuppressive therapy." Resp. Ex. C, Tab 18 at 1. Often only one ear is affected in the early stage. Id. at 3. "The hearing deficit sometimes presents [with] threshold

[6] Andrea Ciorba et al., Autoimmune Inner Ear Disease (AIED): A Diagnostic Challenge, 32 Int'l J. Immunopathol. & Pharmacol. 1 (2018).

[7] Sujana S. Chandrasekhar et al., Clinical Practice Guidelines: Sudden Hearing Loss (Update), 161 Otolaryngol. Head & Neck Surg. s1 (2019).

fluctuations." Id. In 25-50% of cases, tinnitus[8] can be present. Id. Importantly, "there are no standardized diagnostic criteria or reliable diagnostic tests for the diagnosis of AIED." Id. at 1. As such, the diagnosis of "immune-mediated cochleovestibular disorders" is based on clinical symptoms, laboratory tests ("demonstrating the presence in the serum of antibodies or activated T cells against inner ear antigens"), and on the response to immunosuppressive treatment. Id. at 3. "Essentially, AIED is a diagnosis of exclusion, suspected in case of a documented progressive SNHL, when other etiologic causes have been ruled out." Id.

2. Sensorineural Hearing Loss

SNHL is "[h]earing loss resulting from abnormal function of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing." Resp. Ex. C, Tab 19 at 4 tbl.1. SNHL is "generally idiopathic," but some cases are "associated with infections, vasculitides, tumors, [] genetic conditions, and cardiovascular risk factors." Resp. Ex. A, Tab 3 at 2.[9]

SSNHL is a subset of SNHL that "occurs within a 72-hour window" and meets specific audiometric criteria. Resp. Ex. C, Tab 19 at 3. "Possible etiologies of SSNHL include viral infection, vascular compromise, autoimmune disease, inner ear pathology, and central nervous system pathophysiology." Id. at 16. Idiopathic SSNHL has "no identifiable cause despite investigation" and accounts for "90% of patients with SSNHL." Id. at 3.

C. Factual History

1. Summary of Medical Records[10]

On March 15, 2019, Petitioner received an MMR vaccine at the Northwestern Medicine ("NM") employee health office in Winfield, Illinois. Pet. Ex. 1 at 1. Petitioner was employed as an operating room nurse at NM Central DuPage Hospital. See, e.g., Pet. Ex. 2 at 1105. On April 19, 2019, 35 days later, Petitioner received a second dose of the MMR vaccine. Pet. Ex. 1 at 1. She was sixty-five years old at the time of the vaccinations. Id. Petitioner's medical history prior to receiving the MMR vaccines was unremarkable. See, e.g., Pet. Ex. 2 at 1400-16, 1512-30 (documenting routine annual visits).

On May 25, 2019, 36 days after receiving a second dose of MMR vaccine, Petitioner presented to NM urgent care, reporting "bilateral ear fullness" beginning "[four to five] days

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[8] 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 Dec. 17, 2025).

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

[10] This summary of medical records is taken from the parties' briefs, with edits from the undersigned, as the undersigned finds they provided an accurate representation of the records. See Pet. Mot. at 4-30; Resp. Response at 3-9.

ago." Pet. Ex. 2 at 1365. She reported she had "flown and been in [the] ocean [four] times over the past 'few weeks.'" Id. She reported taking decongestants without relief. Id. On examination, her tympanic membranes[11] were "dull" bilaterally with no other significant findings. Id. at 1367. She was diagnosed with bilateral acute serous otitis media,[12] prescribed Flonase, and encouraged to continue taking decongestants. Id. at 1368.

On June 4, 2019, Petitioner underwent an audiogram at NM, which showed moderate bilateral SNHL. Pet. Ex. 5 at 1. According to Petitioner's declaration, the audiogram was ordered by ear, nose, and throat specialist ("ENT") Riddhi Patel, M.D., at NM. Pet. Ex. 6 at ¶ 4. Petitioner states that she knew Dr. Patel from her work in the hospital and was also informally examined by Dr. Patel on June 4, 2019; however, Dr. Patel's examination was not formally documented in the medical records. Id.; see also Pet. Mot. at 6 n.5.

On June 5, 2019, Petitioner saw neuro-ophthalmologist Jeffrey Haag, M.D., at the Wheaton Eye Clinic, reporting the "sudden loss of hearing bilaterally [two] weeks ago [and] trouble with balance." Pet. Ex. 3 at 25. Petitioner reported that her symptoms "began after an airplane flight." Id. Dr. Haag noted Petitioner's prior appointment with Dr. Patel, who found bilateral hearing loss. Id. The eye examination showed mild nuclear sclerosis[13] bilaterally but was otherwise normal. Id. at 26-27. Dr. Haag's impression was "[d]izziness and decreased hearing (bilateral, symmetrical), cause uncertain." Id. at 25.

Dr. Haag later added an undated addendum to his chart note, indicating that he had consulted with neurotologist Andrew Fishman, M.D., who reviewed Petitioner's audiogram from the day prior and believed it was consistent with bilateral SNHL. Pet. Ex. 3 at 25. Per Dr. Fishman's recommendation, Dr. Haag started Petitioner on prednisone[14] 60 mg daily. Id.

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[11] The tympanic membrane, also called the eardrum, is "the obliquely placed, thin membranous partition between the external acoustic meatus and the tympanic cavity." Membrana Tympanica, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=88565 (last visited Nov. 4, 2025).

[12] Otitis media is "inflammation of the middle ear." Otitis Media, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=95455 (last visited Nov. 4, 2025). Serous otitis media is "chronic otitis media marked by serous effusion into the middle ear." Otitis Media, Serous, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=95462 (last visited Nov. 4, 2025).

[13] Nuclear sclerosis, or nuclear cataract, refers to a congenital or degenerative opacity within the central portion of the lens. Leila M. Khazaeni, Cataract, Merck Manual, https://www.merckmanuals.com/professional/eye-disorders/cataract/cataract (last visited Dec. 16, 2025). "The main symptom is gradual, painless vision blurring." Id.

[14] Prednisone is "a synthetic glucocorticoid [i.e. steroid] . . . [administered] as an antiinflammatory and immunosuppressant in a wide variety of disorders." Prednisone, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=40742 (last visited Nov. 4, 2025).

On June 12, 2019, Petitioner saw neurotologist Dr. Fishman at NM, reporting the onset of bilateral hearing loss on May 22, 2019, associated with tinnitus, pressure in her ears, right ear pain, dizziness, and headaches. Pet. Ex. 2 at 1340-41.

Also, on June 12, 2019, Petitioner underwent a second audiogram, which was unchanged from the earlier study six days prior. Pet. Ex. 2 at 1331-32; Pet. Ex. 5 at 2. The audiologist Krystine Mullins noted Petitioner had a family history of hearing loss, involving her father and aunt. Pet. Ex. 2 at 1331-32.

On June 13, 2019, Petitioner underwent magnetic resonance imaging ("MRI") of her brain and internal auditory canals that showed a small meningioma[15] in the left occipital node without any evidence of brain compression or mass effect. Pet. Ex. 2 at 1321-22.

On June 17, 2019, Petitioner saw ENT Seth Kay, M.D., for persistent vertigo. Pet. Ex. 2 at 1296. Dr. Kay noted Petitioner's history of sudden onset bilateral SNHL and vertigo that developed "[two] weeks ago after a flight." Id. High-dose prednisone had improved Petitioner's hearing, but her vertigo persisted. Id. The ENT examination was normal. Id. at 1299. Dr. Kay administered an intratympanic steroid injection in the right ear. Id. Dr. Kay's diagnosis was "[b]ilateral vertigo and hearing loss of unclear etiology." Id. at 1300. The differential diagnoses included bilateral Meniere's disease,[16] bilateral labyrinthitis,[17] an autoimmune process, tumor, or central nervous system process. Id. He referred Petitioner to a neurologist for further evaluation. Id. Dr. Kay also noted Dr. Fishman "thought this was either bilateral Meniere's or an autoimmune process." Id. at 1296.

On June 26, 2019, Petitioner underwent a third audiogram, which showed improved low frequency hearing with otherwise moderate to severe bilateral SNHL. Pet. Ex. 2 at 1282; Pet. Ex. 5 at 3. She was also evaluated again by Dr. Kay, complaining of right ear fullness that had worsened when stopping diuretics for several days and improved after restarting them. Pet. Ex. 2 at 1268. Petitioner continued to report poor balance. Id. Dr. Kay favored a diagnosis of Meniere's disease given the improvement in her low frequency hearing, response to diuretics, and minimal response to the middle ear steroid injection. Id. at 1272. Dr. Kay started to taper Petitioner off prednisone and referred her to physical therapy ("PT") for vestibular rehab. Id.

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[15] A meningioma is "a benign, slow-growing tumor of the meninges, usually next to the dura mater." Meningioma, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=30336 (last visited Nov. 4, 2025).

[16] Meniere's disease "is a clinical syndrome that consists of episodes of spontaneous vertigo usually associated with unilateral fluctuating [SNHL], tinnitus, and aural fullness." Pet. Ex. 39 at 2 (Jose A. Lopez-Escamez et al., Diagnostic Criteria for Menière's Disease, 25 J. Vestib. Rsch. 1 (2015)).

[17] Labyrinthitis is "inflammation of the internal ear; it may be accompanied by hearing loss or vertigo." Labyrinthitis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=27360 (last visited Nov. 4, 2025).

On June 27, 2019, Petitioner had a PT evaluation for Meniere's disease of both ears. Pet. Ex. 2 at 1257. She reported a history that she "felt [her] ears were full as she came off a plane" on May 22, 2019, with bilateral hearing loss that was worse on the right side. Id. Petitioner also reported "[d]ifficult to tolerate busy visual stimulation" and dizziness. Id. Petitioner continued to attend PT through November 26, 2019. Id. at 769-779, 816-26, 857-66, 918-48, 1039-41, 1052-60, 1084-91, 1152-77, 1247-63.

On July 10, 2019, Petitioner saw Dr. Fishman for a "follow up [regarding] [M]eniere's disease." Pet. Ex. 2 at 1229. Petitioner reported that her vertigo had worsened since her last visit and that she had obtained no relief from a right ear steroid injection. Id. She reported some improvement of dizziness with PT. Id.

On July 11, 2019, Petitioner returned to Dr. Kay reporting worsening hearing since stopping steroids. Pet. Ex. 2 at 1213. Dr. Kay noted that Dr. Fishman felt this was a progressive autoimmune process. Id. The ENT examination was normal. Id. Dr. Kay diagnosed bilateral hearing loss and vertigo of unclear etiology but "likely [AIED] given bilateral component and only response to steroids." Id. He restarted prednisone, continued vestibular rehab, recommended hearing aids, and referred her to a rheumatologist. Id.

Also, on July 11, 2019, Petitioner underwent a fourth audiogram that showed a marked decrease in hearing in the left ear. Pet. Ex. 2 at 1204; Pet. Ex. 5 at 5.

Petitioner next returned to Dr. Kay on July 25, 2019, and reported that she had obtained hearing aids and her balance was slowly improving. Pet. Ex. 2 at 1134. Dr. Kay noted that Petitioner had received MMR vaccines "[one to two] months before onset of symptoms" and that there were "reports in the literature of similar vaccines causing hearing loss and vestibular dysfunction." Id. at 1134. He further stated that it was "unclear" whether the prior receipt of MMR vaccine was "coincidental [versus] possible causation." Id. at 1138. Dr. Kay's assessment remained "likely" AIED, and he noted Petitioner's vertigo was severely limiting and prevented her from returning to work. Id.

Later that day, Petitioner saw rheumatologist Brittany Panico, M.D., at NM, for an evaluation of acute bilateral SNHL. Pet. Ex. 2 at 1104. Dr. Panico noted Petitioner's vestibular testing showed bilateral vestibular loss. Id. Petitioner continued "to have symptoms of oscillopsia."[18] Id. She continued to take prednisone, struggled with balance, and had intermittent episodes of blurry vision. Id. In the history of the present illness, Dr. Panico noted Petitioner "did receive MMR vaccine titers in March and April, approximately [one] month before the onset of her hearing loss." Id. at 1105. Further, Petitioner denied any rashes or skin lesions or chemical exposure, nor recalled "any flulike symptoms, [upper respiratory infection] symptoms[,] or recent infections." Id. The physical examination was unremarkable besides a

[18] Oscillopsia is "a symptom in which objects appear to wiggle, jerk, or move back and forth; it sometimes accompanies nystagmus." Oscillopsia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=35681 (last visited Nov. 4, 2025).

positive Romberg's sign.[19] Id. at 1107-08. Dr. Panico opined findings by "neuro-ophthalmology, neurotology, [and] ENT" were "most consistent with autoimmune hearing loss" but stated that Petitioner's clinical features were "somewhat concerning for Cogan's disease."[20] Id. at 1110. Dr. Panico continued Petitioner's prednisone taper and started her on methotrexate, an immunosuppressive therapy. Id.

On August 1, 2019, Petitioner returned to neuro-ophthalmologist Dr. Haag, per a referral from Dr. Panico, for an eye examination to rule out Cogan's syndrome. Pet. Ex. 3 at 23. Petitioner reported that her dizziness was worse since her last visit and that her "visual images bounce a lot," with intermittent vertical oscillopsia. Id. She had stopped driving in mid-June 2019. Id. The eye examination was normal and ruled out Cogan's syndrome. Id. at 23-24. Dr. Haag diagnosed Petitioner with "[v]estibular system dysfunction with bilateral hearing." Id. at 23. He noted an "autoimmune etiology [was] suspected." Id.

Petitioner had a follow up visit with Dr. Fishman on August 14, 2019. Pet. Ex. 2 at 1039. Petitioner reported she was not sure if her dizziness was better and that she had periodic vision changes. Id.

On August 27, 2019, Petitioner followed up with rheumatologist Dr. Panico for autoimmune hearing loss. Pet. Ex. 2 at 994. Dr. Panico recommended Petitioner continue to taper her prednisone. Id. at 1000. Her weekly methotrexate dosage was decreased due to nausea. Id. The assessment remained SSNHL "concerning for autoimmune hearing loss." Id.

On August 28, 2019, Petitioner saw neurosurgeon Andrew Chenelle, M.D., at NM, for evaluation of the meningioma identified on her brain MRI. Pet. Ex. 2 at 978. Dr. Chenelle believed the meningioma was an incidental finding unrelated to her current hearing loss and balance problems. Id. at 981.

Later that day, Petitioner had a follow-up visit with Dr. Kay. Pet. Ex. 2 at 951. She reported that her balance was slowly improving but she continued to have vertigo provoked by visual and auditory stimuli. Id. Dr. Kay's assessment remained "likely" AIED. Id. at 956. Petitioner also underwent an audiogram. Id. at 968. Petitioner's next follow-up with Dr. Kay was October 2, 2019. Id. at 886-87. The assessment was unchanged. Id. at 899.

On October 3, 2019, Petitioner returned to Dr. Panico for follow-up of her autoimmune hearing loss. Pet. Ex. 2 at 869. She advised Dr. Panico that she planned to resign from work "as

[19] Romberg's sign is the "swaying of the body or falling when standing with the feet close together and the eyes closed." Romberg Sign, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=106448 (last visited Nov. 4, 2025).

[20] Cogan's syndrome is "a rare autoimmune disease involving the eye and the inner ear." Vatinee Y. Bunya, Cogan Syndrome, Merck Manual, https://www.merckmanuals.com/professional/eye-disorders/corneal-disorders/cogan-syndrome (last visited Nov. 5, 2025).

she feels this is the best decision for her."[21] Id. She noted her father was also ill and receiving hospice care and that she wanted to spend more time with him. Id. Petitioner reported that she continued to experience vertigo in loud environments. Id. Dr. Panico's assessment remained SSNHL "concerning for autoimmune hearing loss." Id. at 874.

On October 14, 2019, Petitioner saw optometrist Ann Clark, M.D., at Wheaton Eye Clinic, complaining of blurry vision in her right eye along with "intermittent loss of vision, loss of hearing, and loss of equilibrium." Pet. Ex. 3 at 21. Petitioner reported she had to suppress her right eye vision to see clearly. Id. at 21. Dr. Clark diagnosed diplopia (double vision). Id. at 22.

On November 6, 2019, Petitioner saw neurologist Timothy Hain, M.D., at Chicago Dizziness and Hearing. Pet. Ex. 2 at 792. In the history of present illness, Petitioner reported sudden onset of bilateral hearing loss on May 22, 2019, which worsened over the next two weeks. Id. at 794. She said that her symptoms persisted despite treatment with prednisone and methotrexate and that she had been unable to work as an operating room nurse since June 7, 2019. Id. Petitioner reported that she lost her balance easily in low light situations and that her dizziness was triggered or worsened by rapid head movements, walking in poor lighting, traveling in a car, and loud noises or bright lights. Id. She reported that her vertigo started around June 5, 2019. Id. She had fallen three times due to her disequilibrium. Id. She also reported that she had been diagnosed with oscillopsia and that her vision worsened around loud noises. Id. On examination, Petitioner was unable to stand "in eyes closed tandem [R]omberg for [six] seconds," but her gait was otherwise unaffected. Id. at 804. She had "very slight horizontal nystagmus."[22] Id. Vestibulo-ocular reflex[23] "was very poor in all [three] directions." Id.

Dr. Hain diagnosed Petitioner with a "presumed" AIED (noting that "Cogan's still seems possible"), bilateral vestibular loss, and bilateral hearing reduction. Pet. Ex. 2 at 792. Dr. Hain provided a detailed impression:

> [Petitioner] is a very unusual patient with a recent onset of complete vestibular loss and partial bilateral vestibular loss. Her presumptive diagnosis is [AIED], although there has not been an autoimmune disease identified (as yet).

[21] Petitioner resigned from her job at NM on October 19, 2019. Pet. Ex. 2 at 829.

[22] Nystagmus is "involuntary, rapid, rhythmic movement of the eyeball." Nystagmus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=34565 (last visited Nov. 4, 2025).

[23] Vestibulo-ocular reflex is "nystagmus or deviation of the eyes in response to stimulation of the vestibular system by angular acceleration or deceleration or when the caloric test is performed (irrigation of the ears with warm or cool water or air)." Vestibuloocular Reflex, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=103130 (last visited Dec. 16, 2025).

> The rarest aspect to her situation is her bilateral vestibular loss, which has a prevalence of about 1/25,000 in the general population. . . . This combined with bilateral sensorineural hearing loss is even more uncommon, and the only cases I have seen in the last 30 years with a similar picture were again attributed to [AIED]. [Petitioner] does not have a history of exposure to an ototoxic medication such as an aminoglycoside.
>
> [Petitioner] does not have Meniere's disease—although her hearing resembled Meniere's at the beginning, Meniere's does not have this pattern of complete vestibular loss over a short time.
>
> The associations of this syndrome with autoimmune disorders include nearly [all] known autoimmune illness, but primarily there are reports in Cogan's, [ulcerative colitis ("UC")], Wegener's, Ankylosing spondylitis [("AS")], relapsing polychondritis, [Rheumatoid Arthritis ("RA")], and Scleroderma. Of these, Cogan's and Susac's has been largely ruled out by a normal [ophthalmic] exam although her inner ear MRI was not definitive . . . in ruling out Cogan's. Wegeners is unlikely due to her negative [antineutrophil cytoplasmic antibodies], and RA is also unlikely. UC is unlikely due to lack of [gastrointestinal] symptoms. AS and Scleroderma are very rare. Relapsing Polychondritis remains a possibility, but it is difficult to rule out.
>
> Regarding this picture arising post-vaccination (MMR), I have never encountered this situation although I have seen about 300 patients with bilateral loss in my career. It cannot be common.

Id. at 792-93. Dr. Hain suggested another ophthalmology evaluation to "be sure about Cogan's." Id. at 793. Dr. Hain referred Petitioner to neurotologist Akihiro Matsuoka, M.D., who Dr. Hain said had more experience with AIED than anyone he knew in the Chicago area. Id. at 794.

On December 2, 2019, Petitioner saw neurotologist Dr. Matsuoka at NM, for a second opinion on AIED. Pet. Ex. 2 at 757-59. Dr. Matsuoka's assessment was steroid-dependent AIED, and he ordered additional work-up. Id. at 759. In his assessment, Dr. Matsuoka observed Cogan's and Susac's syndromes had "notably" been "ruled out." Id.

On December 9, 16, and 23, 2019, Petitioner was seen by Dr. Matsuoka and received transtympanic steroid injections. Pet. Ex. 2 at 718, 739, 693.

On December 31, 2019, Petitioner was evaluated by rheumatologist Anisha Dua, M.D., at NM, for SNHL and problems with balance and vision. Pet. Ex. 2 at 664. Dr. Dua opined that Petitioner's "clinical presentation and steroid responsiveness [were] consistent with AIED." Id. She opined the work-up showed no evidence of systemic autoimmune disease, and believed the

treatment needed to be more aggressive, including an increased dose of methotrexate and Rituxan.[24] Id.

On January 3 and 17, 2020, Petitioner received additional transtympanic steroid injections, administered by Dr. Matsuoka. Pet. Ex. 2 at 601, 628.

On February 26, 2020, Petitioner followed up with Dr. Dua after receiving two Rituxan infusions that month. Pet. Ex. 2 at 483-87. Petitioner reported that her balance was possibly a little bit better, and her hearing loss fluctuated with no major improvement or worsening. Id.

On March 13, 2020, Petitioner followed up with Dr. Matsuoka regarding her AIED. Pet. Ex. 2 at 464. Dr. Matsuoka noted that an audiogram was unchanged since Petitioner's last test. Id. His assessment was AIED Type I with stable condition. Id.

The records filed show that Petitioner continued to follow up with Dr. Matsuoka for treatment through 2021. See Pet. Ex. 2 at 74-308. She had tympanostomy tubes placed in her right ear in July 2020 and left ear in November 2020. Id. at 197, 308. In December 2020 and January 2021, Petitioner received additional transtympanic steroid injections. Id. at 125, 146, 156, 173. She remained on Rituxan and methotrexate for treatment of AIED. Id. at 94-103. An audiogram on March 1, 2021 showed moderate to severe bilateral SNHL. Id. at 84.

On June 5, 2023, Petitioner underwent right cochlear implant[25] surgery. See Pet. Ex. 51 at 394-95. The following year, in June 2024, Petitioner underwent left cochlea implant surgery. Pet. Mot. at 31.

2. Petitioner's Declaration[26]

At the time of vaccination, Petitioner was working as an operating room nurse at NM Central DuPage Hospital. Pet. Ex. 6 at ¶ 1. An annual health screening done by her employer in 2019 found Petitioner had a negative mumps titer. Id. Petitioner's employer then required her to

[24] Rituxan, known generically as rituximab, is a "B cell-targeting [biologic agent] for the treatment of immune-mediated diseases." Pet. Ex. 35 at 1 (Celine Kaegi et al., Systematic Review of Safety and Efficacy of Rituximab in Treating Immune-Mediated Disorders, 10 Frontiers Immunol. 1990 (2019)).

[25] Cochlear Implant is a "a device consisting of a microphone, signal processor, external transmitter, and implanted receiver; the receiver is surgically implanted under the skin near the mastoid process above and behind the ear." Cochlear Implant, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=82067 (last visited Dec. 16, 2025).

[26] Although titled an affidavit, it was not notarized. Therefore, it is referenced as a declaration. Petitioner also submitted a declaration stating no prior civil action had been filed for her alleged vaccine injury. See Pet. Ex. 7.

be vaccinated to protect against mumps. Id. She received the first dose of the MMR vaccine on March 15, 2019, and her second dose on April 19, 2019. Id.

Petitioner averred that her hearing loss occurred 32 days after receiving the second dose of the MMR vaccine. Pet. Ex. 6 at ¶ 3. In May 2019, Petitioner and her husband traveled to Hawaii. Id. at ¶ 1. At the end of her trip, Petitioner noticed that her hearing was "muffled." Id. On May 25, 2019, three days after she returned home from Hawaii, Petitioner visited an urgent care "to see if there was an obvious and fixable problem." Id. At this visit, Petitioner's problem of "what felt like blocked ears" was "misdiagnosed" as fluid in the ears, and Petitioner was told by the nurse practitioner "it would go away." Id. at ¶ 3. "Over the following two and a half weeks, [her] hearing loss, balance[,] and visual symptoms became more prominent and debilitating." Id. at ¶ 2. Petitioner explained that she began "using a wooden staff to walk," she could no longer navigate poorly lit spaces, and she had difficult driving. Id.

Petitioner consulted with Dr. Patel, an ENT surgeon that she worked with as an OR nurse, regarding "how long [she] should wait for [her] ears to clear." Pet. Ex. 6 at ¶ 4. Dr. Patel offered to examine Petitioner. Id. On June 4, 2019, Petitioner went to Dr. Patel's office. Id. Dr. Patel found no fluid in Petitioner's ears and had an audiologist run an audiogram. Id. The audiogram showed significant bilateral, symmetrical SNHL. Id. "When Dr. Patel saw the audiogram her response was essentially 'how have you been able to hide this much hearing loss at work?'" Id. Dr. Patel discussed next steps with Petitioner. Id. Petitioner made an appointment the next morning, June 5, with a neuro-ophthalmologist. Id. The balance of Petitioner's declaration recounted her clinic course and her visits with various specialist as documented in her medical records. Pet. Ex. 6 at ¶¶ 4-11.

Petitioner's declaration also addressed the impact of her injury on her ability to work and her quality of life. Due to her injury, Petitioner "had to leave a job that [she] loved and excelled at." Pet. Ex. 6 at ¶ 14. Petitioner was unable work in the OR due to her balance, hearing, and visual symptoms. Id. at ¶ 6. Since leaving work, Petitioner is "longer able to plan for [an] active retirement." Id. at ¶ 14.

Petitioner averred that prior to her hearing loss, she was "a healthy and active adult." Pet. Ex. 6 at ¶ 1. As of the February 1, 2022 declaration, Petitioner relies on a "staff" when walking around and continues to have difficulties driving. Id. at ¶ 12. She is unstable is "low light surroundings" and unable "take a walk and casually look around because [she] lose[s] [her] balance if [she] do[es] not concentrate." Id. "Walking on uneven surfaces requires a great deal of effort" and "[g]oing up or down stairs or escalators is frightening." Id. Petitioner cannot hear in noisy settings, even with her hearing aids in. Id. at ¶ 13. She is "no longer able to hear music clearly; concerts and movies no longer are enjoyable." Id. And she has difficulties communicating with her family. Id. She concluded that it "has been stunning to go from being a busy healthy person . . . to dealing with this much change and loss." Id. at ¶ 16.

D. Expert Reports[27]

1. Petitioner's Expert, Edwin M. Monsell, M.D., Ph.D.[28]

a. Background and Qualifications

Dr. Monsell is "board-certified by the American Board of Otolaryngology—Head and Neck Surgery and hold[s] a Certificate of Added Qualifications from the same board in Neurotology (diseases and surgery of the inner ear and related skull base)." Pet. Ex. 11 at 1; see also Pet. Ex. 12 at 4. He obtained a Ph.D. in cell biology and neuroscience from Duke University in 1977 and an M.D. from University of North Carolina School of Medicine in 1979. Pet. Ex. 12 at 1. He then completed a surgical internship and a residency in the Otolaryngology-Head and Neck Surgery department at Northwestern University, followed by a fellowship at the House Ear Institute in Los Angeles, CA. Id. Since 1986, Dr. Monsell has held various hospital or other professional appointments and since 2000, he has also held faculty appointments. Id. at 1-2. He currently holds two hospital appointments in Seattle, Washington and teaches in the Otolaryngology-Head and Neck Surgery department at University of Washington in Seattle. Id. He is a member and has held various positions for the American Academy of Otolaryngology-Head and Neck Surgery, Association for Research in Otolaryngology, and other professional societies. Id. at 2-3; Pet. Ex. 11 at 1. In 2003, Dr. Monsell "received the Harris P. Mosher Award, the highest award for clinical and translational research in Otolaryngology by the American Laryngological, Rhinological[,] and Otological Society (a/k/a the Triological Society) for [his] research on mechanisms of hearing loss." Pet. Ex. 11 at 1. Throughout his career, he has published on the mechanisms of hearing loss, "treated many thousands of patients with hearing loss[,] and performed over 3,500 major ear operations to remove tumors or infections and restore hearing." Id.; see also Pet. Ex. 12 at 10-18.

b. Opinion

Dr. Monsell opined that Petitioner suffered from AIED, a form of "fluctuating or rapidly progressing sensorineural hearing loss that is responsive to immunosuppressive therapy." Pet. Ex. 11 at 13. Dr. Monsell opined that "more likely than not" Petitioner's "MMR vaccination had a substantial causal role in the development of her AIED." Id. at 18.

i. Althen Prong One

Dr. Monsell's causal theory focused on MMR vaccination as a live attenuated virus vaccination. Pet. Ex. 11 at 14. Dr. Monsell proposed that live components of the MMR vaccine can stimulate the immune system and lead to a vaccine-induced autoimmune response. Id. at 15. He posited that the "many associations between the naturally occurring viruses, the attenuated

[27] Although the undersigned has reviewed all of the expert reports and medical literature, for the sake of brevity this Ruling does not include all details of the experts' opinions. Instead, the undersigned focuses on the experts' material opinions, as they relate to the relevant issues.

[28] Dr. Monsell submitted one expert report. Pet. Ex. 11.

viruses in the MMR vaccine, and hearing loss" explain "how the attenuated live viruses in the MMR vaccine are likely responsible for developing autoimmune hearing loss and vestibular disease in [Petitioner]." Id.

In support of his opinion, Dr. Monsell cited a publication from the U.S. Department of Health and Human Services explaining that live attenuated virus vaccines "use a weakened (or attenuated) form of the germ that causes a disease." Pet. Ex. 31 at 2.[29] Live virus vaccines include both measles and mumps. Id. at 3. Dr. Monsell explained that live attenuated viruses are genetically altered to be less virulent than the live wild-type virus. Pet. Ex. 11 at 14. While less virulent, "[a] live virus vaccine must infect cells in the recipient to stimulate an immune response." Id. He opined that evidence that measles, mumps, and/or rubella infections cause hearing loss "suggests that live attenuated virus vaccination can cause hearing loss, at least in rare instances." Id.

Dr. Monsell noted there is "significant medical literature" discussing an increased incidence of hearing loss after mumps and measles infections. Pet. Ex. 11 at 14; see, e.g., Pet. Ex. 30 at 1 (describing profound hearing loss after mumps);[30] Pet. Ex. 40 at 1 (acknowledging "a well established association between viral infection and sensorineural hearing loss" including infections with measles and mumps);[31] Pet. Ex. 43 at 1 (describing measles-included hearing loss in children);[32] Pet. Ex. 49 at 1 (noting mumps induced hearing loss "is not rare").[33]

For example, the study by Olajuyin et al. followed 112 children with measles-induced hearing loss. Pet. Ex. 43 at 2. Seventy-two of these children had profound bilateral SNHL. Id. at 3. In McKenna, the author explained measles infections accounted for five to 10 percent of all cases of profound bilateral SNHL prior to the advent of vaccination. Pet. Ex. 40 at 3. McKenna also noted that in "some individuals the attenuated [measles] virus [in vaccines] is pathogenic. . . . Cases of unilateral and bilateral profound sudden deafness have been reported with the administration of the vaccine." Id. Further, the article noted that infection following the mumps

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[29] Vaccine Types, U.S. Dep't Health & Hum. Servs., https://www.hhs.gov/immunization/basics/types/index.html (last accessed June 21, 2023).

[30] R. Hall & H. Richards, Hearing Loss Due to Mumps, 62 Arch. Dis. Child. 189 (1987). This article was also filed as Resp. Ex. C, Tab 12.

[31] Michael J. McKenna, Measles, Mumps, and Sensorineural Hearing Loss, 830 Ann. NY Acad. Sci. 291 (1997). This article was also filed as Resp. Ex. C, Tab 6.

[32] Oyebanji A. Olajuyin et al., Measles-Induced Hearing Loss: Pattern, Diagnosis, and Prevention Among Children in Ekitis State, Southwest Nigeria, 23 Saudi J. Otorhinolaryngol. Head & Neck Surg. 65 (2021).

[33] Martti Vuori et al., Perceptive Deafness in Connection with Mumps: A Study of 298 Servicemen Suffering from Mumps, 55 Acta Otolaryngol. 231 (1962). This article was also filed as Resp. Ex. C, Tab 8.

vaccination "is known to occur, and complications . . . including sudden unilateral and bilateral hearing loss has been reported." Id. at 5.

The study from Hall and Richards examined 33 children with unilateral SNHL hearing loss and concluded "mumps could be a considered a cause in a third of the cases of hearing loss studied." Pet. Ex. 30 at 2-3. The authors explained hearing loss as a complication of mumps infection is "characteristically unilateral and sensorineural in nature, and is thought to result from endolymphatic labyrinthitis."[34] Id. at 2. The authors also reported that "permanent hearing loss can result from subclinical or unrecognized infections." Id. at 4.

Next, Dr. Monsell discussed the pathogenesis of virus-induced SNHL. Pet. Ex. 11 at 15-16. Relying on Cohen et al.,[35] Dr. Monsell first explained that the mechanism of SNHL in mumps included "atrophy of hair cells in the organ of Corti[36] and stria vascularis,[37] and damage to the myelin sheath around the vestibulocochlear nerve."[38] Id. at 15 (quoting Pet. Ex. 23 at 11); see also Pet. Ex. 40 (discussing mechanisms of SNHL). Dr. Monsell opined that rubella, measles, and mumps virus infections produce a similar pathology. Pet. Ex. 11 at 15 (citing Pet. Ex. 24).[39] The viruses "are believed to infiltrate the stria vascularis of the cochlea

[34] Endolymphatic labyrinthitis is "inflammation of the membranous labyrinth of the inner ear." Resp. Ex. C at 6; see also supra note 17.

[35] Brandon E. Cohen et al., Viral Causes of Hearing Loss: A Review for Hearing Health Professionals, 18 Trends Hear. 1 (2014). This article was also filed as Resp. Ex. C, Tab 5.

[36] Organ of Corti is "the organ, resting on the basilar membrane of the cochlear duct, that contains the auditory hair cells, special sensory receptors for hearing, as well as several types of supporting cells." Organum Spirale, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=94965 (last visited Dec. 18, 2025).

[37] Sria Vascularis is "a layer of vascular tissue consisting of epithelial cells, mesothelial cells, and probably some neuroectoderm; it covers the outer wall of the cochlear duct and is thought to secrete the endolymph." Sria Vascularis Ductus Cochlearis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=108900 (last visited Dec. 18, 2025).

[38] Vestibulocochlear nerve is the "eighth cranial nerve; it . . . is connected with the brain by corresponding roots, the vestibular and the cochlear roots." Nervus Vestibulocochlearis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92439 (last visited Dec. 18, 2025).

[39] A.D. Dunmade et al, Profound Bilateral Sensorineural Hearing Loss in Nigerian Children: Any Shift in Etiology?, 12 J. Deaf Stud. Deaf Educ. 112 (2007).

during the viremic stage, and from there they either enter the endolymph[40] directly or damage the metabolic functions of the stria vascularis in some way." Pet. Ex. 24 at 6.

In Cohen et al., the authors noted the mechanisms involved in viral-induced SNHL "vary greatly, ranging from direct damage to inner ear structures, including inner ear hair cells and organ of Corti (as seen in some of the classically described causes of viral hearing loss such as measles), to induction of host immune-mediated damage." Pet. Ex. 23 at 1. The authors specified that rubella- and mumps-induced SNHL was associated with direct damage to the inner ear structures. Id. at 2 tbl.2. Measles-induced SNHL was associated with both direct damage as well as an indirect etiology of "[d]ecreased immunity and secondary infection." Id. The authors furthered explained temporal bone studies of patients with measles-induced SNHL have "shown degeneration of cochlear neurons most prominently in the basal turn, degeneration of the organ of Corti and stria vascularis, and cellular infiltration of the cochlea." Id. at 9. Of note, in their discussion of measles-induced SNHL, Cohen et al. stated MMR vaccination was "rarely associated with SNHL, with a time course of onset corresponding to incubation period of measles infection and an incidence of [one] case per [six] to [eight] million vaccine doses." Id.

The article from McKenna examined the histopathology of the temporal bones in patients with measles- or mumps-induced SNHL. Pet. Ex. 40 at 3. The author noted "destruction or degeneration of the organ of Corti, stria, and cochlear neurons is typical." Id. "Of particular significance is the presence of fibrous tissue in the scala of the basal turns, which is suggestive of an associated inflammatory process (Fig. 1)." Id.

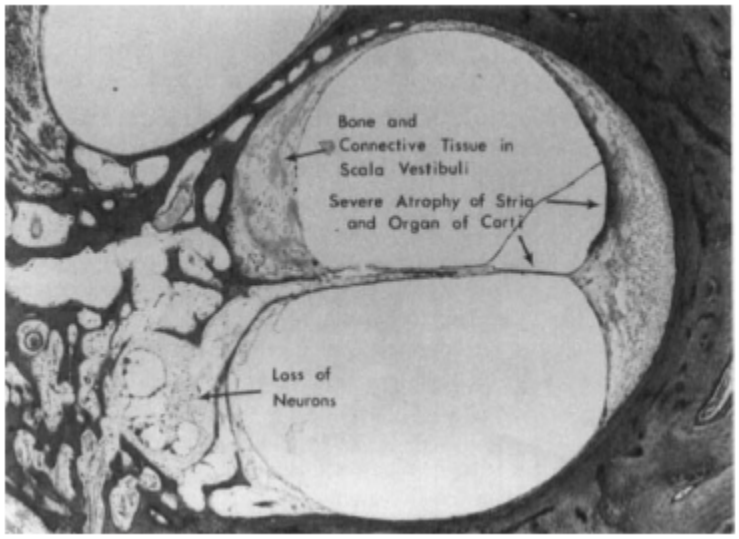

FIGURE 1. Case of profound bilateral hearing loss at age four in association with measles. . . Pathologic changes are similar in both ears. Predominant histopathologic features include atrophy of the organ of

[40] Endolymph is "the fluid contained in the membranous labyrinth of the ear; it is entirely separate from the perilymph." Endolympha, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=16333(last visited Dec. 18, 2025).

> Corti and stria vascularis with degeneration of cochlear neurons.

Id. at 4 fig. 1.

Moreover, Dr. Monsell explained infiltration of the inner ear with acute and chronic inflammatory cells is a characteristic finding in animal models of experimental viral inner infection. Pet. Ex. 11 at 16 (citing Pet. Ex. 41).[41] In Merchant et al., the authors opined that evidence of a viral cause for sudden deafness is based on onset occurring in association with an upper respiratory infection, positive serology studies supporting a systemic viral infection, and histopathological findings similar to those seen after hearing loss associated with mumps or rubella infections. Pet. Ex. 41 at 8. Dr. Monsell described an animal study by Fukuda et al.[42] that studied acute measles infection of the cochlea. Pet. Ex. 11 at 16 (citing Pet. Ex. 27). "Positive immunofluorescence [indicating the presence of viral antigens] was observed in the inflammatory cell infiltrates in the cochlear ducts and the lining of the perilymphatic structure." Id. (citing Pet. Ex. 27 at 2). The findings were consistent with endolymphatic labyrinthitis and were consistent with prior studies of human temporal bone pathology caused by measles. Pet. Ex. 27 at 1.

In humans, MRIs have shown signs of protein infiltrations of the inner ear during viral infections. Pet. Ex. 11 at 16. In support, Dr. Monsell cited to an article by Otake et al.[43] who reported on a case of profound unilateral SNHL following a case of subclinical mumps. Id. (citing Pet. Ex. 45). A 3D-FLAIR MRI revealed an abnormal signal of the right cochlea and vestibule indicating "hemorrhage or a high concentration of protein in the right ear" consistent with labyrinthitis associated with "mumps deafness." Pet. Ex. 45 at 1. Dr. Monsell explained the MRI findings were due to an "intense local inflammatory reaction." Pet. Ex. 11 at 16. Another study, by Westmore et al.,[44] found mumps virus in a perilymph sample (extracellular fluid from the inner ear) collected five days after the onset of deafness. Id. (citing Pet. Ex. 50 at 1-2).

Next, Dr. Monsell opined that "the inner ear actively participates in inflammatory processes." Pet. Ex. 11 at 16. Dr. Monsell explained that "the inner ear is not an immunologically privileged organ." Id. Further, the inner ear is affected by systemic

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[41] Saumil N. Merchant et al., Pathology and Pathophysiology of Idiopathic Sudden Sensorineural Hearing Loss, 26 Otol. Neurotol. 151 (2005).

[42] Saroshi Fukuda et al., Acute Measles Infection in the Hamster Cochlea, 514 Acta Otolaryngol. 111 (1994).

[43] Hironai Otake et al., 3D-FLAIR Magnetic Resonance Imaging in the Evaluation of Mumps Deafness, 70 Int'l J. Pediatr. Otorhinolaryngol. 2115 (2006).

[44] G.A. Westmore et al., Isolation of Mumps Virus from the Inner Ear After Sudden Deafness, 1 Brit. Med. J. 14 (1979). This article was also filed as Resp. Ex. C, Tab 9.

inflammatory events. Id. Dr. Monsell described an experiment by Adams et al.[45] where the authors induced injury within mouse cochlea by injecting liposaccharides to induce systemic inflammation. Id. (citing Pet. Ex. 13). Dr. Monsell explained "the inner ear responded by transcribing and releasing [tumor necrosis factor], an important cytokine that promotes inflammation." Id. Additional medical literature explained it is "well accepted that the inner ear is fully capable of generating an immune response and that this immune response can be destructive to the delicate inner ear." Pet. Ex. 29 at 3-4.[46]

Dr. Monsell noted other ear diseases demonstrate autoimmunity in the inner ear. Pet. Ex. 11 at 14. Dr. Monsell explained that otosyphilis is clinically similar to AIED. Id.; see also Pet. Ex. 29 at 6 (noting otosyphilis should be excluded by serum analysis prior to an AIED diagnosis). Dr. Monsell explained otosyphilis has a disease mechanism that is "at least partly inflammatory and thereby demonstrates the potential for infection to cause autoimmunity in the inner ear." Pet. Ex. 11 at 14.

Dr. Monsell opined that viruses "are common causes of autoimmune disease in general." Pet. Ex. 11 at 15. Further, Dr. Monsell noted that MMR vaccine induction of autoimmune disease has been reported in other disease contexts with "autoimmune thrombocytopenia is the most established of all vaccine-related autoimmune disorders." Id. at 17.

Turning to vaccination-induced hearing loss, Dr. Monsell relied on Agmon-Levin et al.[47] to explain the "proposed mechanism by which infectious agents, including live attenuated viral vaccines, may induce autoimmunity." Pet. Ex. 11 at 16 (citing Pet. Ex. 14). Agmon-Levin et al. stated that "[i]nfectious agents are considered to be the most common triggers of autoimmunity, and vaccines that contain antigens from infectious agents might induced autoimmunity by similar mechanisms such as molecular mimicry, bystander activation, epitope spreading, and polyclonal activation."[48] Pet. Ex. 14 at 2. Dr. Monsell opined the mechanisms discussed in Agmon-Levin et al. "are complex microbiological processes that could be subject to functionally different genetic variants in vaccine recipients and idiosyncratic reactions leading to vaccine caused AIED." Pet. Ex. 11 at 16-17.

Additionally, Dr. Monsell opined medical literature supported an association between MMR vaccination and hearing loss. Pet. Ex. 11 at 14. Dr. Monsell emphasized that the 2012

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[45] J.C. Adams et al., Selective Activation of Nuclear Factor Kappa B in the Cochlea by Sensory and Inflammatory Stress, 160 Neuroscience 530 (2009).

[46] Quinton Gopen & Jeffery P. Harris, Autoimmune Inner Ear Disease, in Head and Neck Manifestations of Systemic Disease 53 (Jeffery P. Harris & Michael H. Weisman eds., 2007). For a detailed description of the "basic steps" of the inner ear immune response, see Pet. Ex. 29 at 4.

[47] Nancy Agmon-Levin et al., Vaccines and Autoimmunity, 5 Nat'l Rev. Rheumatol. 648 (2009).

[48] These mechanisms are defined by Agmon-Levin et al. See Pet. Ex. 14 at 3 Box 2.

Institute of Medicine ("IOM") committee[49] found an association between measles and mumps vaccination and hearing loss, stating they "assesse[d] the mechanistic evidence regarding an association between measles or mumps vaccine and hearing loss as low-intermediate[50] based on knowledge about the natural infection, experimental evidence, and eight cases." Id. at 15 (citing Pet. Ex. 48 at 119). The eight cases[51] presented "clinical and experimental evidence suggestive but not sufficient for the committee to conclude" that the MMR vaccine was a "contributing case of hearing loss." Pet. Ex. 48 at 119.

Dr. Monsell cited a review conducted by Asatryan et al.,[52] which estimated hearing loss after MMR vaccination occurred in one per six to eight million doses. Pet. Ex. 11 at 14 (citing Pet. Ex. 16). Asatryan et al. conducted a review of VAERS[53] data and identified 44 cases of "likely idiopathic" SNHL after MMR vaccination. Pet. Ex. 16 at 2. They also researched for published case reports of SNHL and identified 11 cases following MMR vaccination. Id. at 2. The authors noted the onset of hearing loss in the majority of these cases "was consistent with the incubation periods of wild measles and mumps viruses." Id. Asatryan et al. posited that as

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[49] Inst. of Med., Adverse Events Associated with Childhood Vaccines: Evidence and Causality (Kathleen Stratton et al. eds., 2012). This was also filed as Resp. Ex. C, Tab 15.

[50] The IOM committee developed four categories for mechanistic weight of the evidence assessments: strong, intermediate, weak, and lacking. Inst. of Med., Adverse Events Associated with Childhood Vaccines: Evidence and Causality 12-14 (Kathleen Stratton et al. eds., 2012) [hereinafter 2012 IOM report]. An intermediate assessment is based on a "least two cases, taken together, for which the committee concludes the vaccine may be a contributing cause of the adverse event, based on an overall assessment of attribution in the available cases and clinical, diagnostic, or experimental evidence consistent with relevant biological response to [the] vaccine." Id. at 14. Low-intermediate assessment is based on "at least two cases, that, taken together, while *suggestive*, are nonetheless insufficient to conclude that the vaccine may be a contributing case of the adverse event." Id. Although the parties only filed Chapter 4 of the 2012 IOM report, the undersigned is familiar with the entirety of the 2012 IOM report. See Pet. Ex. 48; Resp. Ex. C, Tab 15.

[51] The eight cases include some cited by Dr. Monsell. For a full discussion of the cases considered by the IOM, see Pet. Ex. 48 at 117-18.

[52] Armenak Asatryan et al., Live Attenuated Measles and Mumps Viral Strain-Containing Vaccines and Hearing Loss: Vaccine Adverse Event Reporting System (VAERS), United States, 1990-2003, 26 Vaccine 1166 (2008).

[53] VAERS, the Vaccine Adverse Event Reporting System, is "a national early warning system to detect possible safety problems in U.S.-licensed vaccines. . . . VAERS is a passive reporting system . . . [and] is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine." About VAERS, U.S. Dep't Health & Hum. Servs., https://vaers.hhs.gov/about.html (last visited Dec. 16, 2025).

"vaccines against measles and mumps contain live attenuated viral strains, it is biologically plausible" that individuals could develop hearing loss as a complication of MMR vaccination. Id. at 1.

Of note, in the 14 cases described by Asatryan et al., many of the patients who reported bilateral hearing loss after vaccination did not describe a history of fever or illness symptoms prior to hearing loss. Pet. Ex. 16 at 3-5 (see Cases 1, 2, 9, 10, 11, 12, and 13).

Finally, Dr. Monsell provided several case reports of SNHL following vaccination for measles, mumps, and/or rubella.[54] Pet. Ex. 11 at 15. In Hulbert et al.,[55] the authors reported a case of bilateral SNHL following a live measles-rubella vaccination. Pet. Ex. 32 at 1. The patient, a 27-year-old woman, experienced hearing loss 22 days after receiving a live measles-rubella vaccination. Id. Audiography taken 29 days after vaccination showed profound bilateral SNHL. Id. She had generalized arthralgias three days after vaccination and developed a fever, tinnitus, dizziness, vomiting, and gait unsteadiness shortly thereafter. Id. Serological tests for syphilis, systemic lupus, Epstein-Barr virus, St. Louis encephalitis virus, and western equine and eastern equine encephalomyelitis viruses were negative. Id. The patient had Immunoglobulin ("Ig") M antibodies for rubella. Id. The authors noted permanent bilateral hearing loss is "a known but uncommon complication of measles, mumps, and rubella infections." Id. "Severe hearing loss has been reported as a complication of the mumps vaccine and of the measles-mumps-rubella trivalent vaccine in children, usually in association with encephalitis." Id. Hulbert et al. concluded that "the patient's symptoms and their temporal sequence after vaccination, coupled with suspicious audiographic findings and serologic evidence of an acute rubella infection, offer compelling evidence that her deafness was a complication of vaccination." Id.

Additional case reports described children with SNHL following measles, mumps, and/or rubella vaccinations. A 1985 report from Brodsky and Stanievich[56] reported a case of a three-year-old-child who developed a "encephalitis-like reaction" 10 days after receiving an MMR vaccine. Pet. Ex. 21 at 2. Soon after, the child's parents became concerned about hearing loss, and the child was ultimately diagnosed with "severe to profound bilateral [SNHL]." Id. The authors noted that the child's hearing loss was "similar to the loss typically seen after infectious

[54] In addition to the below discussed case reports, Dr. Monsell provided a case report from Koga et al. that purported to report "a case of bilateral acute profound deafness most likely due to MMR vaccination." Pet. Ex. 38 at 1 (Keijiro Koga et al., Bilateral Acute Profound Deafness After MMR Vaccination - Report of a Case, 94 Nihon Jibiinkoka Gakkai Kaiho 1142 (1991)). However, while a short abstract of the Koga et al. article is written in English, the case report is written in Japanese.

[55] Tim V. Hulbert et al., Bilateral Hearing Loss After Measles and Rubella Vaccination in an Adult, 325 NEJM 134 (1991).

[56] Lisa Brodsky & John Stanievich, Sensorineural Hearing Loss Following Live Measles Virus Vaccination, 10 Int'l J. Pediatr. Otorhinolaryngol. 159 (1985).

measles." Id. at 4. A 1995 case report from Jayarajan and Sedler[57] described the development of unilateral SNHL in a 15-month-old child. Pet. Ex. 34 at 1. Twenty-four hours after measles vaccination, she became unwell and began to stagger while walking, and two weeks later she was admitted to the hospital with ataxia, drowsiness, and general irritability. Id. The child was found to have profound left-sided hearing loss during routine screening when she was five years old. Id. The authors noted measles infections account for five to 10 percent of SNHL in children and noted incidence of neurological sequala following measles vaccination was one per 1.6 million doses of the vaccine. Id. Jayarajan and Sedler concluded the "sequence of events suggests that a labyrinthitis which developed after measles vaccination may have resulted in unilateral left sided hearing loss." Id. at 1-2.

Stewart and Prabhu[58] reported nine cases of SNHL in children following MMR vaccination. Pet. Ex. 47 at 1. In three cases, the deafness was found to be unrelated to the MMR vaccine. Id. In six cases, the cause was unknown, but MMR vaccination remained a possible etiology. Id. The authors concluded "[a]ny risk of deafness after MMR [immunization] is small and must be weighed against the risks of the natural diseases." Id. at 2.

A more recent case report, published in 2018, from Rikitake et al.[59] in Japan, reported onset of bilateral hearing loss in a five-year old girl 18 days after receiving a mumps vaccine and a measles-rubella vaccine. Pet. Ex. 46 at 2. Twelve days after vaccination the child had a fever for one day, and vomited once the following day, before her symptoms remitted. Id. Eighteen days after vaccination, the child was noted to have poor hearing and was brought to the hospital. Id. She was examined by otorhinolaryngology and diagnosed with "bilateral acute [SNHL] associated with a side reaction of the vaccination." Id. The authors explained there was no other finding or symptom to induce disease in this patient and concluded that SNHL about three weeks after vaccination suggests the hearing loss was caused by vaccination. Id. at 3. Further, they noted that unlike other case reports of SNHL, the child did not have encephalitis. Id. Rikitake et al. explained the mumps vaccine is a live vaccine and noted that since the blood inner ear barrier is immature in infants, "hearing loss may be easily caused by mumps virus." Id. The authors reported that incidence of hearing loss following natural mumps infection were 1/1,000-20,000 and the risk of hearing loss following mumps vaccination was reported to be about 1/6-8 million. Id.

[57] V. Jayarajan & P.A. Sedler, Hearing Loss Following Measles Vaccination, 30 J. Infect. 184 (1995).

[58] Barbara J.A. Stewart & P. Umesh Prabhu, Reports of Sensorineural Deafness After Measles, Mumps, and Rubella Immunization, 69 Arch. Dis. Child. 153 (1993).

[59] Masahiro Rikitake et al., Bilateral Deafness as a Complication of the Vaccination - A Case Report, 22 Int'l Tinnitus J. 19 (2018).

ii. Althen Prong Two

Dr. Monsell concluded that "more likely than not," Petitioner's MMR vaccination had a "substantial causal role" in her development of AIED. Pet. Ex. 11 at 18. He opined that but for this vaccination, Petitioner would not have developed AIED. Id.

Dr. Monsell opined that the evidence that Petitioner suffered an MMR vaccine injury was "compelling." Pet. Ex. 11 at 17. He summarized his opinion as follows.

First, as discussed above, there is an association between the MMR vaccine, clinical measles, mumps, and rubella, and hearing loss. Pet. Ex. 11 at 17. Second, Petitioner was "serologically negative, and thus immunologically naïve to mump antigens" when she received the MMR vaccine. Id. Third, Dr. Monsell noted that the MMR vaccine "is not often administered to adults, who may not have as a robust immune system as children." Id. Next, Dr. Monsell explained the MMR vaccine received by Petitioner contains three different live attenuated viruses plus an adjuvant. Id.: see also Pet. Ex. 52 (vaccine package insert).[60] Dr. Monsell explained that, theoretically, a vaccine with "more varied array of antigens," was more likely "to trigger an immune response that might eventually turn into autoimmune disease." Id. (quoting Pet. Ex. 14 at 2). Fifth, he noted that MMR vaccine induction of autoimmune disease had been reported for other diseases such as autoimmune thrombocythemia. Id. Finally, Dr. Monsell noted that Petitioner's treating physicians agreed she suffered from AIED, an autoimmune disease, with "no other autoimmune disease that her AIED could be secondary to." Id.

Additionally, Dr. Monsell opined that Petitioner's clinical course was consistent with AIED. Pet. Ex. 11 at 13-14. Dr. Monsell emphasized that Petitioner's AIED was not associated with any another autoimmune condition such as psoriasis, idiopathic thrombocytopenic purpura, rheumatoid arthritis, primary biliary sclerosis, inflammatory bowel disease, connective tissue diseases, or systemic autoimmune disease. Id. at 13, 17.

Moreover, Dr. Monsell ruled out several causes of SNHL such as age-related hearing loss, toxic noise exposure, ototoxicity, Meniere's disease, vestibular schwannoma, and stroke. Pet. Ex. 11 at 12-13. He also ruled out eustachian tube dysfunction as a cause of Petitioner's hearing loss. Id. at 12. While eustachian tube dysfunction is associated with plane travel, Petitioner's clinical course was not consistent with eustachian tube dysfunction, and eustachian tube dysfunction is not associated with SNHL. Id.

iii. Althen Prong Three

Dr. Monsell placed the onset of Petitioner's symptoms associated with AIED as approximately 30 days after receiving the second dose of her MMR vaccine. Pet. Ex. 11 at 17. He opined Petitioner's onset was "consistent with an immune-mediated response following

[60] Of note, the vaccine package insert identifies "[n]erve deafness" as an adverse reaction. Pet. Ex. 52 at 4.

MMR vaccination." Id. at 18. He further opined Petitioner's onset was "within the timeframe that [is] medically acceptable for autoimmune events following an antigenic trigger." Id. at 17.

In support of this timeframe, Dr. Monsell noted that MMR vaccination has been associated with autoimmune disease and explained that the autoimmune complication of thrombocytopenia is included on the package insert for MMR vaccination. Pet. Ex. 11 at 17. Dr. Monsell noted that package insert described "this autoimmune event following MMR vaccination as occurring within [four to six] weeks after MMR vaccination." Id.

In the summary of case reports of hearing loss after MMR vaccination from VAERS data reviewed by Asatryan et al., onset (when reported) "ranged from [two] to 89 days following vaccination, with a peak on days 10 through 14." Pet. Ex. 16 at 3, 3 fig.1. Of the cases studied, Asatryan et al. summarized 14 with detailed clinical data available. Id. at 3-5. In Case 1, onset of hearing loss was noted the month after vaccination; in Case 6, hearing loss occurred within one month (but "possibly" earlier); in Case 8, ataxia was noted one month after vaccination followed by hearing loss four months after vaccination; in Case 9, hearing loss was noted two months after vaccination; and in Case 13, tinnitus and hearing loss occurred one month after vaccination. Id. at 3-5. Finally, in Case 14, the patient had her first MMR vaccination in August 2003 and the second vaccine in September 2003. Id. at 5. Two weeks following the second vaccination she developed headaches, vertigo, and tinnitus, and a subsequent audiologic evaluation in October showed bilateral hearing loss. Id.

2. Respondent's Expert, Herman Staats, Ph.D.[61]

a. Background and Qualifications

Dr. Staats obtained his B.S. in medical technology from Salisbury University in Salisbury, Maryland and a Ph.D. in basic medical sciences (microbiology and immunology) from the University of South Alabama in Mobile, Alabama. Resp. Ex. B at 1. He is a professor in the Department of Pathology at Duke University School of Medicine and holds joint appointments as an associate professor of immunology and associate professor of medicine. Id.; Resp. Ex. A at 1. He is also a member of the Duke Human Vaccine Institute. Resp. Ex. A at 1. Throughout his career, Dr. Staats has been a member of and/or held positions with various organizations and professional societies. Resp. Ex. B at 3-4. Dr. Staats "perform[s] research on the discovery and evaluation of vaccine adjuvants." Resp. Ex. A at 1. His bibliography consists of over 200 publications. Resp. Ex. B at 22-35.

b. Opinion

Dr. Staats opined "the medical record and the published literature do not support the conclusion that [Petitioner's AIED] and hearing loss was a result of the MMR vaccine." Resp. Ex. A at 13. He further opined there "no evidence" that the MMR vaccine caused Petitioner's AIED "via direct damage to the ear, inflammation, or molecular mimicry." Id.

[61] Dr. Staats submitted one expert report. Resp. Ex. A.

i. Althen Prong One

Dr. Staats summarized and responded to Dr. Monsell's proposed causal mechanisms. Resp. Ex. A at 4-5. He disagreed with Dr. Monsell's conclusion that "the evidence of MMR vaccine-induced injury" in Petitioner was "compelling." Id. at 5.

Dr. Staats characterized Dr. Monsell's causal theory as "vaccine viruses infecting the host and causing hearing loss" due to the MMR vaccine containing live attenuated viruses. Resp. Ex. A at 4. Dr. Staats described the distinctions in the immune response to a wild-type virus and a live attenuated virus. Id. at 6. Relying on Lin et al.,[62] Dr. Staats opined wild-type virus "results in very different host exposure" compared to the live attenuated virus. Id. at 6-7 (citing Resp. Ex. A, Tab 4).

Lin et al. examined the immune response of macaque monkeys to wild-type measles virus and live attenuated measles virus. Resp. Ex. A, Tab 4 at 1. The route of administration was through the respiratory tract. Id. at 2, 9. The authors found wild-type measles viruses "replicated efficiently in B and T lymphocytes with spreading throughout lymphoid tissues resulting in prolonged persistence of viral RNA" and live attenuated measles virus "replicated efficiently in the respiratory tract but displayed limited spread to lymphoid tissue or peripheral blood mononuclear cells." Id. at 1. Three out of 12 macaques infected with the live attenuated virus had detectable measles RNA in their peripheral blood mononuclear cells as compared to the wild-type virus macaques, which all had detectable measles RNA after infection. Id. at 3. None of the animals infected with the live attenuated measles virus had a rash in comparison to those who received the wild-type virus, who all developed skin rashes. Id. Five of the 12 infected with the live attenuated measles virus had detectable measles RNA in their draining lymph nodes. Id. The authors noted that a limitation of their study was that it did not address the role of the subcutaneous immunization route and recommended further study of the effects of route and dosing of live attenuated measles vaccines. Id. at 8.

Dr. Staats agreed "attenuated viruses in the vaccine are similar enough to the wild-type virus to induce host immune response;" however, Dr. Staats asserted that the viral load of after exposure to live attenuated virus is "much lower" than the viral load after exposure to wild-type virus. Resp. Ex. A at 9. Dr. Staats further opined that "[c]onclusions based on infection with the wild-type measles virus are not relevant to exposure to attenuated viruses used in the MMR vaccine." Id.

Dr. Staats disagreed the medical literature cited by Dr. Monsell discussing hearing loss after wild-type measles, mumps, and/or rubella infections provided support for MMR vaccine-induced hearing loss. Resp. Ex. A at 7-10. Dr. Staats noted that articles by Cohen et al., Dunmade et al., Fukada et al., and Olajuyin et al. all discussed wild-type infections and all recommended MMR vaccinations. Id. at 8-9 (discussing Pet. Exs. 23, 24, 27, 43). Accordingly, he opined that none of these articles provided support for or were relevant to Dr. Monsell's

[62] Wen-Hsuan W. Lin et al., A Durable Protective Immune Response to Wild-Type Measles Virus Infection of Macaques Is Due to Viral Replication and Spread in Lymphoid Tissues, 12 Sci. Transl. Med. eaax7799 (2020).

theory. Id. Dr. Staats did not acknowledge that Cohen et al. discussed MMR vaccination as "rarely associated with SNHL." See id.; Pet. Ex. 23 at 9.

Responding to Dr. Monsell's discussion of the inner ear inflammatory response, Dr. Staats first criticized Dr. Monsell for not providing a "specific theory" that would "link the MMR vaccination to inflammation in the inner ear and [Petitioner's] hearing loss." Resp. Ex. A at 10. Next, Dr. Staats opined "vaccine-induced inflammation" causing hearing loss was not supported by the results of Lin et al. Id. at 10, 11 fig.2 (citing Resp. Ex. A, Tab 4 at 7 fig.6). Dr. Staats explained that while wild-type measles virus induced a "potent inflammatory response that persists for days after infection," the live attenuated virus exposure "does not induce robust inflammation." Id. at 10.

Addressing Dr. Monsell's contention that the disease mechanism of syphilis-induced SNHL (otosyphilis) demonstrated "the potential for infection to cause autoimmunity in the inner ear with infection," Dr. Staats acknowledged that syphilis infection "may induce an inflammatory response to cause autoimmunity in the inner ear." Resp. Ex. A at 11-12. However, Dr. Staats again noted that the inflammatory response to live attenuated viruses found in MMR vaccination "is very different to the host response to a live viral infection." Id. at 12. Accordingly, he opined the disease mechanism of otosyphilis did not support Dr. Monsell's theory of MMR-vaccine induced AIED. Id.

Moreover, Dr. Staats disagreed that Dr. Monsell or the medical literature provided support for molecular mimicry as a mechanism for the MMR vaccine to cause AIED. Resp. Ex. A at 12. Dr. Staats noted that molecular mimicry "is often discussed as a similarity in amino acid sequence between a protein antigen in an infectious agent and a host protein that induces an autoimmune disease." Id. While Dr. Monsell invoked molecular mimicry in his report, he did not identify "any regions of similarity between components of the MMR vaccine and host antigens associated with [AIED]." Id. Dr. Staats cited a publication by Rojas et al.[63] that identified structural homology for various viruses and autoimmune diseases. Id. (citing Resp. Ex. A, Tab 6 at 4 tbl.1). Dr. Staats noted the authors did not identify "any antigens in measles, mumps[,] or rubella that exhibit similarity to human antigens that would provide a basis for molecular mimicry." Id. Of note, Rojas et al. acknowledged that the generally referenced criteria used to support molecular mimicry as a mechanism for a known pathogen are rarely fulfilled. Resp. Ex. A, Tab 6 at 3 ("[Molecular mimicry] hypotheses are difficult to prove . . . particularly for rare events/disease."). Further, the authors list of infectious agents with identified structural homology associated with a corresponding autoimmune disease is not described as complete or exhaustive. See id. at 4 tbl.1.

Rojas et al. confirmed that molecular mimicry was "one of the likely mechanisms" for the development of autoimmune disease and acknowledged that "environmental factors, such as . . . vaccines, also have the potential to lead to autoimmunity not only via molecular mimicry but

[63] Manuel Rojas et al., Molecular Mimicry and Autoimmunity in the Time of Covid-19, 139 J. Autoimmun. 103070 (2023).

also by bystander activation, epitope-determinant spreading, and/or hapten carrier." Resp. Ex. A, Tab 6 at 2.

Next, Dr. Staats opined the "exact cause of hearing loss due to [AIED] has not yet been determined." Resp. Ex. A at 13. In support, Dr. Staats cited an article by Miwa and Okano[64] that described AIED as a "an idiopathic disorder characterized by unexpected hearing loss." Id. (quoting Resp. Ex. A, Tab 7 at 1). Miwa and Okano addressed the autoimmune nature of AIED, noting that as "with most autoimmune diseases, it has been postulated that a misdirected assault on the . . . inner ear proteins . . . activate[] the pro-inflammatory T-cell response and autoantibody formation." Resp. Ex. A, Tab 7 at 2. The authors explained that the inner ear is "fully able to mount an immune response" to outside antigens. Id. at 6. The authors also noted that AIED "represents much fewer than 1% of all cases of [SSNHL]." Id. at 1.

Turning to the medical literature on the association of MMR vaccination and hearing loss, Dr. Staats observed that 2012 IOM report found "[t]he evidence inadequate to accept or reject a causal relationship between MMR vaccine and hearing loss." Resp. Ex. A at 5 (citing Pet. Ex. 48 at 118). He further noted that the case reports discussed by the IOM had symptomology of fever, rash, and nystagmus, which were not present in Petitioner. Id. However, Petitioner's medical records documented "very slight horizontal nystagmus" in Petitioner. Pet. Ex. 2 at 794.

Dr. Staats opined that more recent vaccine safety reviews—by Maglione et al.,[65] Gidengil et al.,[66] and Baxter et al.—did not find an association between MMR vaccination and hearing loss. Resp. Ex. A at 5-6 (citing Resp. Ex. A, Tab 1; Resp. Ex. A, Tab 2; Resp. Ex. A, Tab 3).

A 2014 safety review[67] by Maglione et al. sought to update the findings published in the 2012 IOM report. Resp. Ex. A, Tab 1 at 16. The authors, however, did not discuss hearing loss, but instead addressed febrile seizures, thrombocytopenia, and other adverse effects. See id. at 126-27. The authors agreed with IOM conclusions that "evidence 'convincingly' supports a causal relationship" between MMR vaccine and febrile seizures and that there is "moderate"

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[64] Toru Miwa & Takayuki Okano, Role of Inner Ear Macrophages and Autoimmune/Autoinflammatory Mechanisms in the Pathophysiology of Inner Ear Disease, 13 Front. Neurol. 861992 (2022).

[65] Margaret Maglione et al., Safety of Vaccines Used for Routine Immunization in the United States, 215 Evid. Rep./Tech. Assess. 1 (2014).

[66] Courtney Gidengil et al., Safety of Vaccines Used for Routine Immunization in the United States: An Update, 244 Compar. Effectiveness Rev. 1 (2021).

[67] This report was based on a systematic review of literature performed by the Southern California Evidence-Based Practice Center ("EPC") through a contract with the Agency for Healthcare Research. See Resp. Ex. A, Tab 1 at 4, 8. The review by Gidengil et al. was also prepared by the EPC. See Resp. Ex. A, Tab 2 at 3.

evidence to support an association between MMR vaccination and thrombocytopenic purpura in children. Id. at 127. In his report, Dr. Staats acknowledged that Maglione et al. did not discuss hearing loss. Resp. Ex. A at 5-6.

Gidengil et al. conducted a systematic of the literature on the safety of routine vaccines administered in the United States with the goal of updating the 2014 report published by Maglione et al. Resp. Ex. A, Tab 2 at 8. In their section on MMR vaccination, the authors referenced the Baxter et al. study[68] noting it "detected no association between [SSNHL] and MMR within one week of vaccination." Id. at 11.

Baxter et al. analyzed seven years (2007 to 2013) of data from Kaiser Permanente Northern California ("KPNC") and identified 1,929 cases of SSNHL in the nine months following any vaccine exposure and 57 cases of SSNHL within one week of vaccination. Resp. Ex. A, Tab 3 at 1, 4. Using a case centered methodology, the authors did not find an association between SSHL and any vaccination. Id. at 2. Specific to MMR, there were no cases of SSNHL identified in the one-week risk interval after vaccination. Id. at 12 tbl.3. Relative to the inactivated influenza vaccination, there were 167 cases in the risk interval of one to 28 days after vaccination. Id. at 11 tbl. 2. The authors selected risk intervals of one to seven day, one to 14 days, one to 28 days, and 15 to 28 days. Id. at 4. They selected these intervals "through literature and VAERS review as well as consultation with experts." Id. at 6. They acknowledged that a limitation of the study included the selection of risk intervals, "[i]f the interval selected does not match the timing of increased risk an association may be missed." Id. For the MMR vaccine, the authors only included data from the one-week risk interval after vaccination. Id. at 12 tbl. 3. Further, the number of cases of hearing loss following the MMR vaccination occurring in day seven through 28 days is not known, because the supplemental material was not filed with the article. See id. at 5. Additionally, the study design looked only at diagnosis of SSNHL, and did not study SNHL or AIED following vaccination. Id. at 1-3.

Finally, Dr. Staats questioned the relevance of Dr. Monsell's discussion of autoimmune thrombocytopenia. Resp. Ex. A at 8. Dr. Staats noted Petitioner does not have autoimmune thrombocytopenia and explained "the possible induction of one autoimmune condition (autoimmune thrombocytopenia) does not equate to the induction of other autoimmune diseases." Id.

ii. Althen Prongs Two and Three

Dr. Staats opined "the medical record and the published literature do not support the conclusion that [Petitioner's AIED] and hearing loss was a result of the MMR vaccine." Resp. Ex. A at 13.

Addressing Dr. Monsell's report, Dr. Staats argued there was "no discussion of a logical sequence of cause and effect to support the theory that the MMR vaccine caused [Petitioner's]

[68] In his expert report, Dr. Staats explained that Baxter et al. was the study discussed by Gidengil et al. in their vaccine safety review. Resp. Ex. A at 6. However, Respondent filed only an excerpt of Gidengil et al. and the excerpt did not include the bibliography.

hearing loss." Resp. Ex. A at 13. Dr. Staats also criticized the case reports provided by Dr. Monsell as inconsistent with Petitioner's clinical course in the present case. Id. at 7, 10, 12.

First, Dr. Staats noted that case report from Brodsky and Stanievich involved an encephalitis-like reaction prior to the onset of SNHL. Resp. Ex. A at 7-8 (citing Pet. Ex. 21). As Petitioner did not have any encephalitis-like symptoms after her MMR vaccine, Dr. Staats opined this case report did not support the theory that the MMR vaccine caused Petitioner's hearing loss. Id. Of note, however, in their discussion of hearing loss cases following MMR infection, Brodsky and Stanievich cite to literature describing "idiopathic" cases of severe hearing loss where patients were noted to have an increased measles virus titer. Pet. Ex. 21 at 3.

Next, Dr. Staats distinguished Petitioner's clinical course from the clinical course reported in the Rikitake et al. child who developed bilateral acute hearing loss after mumps and measles-rubella vaccination. Resp. Ex. A at 10 (citing Pet. Ex. 46). In Rikitake et al., 12 days after vaccination, the patient experienced one day of fever, and the following day vomited once, but then her symptoms abated. Pet. Ex. 46 at 2. Hearing loss was noted 18 days after vaccination. Id. The authors concluded the vaccine "caused serious hearing loss in th[e] patient." Id. at 4. Dr. Staats noted Petitioner did not report fever or vomiting. Resp. Ex. A at 10.

Turning to the temporal association between the MMR vaccine and onset of Petitioner's AIED, Dr. Staats placed Petitioner's onset as May 20 or 21, 2019 (approximately 30 days after her second dose of MMR vaccine). Resp. Ex. A at 12. He did not rebut Dr. Monsell's opinion that this temporal association was appropriate given Petitioner's proffered causal theory. Id. at 12-13.

3. Respondent's Expert, Yu-Lan Mary Ying, M.D.[69]

a. Background and Qualifications

Dr. Ying is "a fellowship trained otologist/neurotologist[] and [is] board certified in otolaryngology and neurotology." Resp. Ex. C at 1. After she obtained her M.D. in New York from State University of New York ("SUNY"), Stony Brook School of Medicine, she completed a general surgery internship and otolaryngology residency at the University of Pittsburgh Medical Center. Resp. Ex. D at 1. Dr. Ying also completed a fellowship at the Howard Hughes Medical Institute-National Institute of Health during medical school as well as a post-graduate fellowship in otology/neurotology at Pittsburgh Ear Associates and a post-graduate fellowship in neurotology at Baylor College of Medicine. Id. at 1-2. Since 2014, Dr. Ying has worked as an assistant professor in the Otolaryngology-Head and Neck Surgery Department at Rutgers-New Jersey Medical School. Id. at 2. She has also held various hospital appointments and memberships in various professional societies, and she has served on several committees. Id. at 2-5. Dr. Ying has "a busy academic clinical practice treating many diverse patients with hearing, balance[,] and lateral skull base disorders." Resp. Ex. C at 1. She has co-authored over 30 publications throughout her career. Resp. Ex. D at 7-9.

[69] Dr. Ying submitted one expert report. Resp. Ex. C.

b. Opinion

Dr. Ying agreed Petitioner's bilateral SNHL was "most compatible with a diagnosis of AIED." Resp. Ex. C at 10. She disagreed, however, that there was sufficient evidence to support Petitioner's claim of "bilateral sudden SNHL, dizziness, and visual disturbances due to an adverse reaction to MMR vaccination." Id. at 8

i. Althen Prong One

Dr. Ying opined there was "insufficient scientific evidence indicating AIED is an adverse event to MMR vaccination. There is no compelling evidence to establish causation between MMR vaccination and AIED." Resp. Ex. C at 10.

While Dr. Ying agreed measles and mumps infections can cause SNHL, Dr. Ying opined AIED "has not been identified as a cause of SNHL after either measles or mumps infection." Resp. Ex. C at 6. Dr. Ying's discussion of SNHL following natural measles and mumps infection was largely consistent with Dr. Monsell's description of SNHL following measles and mumps infection. Id. at 5-6.

Dr. Ying agreed hearing loss was a common complication of measles infections. Resp. Ex. C at 5. She noted measles-related hearing loss "is typically bilateral moderate to profound SNHL and may follow measles encephalitis." Id. Dr. Ying explained the pathogenesis of measles encephalitis is "is due to the viral invasion of neurons resulting in inflammation of the brain parenchyma." Id. (citing Resp. Ex. C, Tab 7).[70] The Fisher et al. article cited by Dr. Ying addressed the pathogenesis of measles encephalitis, explaining the virus is highly contagious and usually spreads in the form of respiratory droplets, which infect cells in the alveoli of the respiratory system. Resp. Ex. C, Tab 7 at 2-3. The infected cells drain into the lymph nodes, and then the circulation, spreading to the skin, lung, liver, brain. Id. Hearing loss was not specifically discussed.

After describing hearing loss caused by measles infection, Dr. Ying turned to mumps infection. She opined that mumps "is the most common cause of acquired SNHL" and "has very clearly been shown to be a cause of sudden SNHL." Resp. Ex. C at 6 (citing Pet. Exs. 49-50). She explained that SNHL "due to natural mumps infection results from endolymphatic labyrinthitis, an inflammation of the membranous labyrinth of the inner ear as the primary route of invasion of the virus is hematogenous."[71] Id. (citing Resp. Ex. C, Tab 11).[72] In Mizushima

[70] D.L. Fisher et al., Measles-Induced Encephalitis, 108 QJM 177 (2015).

[71] Hematogenous means "disseminated by the circulation or through the bloodstream." Hematogenous, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=21756 (last visited Dec. 18, 2025).

[72] Norio Mizushima & Yoshihiko Murakami, Deafness Following Mumps: The Possible Pathogenesis and Incidence of Deafness, 13 Auris Nasus Larynx (Tokyo) S55 (1986).

and Murakami, the authors opined hematogenous infection was the "most probable" mechanism of deafness due to mumps. Resp. Ex. C, Tab 11 at 2. The authors explained "the viremic state due to mumps reaches the inner ear hematogenously, causes an inflammatory change in the stria vascularis of the cochlea and then results in severe impairment of the endolymphatic system." Id. They also noted hearing loss in mumps was not associated with meningitis or meningoencephalitis. Id.

Turning to the incubation period for these infections, Dr. Ying agreed the incubation period of natural measles or rubella virus infection is about two weeks, and the incubation period of mumps virus is about two to three weeks. Resp. Ex. C at 6. She explained in mumps-related hearing loss, SNHL tends to occur four to five days after "onset of signs of infection such as flu-like symptoms and parotitis."[73] Id. (citing Pet. Ex. 30). Dr. Ying also acknowledged mumps-induced SNHL can occur in asymptomatic cases of mumps. Id. (citing Resp. Ex. C, Tab 10).[74]

Next, Dr. Ying reviewed the medical literature reporting an association between MMR vaccination and SNHL. Resp. Ex. C at 6-7. Dr. Ying explained that the MMR vaccination "includes live[]attenuated measles and mumps viruses." Id. at 6. She acknowledged that "[t]here are case reports that have associated MMR vaccination with SNHL in rare circumstances." Id. Cases of hearing loss associated with MMR vaccination vary in "severity, can be bilateral or unilateral," and have "been reported in both pediatric and adult patients." Id.

Dr. Ying discussed case reports of bilateral acute SNHL occurring after the mumps and MMR vaccinations. Resp. Ex. C at 7. Rikitake et al. reported bilateral acute hearing loss approximately three weeks after receipt of the mumps vaccine. Id. (citing Pet. Ex. 46 at 3-4). She emphasized that the "[m]umps vaccine was considered the cause based on the incubation period." Id. Next, Hulbert et al. described a patient who developed bilateral acute profound hearing loss 22 days after MMR vaccination. Id. (citing Pet. Ex. 32). Finally, Stewart and Prabhu reviewed nine cases of hearing loss after MMR vaccination, and in six they suggested that vaccine causation was "one possibility." Id. (citing Pet. Ex. 47 at 2). Dr. Ying emphasized that "published case reports are only anecdotes and speculations of MMR vaccination resulting in SNHL" and "might represent coincidental observations." Id.

Additionally, Dr. Ying noted that both the 1994 and 2012 assessments by the IOM committee found insufficient evidence to establish a causal relationship. Resp. Ex. C at 7 (citing

[73] Parotitis is "inflammation of the parotid gland," which is part of the salivary glands. Parotitis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=37103 (last visited Dec. 19, 2025); Glandula Parotidea, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=78815 (last visited Dec. 19, 2025).

[74] Hiromi Hashimoto et al., An Office-Based Prospective Study of Deafness in Mumps, 28 Pediatr. Infect. Dis. J. 173 (2009).

Resp. Ex. C, Tab 14;[75] Pet. Ex. 48). The 2012 IOM committee assessed the mechanistic evidence regarding an association between measles or mumps vaccine and hearing loss as "low-intermediate based on knowledge about the natural infection, experimental evidence, and eight cases." Id. (quoting Pet. Ex. 48 at 118). Regarding natural infection, the committee noted that the wild-type mumps virus infection was associated with deafness and the wild-type measles infection was associated with bilateral "hearing loss in [five to 10] percent of measles cases." Pet. Ex. 48 at 117. "The committee considers the effects of natural infection one type of mechanistic evidence." Id. Experimental evidence included the detection of anti-mumps antibodies in patients who developed idiopathic SSNHL and the finding of measles antigen in animal cochlear ducts. Id. at 118. These findings "suggested the involvement of measles and mumps viruses in the pathogenesis of hearing loss." Id. As Dr. Ying noted in her report, the IOM committee ultimately determined the evidence was "inadequate to accept or reject a causal relationship between MMR vaccine and hearing loss."[76] Resp. Ex. C at 7 (quoting Pet. Ex. 48 at 118). Dr. Ying noted weaknesses in the evidence reviewed by the IOM committee were due to "publications of a case report that did not provide evidence beyond temporality" and "long latencies between vaccine administration and development of symptoms mak[ing] it impossible to rule out other possible causes." Id.

Dr. Ying provided medical literature that discussed the pathogenesis of AIED. See, e.g., Resp. Ex. C, Tab 16.[77] Vambutas and Pathak explained that "[a]s with most autoimmune diseases, it has been postulated that a misdirected attack on self, in this case to inner ear proteins, results in both proinflammatory T-cell responses and autoantibody formation, which represent the basic features of AIED and other autoimmune diseases." Id. at 2; see also Resp. Ex. C, Tab 17 at 3-4 (discussing the mechanisms of autoimmune process in the inner ear);[78] Resp. Ex. C, Tab 18 at 2 ("An uncontrolled attack against inner ear antigens, resulting in both T-cell responses and autoantibody development, has been proposed as the pathogenetic mechanism of AIED"). In Ciorba et al., the authors noted this immunological process may result in cochlear and vestibular damage with the most commonly reported damage being "cochlear vasculitis, atrophy

[75] Kathleen Stratton et al., Adverse Events Associated with Childhood Vaccines Other Than Pertussis and Rubella: Summary of a Report from the Institute of Medicine, 271 JAMA 1602 (1994).

[76] The IOM committee defines this category of causation as evidence that "is not reasonably convincing either in support of or against causality; evidence that is sparse, conflicting, of weak quality, or merely suggestive—whether toward or away from causality falls in this category." 2012 IOM report at 15, 23-24. Of note, the IOM committee determined that the "epidemiologic evidence was insufficient or absent to assess an association between MMR vaccine and hearing loss." Pet. Ex. 48 at 115.

[77] Andrea Vambutas & Shresh Pathak, AAO: Autoimmune and Autoinflammatory (Disease) in Otology: What Is New in Immune-Mediated Hearing Loss, 1 Laryngoscope Investig. Otolaryngol. 110 (2016).

[78] R. Bovo et al., Immune-Mediated Inner Ear Disease, 126 Acta Otolaryngol. 1012 (2006).

of the organ of Corti, otic capsule otospongiosis,[79] endolymphatic hydrops[,[80]] and spiral ganglion degeneration."[81] Resp. Ex. C, Tab 18 at 2.

Additionally, Vambutas and Pathak noted while the pathogenesis contemplates autoantibody formation, no autoantibodies have been found specific to AIED.[82] Resp. Ex. C, Tab 16 at 2. In a small group of patients, anti-cochlin antibodies have been reported that "would represent a cochlear specific antibody response." Id. Studies about AIED are difficult due to limited access of the cochlea, that fact that peripheral blood immune markers may not reflect inner ear immune reactions, and animal studies have been limited. Id.; see also Resp. Ex. C, Tab 18 at 2. Research also suggests that like other autoimmune diseases, AIED may be both an autoimmune and an autoinflammatory disease. Resp. Ex. C, Tab 16 at 2.

Bovo et al. described the "three levels of proof" used in the diagnosis of an autoimmune disease like AIED. Resp. Ex. C, Tab 17 at 1. The three levels of proof, in "descending order of importance" are "(i) direct proof; (ii) indirect proof; and (iii) circumstantial evidence." Id. The authors explained that obtaining direct proof, through "the induction of disease in humans by transferring autoantibodies or autoreactive T cells," was ethically untenable. Id. Instead, researchers must rely upon indirect proof, such as animal models, and circumstantial evidence. Id. at 1-2. Looking at experimental models (a type of indirect proof), the authors explained a "wide variety of antibodies against different ear tissues have been detected [in AIED]," and "multiple antigens" have also been recognized, but none have been identified as "the specific target." Id. at 2. The authors concluded that based on available "clinical and experimental data there is [] strong evidence of immune mechanisms in human inner ear disease." Id. Bovo et al. provided a detailed review of the immune system of the inner ear, noting there is "substantial evidence of autoimmune mechanisms in . . . sudden deafness." Id. at 3. Significantly, Bovo et al. noted that the "'cross-reactions' theory is [] the most favored [mechanism]: antibodies or

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[79] Otospongiosis is "the formation of spongy bone in the bony labyrinth of the ear." Otospongiosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=35990 (last visited Dec. 19, 2025).

[80] Endolymphatic hydrops is "an abnormal accumulation of endolymphatic fluid within the membranous labyrinth of the inner ear." Mickie Hamiter, Meniere Disease, Merck Manual, https://www.merckmanuals.com/professional/ear-nose-and-throat-disorders/inner-ear-disorders/meniere-disease (last visited Dec. 16, 2025).

[81] The spiral ganglion is located within the cochlea and "consists of bipolar cells that send fibers peripherally through the foramina nervosa to the spiral organ and centrally through the internal acoustic meatus [auditory canal] to the cochlear nuclei of the brainstem." See Ganglion Cochleare, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=78034 (last visited Dec. 19, 2025).

[82] Bovo et al. explained clinical testing is not currently done to identify antibodies "to an inner ear supporting cell antigen." Resp. Ex. C, Tab 17 at 6.

rogue T cells cause accidental inner ear damages because the ear share common antigens with . . . a virus . . . the body is fighting off." Id. Other mechanisms were also discussed.[83] Id. at 3-4.

Additionally, Dr. Ying criticized several aspects of Dr. Monsell's report. First, Dr. Ying opined the mechanisms of vaccine-induced autoimmunity proposed by Agmon-Levin et al. "are only just theories as there is still no published evidence demonstrating how MMR vaccine causes AIED." Resp. Ex. C at 9 (citing Pet. Ex. 14). Citing Agmon-Levin et al., Dr. Ying explained "the role of other risk cofactors including environmental exposures [or] genetic susceptibility . . . may affect the causal association between vaccination and autoimmunity." Id. (citing Pet. Ex. 14 at 4). Dr. Ying observed that Dr. Monsell did not discuss the risk co-factors in Petitioner's case. Id. Although Dr. Ying described co-factors such as environmental exposures and genetic susceptibility, she did not describe these in any detail or suggest that they independently can cause AIED. Id.

Next, Dr. Ying faulted Dr. Monsell for not elaborating on his comment that "complex microbiological processes that could be subject to functionally different genetic variants in vaccine recipients and idiosyncratic reactions." Resp. Ex. C at 9. Dr. Ying described this statement as vague and noted it was unclear what "idiosyncratic reactions" Dr. Monsell was referencing. Id.

Dr. Ying also criticized Dr. Monsell's use of autoimmune thrombocytopenia as example of MMR vaccination causing an autoimmune condition. Resp. Ex. C at 9. Dr. Ying opined "the same process does not apply to hearing loss or inner ear." Id. Dr. Ying did not provide further explanation on the differences between autoimmune thrombocytopenia and AIED. Dr. Ying also noted that there is no animal model for AIED to allow for "vaccine experiments." Id.

Dr. Ying concluded "[i]n publications to date, there is insufficient scientific evidence indicating AIED is an adverse event to MMR vaccination." Resp. Ex. C at 10.

iii. Althen Prongs Two and Three

Dr. Ying opined there was "insufficient evidence" that Petitioner's bilateral SNHL, dizziness, and visual disturbances were an adverse reaction to the MMR vaccine. Resp. Ex. C at 8. Further, Dr. Ying disagreed that the onset of Petitioner's AIED was "consistent with an immune-mediated response following MMR vaccination." Id. at 10.

First, Dr. Ying explained Petitioner's clinical presentation was not consistent with published case reports or the medical literature. Resp. Ex. C at 8. Petitioner did not experience any adverse symptomatology such as fever or arthralgia after her MMR vaccination. Id. And, as discussed further below, her hearing loss occurred outside the incubation period for mumps or measles infection cited in the published case reports. Id. Dr. Ying further noted that Petitioner's serial MRIs were unremarkable and did not contain the high signal intensities in the cochlea described by Otake et al. Id. (citing Pet. Ex. 45). However, Otake et al. noted the high signal

[83] For another paper with a thorough discussion about the proposed mechanisms of AIED, see Resp. Ex. C, Tab 18.

intensity present in the 3D-FLAIR imaging was not detected by T1 and T2 weighted MRIs taken in the same patient. Pet. Ex. 45 at 2. Additionally, Dr. Ying opined Petitioner's "subjective visual complaints" were not commonly seen in measles, mumps, or rubella infection. Resp. Ex. C at 8.

Next, Dr. Ying noted Petitioner did not report "any problem/side effects with the first MMR vaccination administered on March 15, 2022." Resp. Ex. C at 8. As Petitioner was "already exposed to a first dose of MMR vaccine," Dr. Ying opined the second dose of MMR administered 30 days later "should not be so novel to trigger another autoimmune response." Id.

Dr. Ying disagreed that Dr. Monsell's comment that "MMR vaccine is not often administered to adults, who may not have as robust an immune system as children" provided support for vaccination causation in Petitioner. Resp. Ex. C at 9. She opined that if adults have a less robust immune system, "then the incidence/occurrence of vaccine-induced autoimmunity should be less in adults." Id.

Additionally, Dr. Ying noted Petitioner's hearing loss symptoms appeared "at the end of her vacation in Hawaii." Resp. Ex. C at 9. Dr. Ying opined "stressors from vacation/traveling away from home could trigger immune responses." Id. Dr. Ying noted "these stressors" occurred closer in time to Petitioner's hearing loss than her MMR vaccination. Id. Dr. Ying suggested additional information regarding Petitioner's "well-being" and symptoms at the end of her vacation "could provide clues of other possible explanations." Id.

Discussing the temporal relationship between Petitioner's MMR vaccination and the onset of her AIED, Dr. Ying explained Petitioner first reported muffled hearing/hearing loss 31 to 32 days after receiving her second dose of the MMR vaccine. Resp. Ex. C at 8. Dr. Ying opined a 31/32-day onset is outside of the incubation period for measles and mumps infections. Id. She reported the incubation for measles is 10 to 12 days "from exposure to prodrome" and seven to 21 from exposure to rash.[84] Id. And Dr. Ying noted case reports that have associated MMR vaccination with SNHL have a time course of onset corresponding to the incubation period of measles infection. Id. at 6 (citing Pet. Ex. 23). Additionally, the case report from Rikitake et al. described an onset of 18 days consistent with the incubation period of mumps. Id. at 7 (citing Pet. Ex. 46). While the bilateral SNHL reported in Hulbert et al. had onset of 22 days, Dr. Ying noted the patient had "body reaction (arthralgias, fever, headaches, tinnitus, dizziness) three days after she receive[d]MMR vaccination." Id. (citing Pet. Ex. 32).

Finally, Dr. Ying opined Petitioner's theory that the onset of her AIED was "consistent with an immune-mediated response following MMR vaccination" was "not based on a reasonable degree of medical probability." Resp. Ex. C at 10. As discussed above, Dr. Ying disagreed that Dr. Monsell's discussion MMR vaccine-induced thrombocytopenia was applicable to AIED. Id. at 9. Dr. Ying did not discuss what a medically appropriate timeframe would be for an immune-mediated response following vaccination.

[84] Dr. Ying cited Epidemiology and Prevention of Vaccine-Preventable Diseases (Elisha Hall et al. eds., 14th ed. 2021) in support of the incubation period of measles infection; however, this source was not filed as an exhibit by Respondent.

Dr. Ying concluded, "[m]ore than likely, [Petitioner] suffered 'idiopathic' AIED without any association to her two doses of MMR vaccinations." Resp. Ex. C at 10.

III. LEGAL FRAMEWORK

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. Factual Issues

Petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records).

Medical records, specifically contemporaneous medical records, are presumed to be accurate and generally "warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013). The weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Id. To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)), mot. for rev. den'd, 142 Fed. Cl. 247 (2019), vacated on other grounds & remanded, 809 F. App'x 843 (Fed Cir. 2020).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. 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 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 his 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 Petitioner's 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, 569 F.3d at 1375; 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 his 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, 618 F.3d at 1347 ("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 that Petitioner has provided preponderant evidence of a sound and reliable causal mechanism as required under Althen prong one for the following reasons.

First, the parties' experts agree that Petitioner's diagnosis is AIED, autoimmune inner ear disease. Thus, there is agreement that the diagnosis at issue here is autoimmune in nature.

Next, both parties' experts and their referenced medical literature provide strong evidence of the following foundational support: (1) The inner ear is not immunologically privileged, (2) the inner ear has a robust immune system and can generate a destructive immune response, (3) viruses are common causes of autoimmune conditions, (4) measles and mumps virus infections are associated with SSNHL, and (5) MMR vaccines are associated with hearing loss as shown in case reports.

While one case report may not provide persuasive evidence of causation, here there are numerous cases of MMR vaccine associated hearing loss. While case reports are generally insufficient to establish causation, they do provide some evidence in favor of causation. See, e.g., Coleman v. Sec'y of Health & Hum. Servs., No. 18-352V, 2021 WL 1291677, at *13 (Fed. Cl. Spec. Mstr. Feb. 16, 2021); Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011) ("[C]ase reports can by their nature only present indicia of causation but that does not deprive them of all evidentiary weight."). For rare conditions, case reports carry more weight than would otherwise be afforded. Raymo v. Sec'y of Health & Hum. Servs., No. 11-0654V,

2014 WL 1092274, at *21 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) (granting "more significance" to case reports when the injury at issue was a "relatively rare condition" with "with only about 1400 new cases in the U.S. diagnosed annually"); see also Songero v. Sec'y of Health & Hum. Servs., No. 18-300V, 2025 WL 3013090, at *16 (Fed. Cl. Spec. Mstr. Oct. 3, 2025) ("In the context of rare conditions, [] where epidemiologic studies are unavailable, [case reports] provide some evidence of causation."). Moreover, the IOM committee considered case reports in determining their assessment as to a mechanistic theory. The committee identified specific publications, including case reports, that provided "clinical, [or] diagnostic . . . evidence that contributed to the weight of the mechanistic evidence." Pet. Ex. 48 at 115.

Agmon-Levin et al. supports the third foundational tenet above and explains the nexus with molecular mimicry. They state "[i]nfectious agents are considered to be the most common triggers of autoimmunity, and vaccines that contain antigens from infectious agents might induced autoimmunity by similar mechanisms such as molecular mimicry, bystander activation, epitope spreading, and polyclonal activation." Pet. Ex. 14 at 2. The MMR vaccine contains antigens of the measles and mumps viruses and are infectious agents which historically are known to induce autoimmune diseases by the mechanism of molecular mimicry.

Further, these foundational tenets formed the basis of the 2012 IOM assessment about the mechanistic evidence related to hearing loss following measles or mumps vaccinations. The IOM's assessment of low-intermediate was "based on knowledge about the natural infection, experimental cases[,] and eight [case reports]." Pet. Ex. 48 at 118. Although the parties here disagree about the import of the assessment "low-intermediate," the undersigned finds that since the 2012 IOM report, the body of knowledge about hearing loss and AIED has grown. While no specific vaccine antigens triggering AIED have been identified, and no specific autoantibodies discovered to prove causation with certainty, molecular mimicry has emerged as the favored causal theory. Due to the information described in the articles about AIED filed herein, combined with knowledge about natural infections of measles and mumps and hearing loss, the knowledge that viral infections cause autoimmune conditions, clinical and experimental data, and numerous case reports, the undersigned finds there is preponderant evidence that the MMR vaccine can cause AIED through molecular mimicry as well as the other mechanisms identified by Dr. Monsell.

Because much about the pathogenesis of AIED is not known, Respondent asserts there is "inadequate reliable evidence to convincingly establish a causal association." Resp. Response at 15-16. However, a lack of knowledge does not automatically preclude a finding of preponderant evidence in Vaccine Act cases. Bovo et al. explained that the diagnosis of an autoimmune disease like AIED "relies on three levels of proof . . . (i) direct proof; (ii) indirect proof; and (iii) circumstantial evidence." Resp. Ex. C, Tab 17 at 1. While there is no direct proof, there is indirect proof and circumstantial evidence from experimental models of autoimmune hearing loss in animals, serology findings in animal models that correlate to serology studies in humans, assessment of autoimmune activity detected by various lab studies, and the finding of multiple antibodies against different ear tissues. Bovo et al. note that the observation of inner ear antibodies "does not always support the cause-and-effect link needed to demonstrate correlation between antibodies and inner ear disease." Id. at 2. They conclude, however, that "based on all these clinical and experimental data there is today strong evidence of immune mechanisms in

human inner ear disease." Id. Further, they identify a "cross-reactions theory" as the "most favored" mechanism for the autoimmune process in the inner ear. Id. at 3.

Moreover, circumstantial evidence is applicable in the context of vaccine causation. See, e.g., Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159, 164 (2021) ("The Vaccine Act permits proof of causation through 'the use of circumstantial evidence envisioned by the preponderance standard.'" (quoting Capizzano., 440 F.3d at 1325)); Harr v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 280, 304 (2012) ("[C]ircumstantial evidence is sometimes enough to prove causation in a Vaccine Act case."); see also R.G.C. & S.S.C. ex rel. A.G.C. v. Sec'y of Health & Hum. Servs., No. 18-1624V, 2025 WL 3142007, at *29 (Fed. Cl. Spec. Mstr. Aug. 28, 2025) ("Experts who testify in this Program often must extrapolate a study's findings then apply that to the case before them. Although doing so does not prove that the subject vaccine can cause the alleged injury to the degree of scientific certainty, it may provide circumstantial evidence that advances a sound and reliable theory.") (citing Doles v. Sec'y of Health & Hum. Servs., No. 2023-2404, 2025 WL 1177875, at *5-9 (Fed. Cir. 2025)).

Next, Respondent asserts that because there are no supportive epidemiological studies showing a causal association between the MMR vaccine and AIED, Petitioner cannot prevail. However, it is well established by case law that epidemiology studies showing a causal association are not required in Vaccine Act cases.

Petitioner has no obligation to provide statistical or epidemiological evidence. See, e.g., Capizzano, 440 F.3d at 1325-26. Additionally, a lack of supportive epidemiological evidence is not dispositive. First, "epidemiological studies cannot absolutely refute a causal connection" and "cannot prove a negative. It is always possible that another epidemiological study involving a bigger population will detect an increased risk not otherwise apparent in smaller studies." Harris v. Sec'y of Health & Hum. Servs., No. 10-322V, 2014 WL 3159377, at *11 (Fed. Cl. Spec. Mstr. June 10, 2014). Additionally, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." Andreu, 569 F.3d at 1378 (quoting Capizzano, 440 F.3d at 1325-26); see also Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in a petitioner's favor).

Moreover, the conclusions reached in the published epidemiological studies cannot be automatically extrapolated to the present case. Although the 2012 IOM report studied hearing loss, the update in 2014 by Maglione et al. did not discuss hearing loss. The 2021 follow up safety review by Gidengil et al. referenced the Baxter et al. epidemiological study. The Baxter et al. study reported no cases of SSNHL within one week of the MMR vaccination. While Baxter et al. also reviewed cases of SSNHL within 28 days of MMR vaccination, this data was only included in the supplemental findings., which were not filed in the present case. Thus, it is difficult to verify the study's results as they related to the MMR vaccine.

Further, the Baxter et al. findings related to MMR do not identify the diagnosis in question as AIED. Instead, the study focused on the broad umbrella of hearing loss cases, not those specifically identified with an autoimmune etiology. Therefore, as observed by Petitioner,

there does not appear to be an epidemiological study of AIED following the MMR vaccination. See Pet. Reply at 4. Moreover, AIED appears to be an extremely rare condition which makes it difficult to study.

Further, epidemiological studies have limited usefulness when the injury at issue is not included in the study parameters. See, e.g., Moberly, 592 F.3d at 1324 (explaining epidemiological studies "provide no evidence pertinent to persons not within the parameters of the test group"); Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1365 (Fed. Cir. 2000) ("In order for [an epidemiological] study to be instructive, however, its conclusions must fit the facts of the case under consideration.").

Another argument against causation raised by Respondent is that the mechanism of hearing loss caused by the wild-type of measles or mumps virus is not applicable because it ignores the differences between immune responses to wild-type viruses and live attenuated viruses. The differences in the natural infections and virus delivered in the form of vaccines is acknowledged by the experts and in the medical literature. This acknowledgement does not negate the reality that natural infections cause autoimmune diseases and that vaccines are also associated with autoimmune diseases. The 2012 IOM committee noted that the wild-type mumps virus infection was associated with deafness and the wild-type measles infection was associated with bilateral "hearing loss in [five to 10] percent of measles cases." Pet. Ex. 48 at 117. The committee "consider[ed] the effects of natural infection [as] one type of mechanistic evidence." Id.

Respondent's arguments based on specific articles are also unavailing as the undersigned's decision does not turn on the findings of any one specific medical article. Overall, the medical literature establishes that measles and mumps infections are associated with hearing loss, that vaccines containing these live attenuated viruses have also been reported to cause hearing loss, and that direct viral infection, molecular mimicry, and inflammatory responses have been implicated as causal, with molecular mimicry being the favored theory for AIED.

The undersigned has adjudicated several SNHL, SSNHL, and hearing loss cases and did not find the petitioners' hearing loss was autoimmune, or that their hearing loss was caused by a vaccine.

In Alsaadeh, 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 petitioner specifically alleged his hearing loss was AIED, however, the undersigned found the petitioner had not provided preponderant evidence for AIED. Id. at *30-31. In Herms, the undersigned also denied entitlement where a petitioner alleged that the diphtheria-tetanus-acellular pertussis vaccination that she received caused SNHL and tinnitus in her left ear. Herms v. Sec'y of Health & Hum. Servs., No. 19-70V, 2024 WL 1340669, at *1 (Fed. Cl. Spec. Mstr. Mar. 4, 2024), mot. for rev. den'd, aff'd, 173 Fed. Cl. 1, appeal docketed, No. 25-1007 (Fed. Cir. Sept. 27, 2024). Although the petitioner's experts put forward a theory based, in part, on autoimmunity, the petitioner "failed to establish her hearing loss was autoimmune in nature." Id. at *23.

In Zikeli and Buen, the undersigned denied entitlement for a flu and SSNHL claim after she analyzed a seven-step theory from Dr. Monsell and found it was not sound and reliable. Zikeli v. Sec'y of Health & Hum. Servs., No. 20-564V, 2025 WL 2306208, at *28-32 (Fed. Cl. Spec. Mstr. July 16, 2025); Buen v. Sec'y of Health & Hum. Servs., No. 21-1314V, 2025 WL 2938046 (Fed. Cl. Spec. Mstr. Sept. 17, 2025) (denying a flu/SSNHL case on the same grounds). In Zikeli, the undersigned again found that the petitioner's SSNHL was not consistent with autoimmune hearing loss. Zikeli, 2025 WL 2306208, at *33 ("Petitioner's hearing loss was unilateral and acute. Autoimmune hearing loss typically affects both ears in a progressive course.").

Here, however, Petitioner was diagnosed with AIED by her treating physicians and both parties' experts agreed Petitioner's diagnosis is an autoimmune hearing loss. Further, none of the undersigned's prior hearing loss denials involved an MMR vaccination.

In summary, Petitioner has shown by preponderant evidence that AIED is an autoimmune form of hearing loss, that hearing loss can be caused by measles and mumps infections, and that there are a number of case reports showing an association between hearing loss and measles and mumps vaccinations. Medical literature shows that the favored casual theory for AIED is molecular mimicry, although no antigenic trigger has been discovered, and the target of such trigger in the inner ear is not yet known. For all of these reasons, the undersigned finds that the weight of the evidence as to Althen prong one preponderates in Petitioner's favor. Therefore, Petitioner has provided preponderant evidence to satisfy prong one.

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, 993 F.2d at 1528. 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").

A 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, 440 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

The undersigned finds that Petitioner has proven Althen prong two by preponderant evidence for the following three reasons.

First, Petitioner's diagnosis of AIED is an autoimmune condition, and the Petitioner has shown that the theory of molecular mimicry is the likely causal mechanism. Her clinical course was consistent with this autoimmune illness.

Respondent suggests that Petitioner's clinical course was not consistent with MMR vaccine-induced hearing loss for two reasons. First, Respondent argues that the eight cases relied on by the 2012 IOM committee for the assessment of "low-intermediate" presented with "fever, rash, and nystagmus," whereas Petitioner did not these symptoms. Resp. Response at 17-18. Petitioner did not report fever or rash. She did develop a "very slight horizontal nystagmus," as documented in the medical records.[85] Pet. Ex. 2 at 804. Notably, Respondent's expert, Dr. Ying, explained that not all patients experience these symptoms. Dr. Ying specifically opined that "asymptomatic cases of mumps can also result in sudden SNHL." Resp. Ex. C at 6. Since Respondent's expert expressly opined that some patients may be asymptomatic, Respondent's argument on this point is not well founded.

Again, related to clinical presentation, Respondent suggests that because Petitioner's MRI done in June 2019 was unremarkable, her course was inconsistent with vaccine causation. Resp. Response at 31 (citing Resp. Ex. C at 8). In her expert report, Dr. Ying noted that Petitioner's MRI studies "did not show high signal intensity in the affected cochlea as reported by Otake et al." Resp. Ex. C at 8 (citing Pet. Ex. 45). Otake et al. described an asymptomatic 10-year-old child who had a 3D-FLAIR technique "applied" to his MRI which showed "high signals in the right cochlea and vestibule . . . indicat[ing] hemorrhage or a high concentration of protein." Pet. Ex. 45 at 1. The authors suggested that the "3D-FLAIR MRI may help to identify and define labyrinthitis in mumps deafness." Id. The mechanism of hearing loss was thought to be due to "direct viral invasion of the cochlea," or direct infection, and not an autoimmune mechanism. See id. at 2. Moreover, the point of the paper was to describe the 3D-FLAIR technique and its ability to detect abnormalities of the inner ear in contrast to other MRI protocols.[86] Finally, there is no question that Petitioner had labyrinthitis like the case reported by Otake et al., even if it was not visualized on the MRI. See, e.g., Pet. Ex. 2 at 1300 (assessing Petitioner with "bilateral labyrinthitis").

The second reason for the undersigned's ruling on prong two is because Petitioner's treating physicians questioned an association between her MMR vaccinations and the onset of

[85] The undersigned acknowledges that Petitioner's nystagmus was not documented in the medical records until November 6, 2019.

[86] Petitioner's MRI done in June 2019 was performed using 3D FIESTA technique for the internal auditory canals. See Pet. Ex. 2 at 1313-14. Dr. Ying did not opine as to the differences or similarities between this MRI technique and the 3D FLAIR technique used in Otake et al.

her AIED. In July 2019, Petitioner's ENT, Dr. Kay, documented the following: "Had MMR vaccine in [two] steps. [One to two] months before onset of symptoms. There are reports on the literature of similar vaccines causation hearing loss and vestibular dysfunction . . . coincidental vs possible causation-unclear". Pet. Ex. 2 at 1134-38. In November 2019, Petitioner consulted with Dr. Hain who wrote, "[r]egarding this picture arising post-vaccination (MMR), I have never encountered this situation although I have seen about 300 patients with bilateral loss in my career. It cannot be common." Id. at 793.

While neither of these physicians opine that Petitioner's AIED was caused by her MMR vaccination, they both question vaccination as the causal trigger of Petitioner's AIED. Treating physician statements are "favored" evidence in support of Althen prong two. Capizzano, 440 F.3d at 1326. Further, statements from treating physicians that "do not amount to [an] opinion[] on causation" may still provide "circumstantial evidence" in support of Althen prong two. Osso v. Sec'y of Health & Hum. Servs., No. 18-575V, 2023 WL 5016473, at *2 (Fed. Cl. Spec. Mstr. July 13, 2023). Here, both Dr. Kay and Dr. Hain note the temporal association of Petitioner's hearing loss with her vaccine. Dr. Kay acknowledges similar vaccine causation in the medical literature. Neither doctor discounted vaccination as an etiology of Petitioner's AIED. Instead, Dr. Kay opined that it was "unclear" whether Petitioner's MMR vaccine was "coincidental" or causative, and Dr. Hain discussed the rarity of vaccine induced hearing loss. Pet. Ex. 2 at 1138. While these statements from Petitioner's treating physicians do not amount to an opinion on causation, they provide circumstantial evidence that Petitioner's treating physicians associated her MMR vaccine with the development of her AIED.

The third reason for the undersigned's finding on Althen prong two is that no alternative cause for Petitioner's hearing loss was found, although Petitioner had a very thorough work up and saw many specialists in consultation for her AIED. Petitioner's AIED was not secondary to another autoimmune disease. Petitioner's expert, Dr. Monsell ruled out several alternate causes of SNHL such as age-related hearing loss, toxic noise exposure, ototoxicity, Meniere's disease, vestibular schwannoma, and stroke. He also explained that Petitioner's clinical course was not consistent with eustachian tube dysfunction associated with plane travel. While Dr. Ying suggested that "stressors from vacation/traveling . . . could trigger immune response," Dr. Ying did not expand on this theory. Resp. Ex. C at 9.

While petitioners are not required to eliminate all alternative causes, the lack of alternative cause "may be included as part of evidence to satisfy" Althen prong two. Ramsey v. Sec'y of Health & Hum. Servs., No. 21-1486V, 2023 WL 2823403, at *6 (Fed. Cl. Spec. Mstr. April 6, 2023); see also Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007) (noting petitioners may use rely on "evidence eliminating other potential causes to help carry the burden on causation"). Here, Petitioner's evidence that no alternative cause was found for her AIED provides additional support for her prong two showing.

Therefore, the undersigned finds Petitioner has proven Althen prong two by preponderant evidence.

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). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1579, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542.

Petitioner received her first MMR vaccination on March 15, 2019, and her second MMR vaccination on April 19, 2019. She presented for bilateral ear fullness on May 25, 2019, reported onset of symptoms occurred four to five days before. Therefore, onset of symptoms began approximately May 19 or 20, or 30 days after her second MMR vaccination.

Petitioner's expert, Dr. Monsell, opined that this onset was consistent with an immune-mediated response following her MMR vaccination. The time frame of four to six weeks is consistent with case reports of hearing loss after MMR vaccination. The summary of cases by Asatryan et al. showed that onset "ranged from [two] to 89 days following vaccination, with a peak on days 10 through 14." Pet. Ex. 16 at 3, 3 fig.1. Additional case reports illustrate an onset of three weeks. For example, Rikitake et al. described bilateral acute hearing loss three weeks following the mumps vaccine and Hulbert et al. reported bilateral hearing loss 22 days following MMR vaccination.

Moreover, although Respondent's expert immunologist Dr. Staats disagreed that the MMR vaccination caused Petitioner's hearing loss, he did not take issue with the onset time frame. Dr. Staats acknowledged the temporal association between Petitioner's vaccination and AIED. Resp. Ex. A at 5 ("Other than a temporal association between the MMR vaccine and [Petitioner's] hearing loss, there is no compelling evidence."). Dr. Ying opined that the onset was too long to implicate hearing loss caused by infection, but she did not appear to refute the opinion that 30 days would be appropriate for the theory of molecular mimicry.

Therefore, undersigned finds that Petitioner has met her burden of proof as to Althen prong three.

V. CONCLUSION

Based on the record, and for the reasons discussed above, the undersigned finds there is preponderant evidence to satisfy all three Althen prongs and to establish that Petitioner's MMR vaccination caused her to develop AIED. Therefore, the undersigned finds that Petitioner is entitled to compensation.

A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master