

# In the United States Court of Federal Claims

No. 19-70V

(Filed under seal: July 29, 2024)

(Reissued for Publication: August 15, 2024)

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<b>SALLY HERMS,</b>	)
	)
Petitioner,	)
	)
v.	)
	)
<b>SECRETARY OF HEALTH AND</b>	)
<b>HUMAN SERVICES,</b>	)
	)
Respondent.	)
_____	)

John F. McHugh, Law Office of John McHugh, New York, NY, for Petitioner.

Mitchell H. Jones, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent. With him on the briefs were Brian M. Boynton, Principal Deputy Assistant Attorney General, Civil Division, as well as C. Salvatore D’Alessio, Director, Heather L. Pearlman, Deputy Director, and Colleen C. Hartley, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

## OPINION AND ORDER<sup>1</sup>

LETTOW, Senior Judge.

Pending before the court is petitioner’s motion for review of Special Master Dorsey’s decision issued on March 4, 2024, denying petitioner compensation under the National Vaccine Injury Compensation Program (“Vaccine Act” or “the Program”), 42 U.S.C. §§ 300aa-10 to aa-34. Petitioner, Ms. Sally Herms, claims that the diphtheria tetanus toxoid acellular pertussis (“DTaP” or “TDaP”) vaccination<sup>2</sup> that she received on June 18, 2017, caused sensorineural

<sup>1</sup> In accord with the Rules of the Court of Federal Claims (“RCFC”), App. B (“Vaccine Rules”), Vaccine Rule 18(b), this opinion and order was initially filed under seal. By rule, the parties had fourteen days within which to propose redactions.

<sup>2</sup> The DTaP vaccine is meant “to prevent diphtheria, tetanus, and pertussis.” Pet’r’s Ex. 4, ECF No. 12-3.

hearing loss (“SNHL” or “hearing loss”) and tinnitus in her left ear. Pet’r’s Mot. for Review of the Special Master’s March 4, 2024 Decision (“Pet’r’s Mot.”), ECF No. 144.

Because petitioner does not allege that she sustained an injury included in the Vaccine Injury Table, she must establish causation. 42 U.S.C. § 300aa-11(c)(1)(B), (C)(ii)(I). In her decision, the Special Master applied the causation prongs set forth in *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005), and concluded that petitioner had not shown by a preponderance of the evidence that the DTaP vaccine caused her tinnitus and hearing loss. *See generally Herms v. Sec’y of Health & Hum. Servs.* (“*Entitlement Decision*”), No. 19-70V, 2024 WL 1340669 (Fed. Cl. Spec. Mstr. Mar. 4, 2024). Petitioner’s motion for review is fully briefed and a hearing was held on May 29, 2024. Resp’t’s Resp. to Pet’r’s Mot. for Review (“Resp’t’s Resp.”), ECF No. 146; Hr’g Tr. (May 29, 2024), ECF No. 149. Accordingly, the court reviews the Special Master’s finding of no causation.

## **BACKGROUND<sup>3</sup>**

### ***A. Sensorineural Hearing Loss and Tinnitus***

Ms. Herms seeks compensation for two conditions: SNHL and tinnitus. SNHL is defined as “hearing loss of at least 30 [decibels] in three sequential frequencies in the standard pure tone audiogram. SNHL results from dysfunction of the inner ear, the vestibulocochlear nerve, or the central processing centers of the brain.” Pet’r’s Ex. 163-5 at 12, ECF No. 141. Establishing a diagnosis of SNHL requires both “[a] physical examination to exclude conductive hearing loss” and “[a]n audiometric evaluation consistent with SNHL.” *Id.* at 11-12. The medical community has not yet definitively identified a known etiology or pathogenesis of SNHL. Pet’r’s Ex. 163-3 at 1-2, ECF No. 141. SNHL is commonly unilateral. *Id.* at 1.

SNHL is also frequently associated with tinnitus. *Id.* (reporting that “[t]innitus occurs in about 80% of patients” with SNHL); *see also* Pet’r’s Ex. 163-7 at 7, ECF No. 141 (reporting that “all (100%) patients in [SNHL] study had tinnitus”). Tinnitus is the “[p]erception of a sound,” e.g., “a pure tone or noise including (ringing, whistling, hissing, roaring, or booming),” “in the absence of an environmental acoustic stimulus.” *Tinnitus*, Stedmans Med. Dictionary 921820, Westlaw (database updated November 2014).

### ***B. Ms. Herms’ Medical History***

The parties stipulate that on June 18, 2017, petitioner was administered the DTaP vaccination. Joint Submission of Mar. 24, 2023 at 1, ECF No. 132. The parties also stipulate that “[t]wo days later, [Ms. Herms] experienced fever, muscle aches[,] and a feeling of being in a tunnel. She awoke and found she was deaf in her left ear” and the next morning “she had tinnitus in her left ear.” *Id.*

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<sup>3</sup> The following recitations are drawn from the factual and procedural history detailed in the Special Master’s decision and the attendant referenced sources.

Petitioner visited her primary care provider, Dr. Nasseredin Shariati on June 20, 2017, two days after receiving the DTaP vaccination, with symptoms including chills, ear congestion, hearing loss, stiffness, body aches, and a fever. Pet'r's Ex. 1 at 1, ECF No. 8-1. Dr. Shariati indicated Ms. Herms was "obviously concerned about the possibility of [a] side effect" from the vaccination, and he concluded that Ms. Herms' symptoms were "[p]robable side effects from receiving [the] DTaP" vaccination, coupled with "wax buildup on the left ear." *Id.* He also expressed concern that Ms. Herms could have a possible acoustic neuroma, given that Ms. Herms' daughter "suffered from acoustic neuroma on her left ear and [as a] result[] of that[,] she lost hearing on that side permanently." *Id.*

Nine days later, on June 29, 2017, Ms. Herms visited Dr. Gregory Fleming, an otolaryngologist, and expressed symptoms of "seashell type tinnitus but no vertigo or ear pain." Pet'r's Ex. 1 at 3-4. Audiological testing revealed "moderate to severe [SNHL] in [Ms. Herms'] left ear with no discernible speech discrimination," and Dr. Fleming prescribed a steroidal taper of prednisone, a magnetic resonance imaging ("MRI") test to ensure Ms. Herms did not have an acoustic neuroma, and a serology screening. *Id.* at 4. Following her prednisone steroidal taper, Ms. Herms returned to Dr. Fleming to review the results of a second audiological test conducted on July 18, 2017. *Id.* at 16, 20. Dr. Fleming identified "good improvement of [Ms. Herms'] speech discrimination but persisting moderate [SNHL] on pure tone testing." *Id.* at 20. Then, on July 27, 2017, petitioner visited otolaryngologist Dr. Jed Kwartler with similar symptoms to those she experienced a month prior. *Id.* at 22-23. Dr. Kwartler noted that intratympanic steroid injections would not likely help Ms. Herms given the time that had passed since her symptoms began and discussed "the pathophysiology of idiopathic sudden [SNHL]." *Id.* at 23.

On April 12, 2018, Ms. Herms visited Dr. Samuel Selesnick, an otolaryngologist at Weill Cornell Otolaryngology Head and Neck Surgery, following an updated hearing test administered the prior day. Pet'r's Ex. 1 at 24-27. Dr. Selesnick noted Ms. Herms' familial history of ear disease (her daughter's acoustic neuroma) and that Ms. Herms had no other otologic history. *Id.* at 27. Finally, Dr. Selesnick noted that Ms. Herms' third through seventh cranial nerves were "grossly intact with the exception of the left VIII[] cranial nerve." *Id.* Following examination and review of testing, Dr. Selesnick noted that "[d]ue to the close time proximity of the administration of the vaccine, it is likely that the vaccine is at least in some way responsible for [petitioner's] [SNHL]." *Id.*

On September 20, 2018, Petitioner had a routine visit with her primary care provider, Dr. Shariati, where she reported deafness on her left side and constant tinnitus. Pet'r's Ex. 3 at 1, ECF No. 12-1. Following an audiometry, Dr. Shariati confirmed that Ms. Herms had "[s]ignificant hearing loss on the left side associated with tinnitus," which he believed was "probably secondary to [the] administration of" the DTaP vaccination. *Id.* at 2.

Several months later, on April 16, 2019, Dr. Herms had a follow-up appointment with Dr. Selesnick, during which Ms. Herms reiterated her complaints of tinnitus and Dr. Selesnick discussed possible treatment and therapeutic options. Pet'r's Ex. 2 at 1-2, ECF No. 8-2. Finally, petitioner returned to Dr. Shariati on May 20, 2019, complaining of a "pounding headache, significant hearing loss, and significant ringing in her left ear." Pet'r's Ex. 1-2 at 2, ECF No. 67-5. Dr. Shariati reiterated his prior impression that Ms. Herms' "[s]ignificant hearing loss on

the left side” was “associated with tinnitus” and was “probably secondary to” her DTaP vaccination. *Id.* at 2-3.

Petitioner also recounts her medical experiences in two declarations, dated January 7, 2018, and July 30, 2021. *See* Pet’r’s Ex. 6, ECF No. 13-1; Aff. of Sally Herms, July 30, 2021, ECF No. 93-1. In her 2021 declaration, Ms. Herms states she received a DTaP vaccine at a pharmacy on June 18, 2017, in preparation to visit her newborn grandchild. *See* Aff. of Sally Herms ¶ 3, July 30, 2021. At that time, Ms. Herms was 58 years of age. *See* Pet’r’s Ex. 4 at 1. She attests that she did not have any conditions that would have necessitated her taking antibiotics at that time, and that she had completed a prior course of antibiotics “by April 1 or 2” Aff. of Sally Herms ¶ 2, July 30, 2021. Ms. Herms’ primary care provider, Dr. Shariati, further confirmed that she “was not on antibiotics at the time she received the DTaP vaccine.” ECF No. 93-2 at 2.

Petitioner attests that later in the evening on June 18, 2017, she “noticed soreness at the injection site” of the vaccination and that at around 1:00 am the next day, she “began to experience full body tremors, chills, aches[,] and stiffness which lasted approximately two and a half hours.” Pet’r’s Ex. 6 ¶ 3. Petitioner recalls that she then experienced “loss of hearing in [her] left ear,” the next morning, which had become “nearly total,” with the addition of tinnitus, by the following day, June 20, 2017. *Id.* ¶¶ 4-5. She also reports experiencing “approximately 3 hours of full body tremors,” as well as the sensation that she was “listening to a sea shell or wind tunnel, but soon after, the noise became [a] loud roaring [t]innitus which continues.” Aff. of Sally Herms ¶ 4, July 30, 2021.

Petitioner recounts that she visited Dr. Shariati, on June 20, 2017, due to the symptoms she had been experiencing the prior evening and early that morning. Aff. of Sally Herms ¶ 4, July 30, 2021. Ms. Herms attests that Dr. Shariati advised her that her symptoms “were a reaction to the DTaP vaccination [she] had received, *i.e.* an adverse reaction to that DTaP vaccination.” Pet’r’s Ex. 6 ¶ 6. Petitioner also explains that she visited two additional specialists who “both confirmed [her] hearing loss”—one of whom “stated that the cause of [her] condition was a reaction to the vaccine,” while the other “stated that he could not determine any cause.” *Id.* ¶ 7.

### ***C. The Expert Reports***

Petitioner advanced the reports of two experts, Dr. Arthur E. Brawer and Dr. Marcel Kinsbourne, in support of her claim, while the government advanced those of one expert, Dr. Ross Kedl.

#### *1. Petitioner’s experts*

Dr. Arthur Brawer is board-certified in internal medicine and rheumatology and operates a rheumatology private practice. Pet’r’s Ex. 55 at 1, 3, ECF No. 40-5. Dr. Brawer provided two expert reports detailing his opinion as to Ms. Herms’ condition. Pet’r’s Ex. 10, ECF No. 25; Pet’r’s Ex. 50, ECF No. 41-1. In his first report, Dr. Brawer opines that “[b]ased on a reasonable degree of medical certainty, [he] [is] in complete agreement” with petitioner’s diagnosis of

“permanent sensorineural hearing loss in her left ear as a direct consequence of the TDaP vaccination she received on June 18, 2017.” Pet’r’s Ex. 10 at 2. Dr. Brawer relies on the theory of molecular mimicry and explains that “[i]t has been known for well over 20 years that there exists a cross reactivity between routinely used vaccine materials and self-antigens in the body.” *Id.* at 3-4. He further notes that Ms. Herms began experiencing SNHL and tinnitus “within 36 to 48 hours following the TDaP vaccination on June 18 of 2017.” *Id.* at 5. Dr. Brawer also explains that Ms. Herms underwent “comprehensive evaluations” that “clearly excluded a multitude of other potential causes for Ms. Herms’ hearing loss.” *Id.* at 1-2. Moreover, she did not suffer any “systemic . . . condition[s]” before receiving the vaccination, and her SNHL and tinnitus “cannot be attributed to any other well-defined and well-known causes.” *Id.* at 5. Ultimately, Dr. Brawer concludes that “[b]ased on a reasonable degree of medical certainty, were it not for the TdaP vaccination of June 18, 2017, Ms. Herms would not now be suffering from [SNHL] and tinnitus.” *Id.*

Dr. Brawer’s first report includes citations to several publications in support of his theory. *See* Pet’r’s Ex. 10 at 2-5. One such publication, entitled “Post Vaccinal Temporary Sensorineural Hearing Loss” and authored by De Marco et al., involves both the DTaP vaccination and SNHL. Pet’r’s Ex. 11, ECF No. 25-1. The De Marco article details the case of a 33-year-old man who experienced sudden hearing loss after receiving intramuscular tetanus and diphtheria vaccines and a subcutaneous meningococcal polysaccharide vaccine. *Id.* at 1. The article opines that “[s]udden neurosensory hearing loss (SHL) is usually idiopathic but in some cases it may be associated with infections, vasculitis, tumors, some genetic diseases and cardiovascular diseases.” *Id.* at 2. Although the authors posit that “[t]he close association between the vaccinations and the onset of hearing loss suggests . . . that it may be the result of an adverse reaction to vaccines,” they conclude that “[t]he cause of [their] patient’s neurosensory hearing loss remain[ed] unknown.” *Id.* at 4. Moreover, the authors admit that “the data on possible neurological collateral effects following vaccination in the literature are few and inconsistent.” *Id.* at 3. Ultimately, the authors conclude that “the sudden onset of transient sensorineural hearing loss is more likely to have been triggered by a post-vaccinal damage rather than onset of a new pathology,” but that the cause in this particular case remained “unknown.” *Id.* at 4. The other publication Dr. Brawer cites which involves the DTaP vaccination is that of Cabrera-Maqueda et al., entitled “Optic neuritis in pregnancy after Tdap vaccination: Report of two cases.” Pet’r’s Ex. 20, ECF No. 25-10. This publication involved case reports of two pregnant women who “developed one-eye blurring vision within three weeks after Tdap vaccination.” *Id.* at 1. This case study did not discuss SNHL, and ultimately concluded that “[w]hile [the authors] have no definitive link for the relationship between vaccination and [optic neuritis][,] causation is suggested” due to a variety of factors such as temporal relationship and lack of alternative etiology. *Id.* at 2-3.

In his second report, Dr. Brawer supplements and confirms the opinion he provided in his first report. Pet’r’s Ex. 50. Overall, Dr. Brawer notes that he reviewed Dr. Kedl’s report and its summary of the relevant medical records of Ms. Herms, and that nothing refutes the fact that the vaccination “is solely the cause of her injury.” *Id.* at 1. In support of his theory of causation, Dr. Brawer cites four self-authored, peer-reviewed publications and “the persuasive medical theories” and “the sum total of the medical literature submitted as exhibits.” *Id.* at 1-2. On these

bases, Dr. Brawer reiterates his opinion that “there is a preponderance of evidence clearly demonstrating that petitioner’s vaccination was the reason for her injury.” *Id.* at 2.

Dr. Marcel Kinsbourne, petitioner’s second expert, is a former licensed and board-certified pediatric neurologist, who has served as a professor at several institutions. *See* Pet’r’s Ex. 170, ECF No. 137-1. Dr. Kinsbourne provided two reports, the first establishing his theory of causation with respect to petitioner’s diagnosis, Pet’r’s Ex. 163, ECF No. 111-1, and the second addressing respondent’s expert report. Pet’r’s Ex. 164, ECF No. 123-1. In his first report, Dr. Kinsbourne provides an overview of SNHL and the various possible causes of inner ear damage, which he notes “can be caused by viral infections, genetic mutations, trauma, toxic agents, neoplastic diseases, vascular damage, and immune mechanisms.” Pet’r’s Ex. 163 at 2. He opines that “Ms. Herms had no evidence of any of the” pathologies he described as generally resulting in SNHL, “other than the close temporal relationship to the Tdap vaccination, which suggests an immune mechanism.” *Id.* Accordingly, he concludes “it is very likely that she was a victim of an isolated autoimmune attack.” *Id.* That Ms. Herms’ symptoms were treated with an oral corticosteroid, Dr. Kinsbourne explains, “implies an assumption of autoimmunity.” *Id.* at 2-3. Dr. Kinsbourne further summarizes various case reports of other instances where vaccinations were found to have triggered SNHL, although most of the case reports did not deal with the specific vaccination Ms. Herms received. *Id.* at 2-4. The case-centered study that did deal in part with both the DTaP vaccination and SNHL, authored by Baxter et. al, ultimately concluded that there was no “statistically significant” association between this vaccine (or any, for that matter), and SNHL. *Id.* at 4 (citing Pet’r’s Ex. 163-1 at 1, 5). The authors of that study further caution against assuming “that if an event follows immunization, it is due to immunization.” Pet’r’s Ex. 163-1 at 5. Ultimately, Dr. Kinsbourne’s report concluded that “[b]ased on the circumstantial evidence presented [in his report], it is [his] opinion, to a reasonable degree of medical probability, that the Tdap vaccination triggered an immune attack on Ms. Herms’ left inner ear, resulting in her permanent left-sided hearing loss.” Pet’r’s Ex. 163 at 5.

Dr. Kinsbourne’s second report rebuts the report advanced by Dr. Kedl, respondent’s expert. Pet’r’s Ex. 164 at 1. Specifically, Dr. Kinsbourne contends that “Dr. Kedl did not confine himself to his field of specialization,” immunology, improperly opined on “the standard to which evidence in Vaccine Court proceedings should be held,” and failed to provide an alternative theory to molecular mimicry. *Id.* at 1-2. Dr. Kinsbourne also critiqued Dr. Kedl’s “reliance on epidemiological studies” because they often fail “to detect rare events, such as serious adverse effects of vaccinations,” and are “therefore a plentiful source of false negatives.” *Id.* at 3. Dr. Kinsbourne further insists the case reports he relies upon are not coincidental. *Id.* at 4. Finally, Dr. Kinsbourne argues that, as a researcher, Dr. Kedl lacks relevant experience with “the compromises that clinicians make when dealing with rare events involving individual patients.” *Id.* at 5. Dr. Kinsbourne states that “Dr. Kedl’s objections do not change [his] opinion that a Tdap vaccination caused/triggered Ms. Sally Herms’ acute unilateral hearing loss.” *Id.*

## 2. Respondent’s expert

The government’s expert was Dr. Ross Kedl, an immunology professor and researcher with a PhD in pathobiology. Resp’t’s Ex. A at 1, ECF No. 44-1. In his first report, Dr. Kedl

responds to Dr. Brawer's molecular mimicry theory, and opines that it "is an outdated theory that fails to accommodate known parameters of immunology, is fundamentally flawed in its assumptions[,] and as such is one of the most *unlikely* causes of Ms. Herms' clinical manifestations." *Id.* at 3-8. Relatedly, Dr. Kedl indicates that Dr. Brawer improperly ruled out alternative possible causes of Ms. Herms' condition, namely the antibiotics she had taken, Ciprofloxacin and Bactrim. *Id.* at 3. He notes that Ciprofloxacin has "a well-established side effect [of] ototoxicity and hearing loss," and that these antibiotics are often prescribed to treat ear infections. *Id.* Moreover, Dr. Kedl challenges the case studies cited by Dr. Brawer, because "medical case studies presuppose that a preceding event is a precipitating event. . . . In other words, the case is essentially built around coincidence." *Id.* at 3-4. Dr. Kedl also debunks the theory of molecular mimicry, asserting that "a growing majority of immunologists question[ ]" the "usefulness" of the theory "in explaining autoimmune phenomenon," and noting that "there are no human conditions in which molecular mimicry is a confirmed causal mechanism" because "antibodies or T cells cross reactive between infectious/vaccine antigens and self-antigens can never be convincingly shown to be the cause of autoimmunity and not the effect of tissue damage elicited by other means." *Id.* Dr. Kedl then goes on to set out various reasons why he considers molecular mimicry to be "highly questionable as a relevant mechanism of pathology." *Id.* at 4-8. Moreover, Dr. Kedl critiques that "Dr. Brawer has completely failed to lay out any logical course of events connecting Tdap antigens to ear-related antigens" in support of his proffered theory. *Id.* at 8. Ultimately, Dr. Kedl "conclude[s] that the preponderance of evidence does *not* support a vaccine-related cause for Ms. Herms' hearing loss." *Id.*

In his second report, Dr. Kedl responds to petitioner's supplemental materials. Resp't's Ex. C, ECF No. 121-1. With respect to Dr. Brawer's supplemental report, Dr. Kedl asserts that "reliable scientific literature" has yet to confirm an association "between vaccines and hearing loss." *Id.* at 1-2. He further notes that the articles Dr. Brawer cites "are authored by Dr. Brawer himself, and as such do not constitute robust evidence for anything other than Dr. Brawer's already offered opinions." *Id.* Dr. Kedl similarly critiques Dr. Kinsbourne's report on the basis that it merely reiterates the lack of alternative possible causes for Ms. Herms' condition "without being guided by a scientifically valid theory of causation." *Id.* at 2. Relatedly, Dr. Kedl critiques the two additional sources supporting Dr. Kinsbourne's report, noting that the first, a 1994 Institute of Medicine report, "has been superseded numerous times by more recent data" and that the cited portions "concern Guillain-Barre syndrome," not SNHL or tinnitus. *Id.* at 2-3. And the remaining case studies "are all coincidence-based" and "do nothing to support a reliable theory of causation." *Id.* As in his first report, Dr. Kedl then goes on to further his critique of molecular mimicry theory and contends that his opinions were not adequately addressed in the supplemental reports of petitioner's experts. *Id.* at 3-6. Moreover, Dr. Kedl emphasizes that, even if molecular mimicry were a "reliable theory of causation," the notion that Ms. Herms suffered an "inflammatory or immune-related medical incident" in this case is "preposterous," given what he perceived as "the complete absence of any clinical signs of a local destructive inflammatory response" and the fact that "oral steroids had absolutely no benefit to Ms. Herms' condition." *Id.* at 4. As such, Dr. Kedl ultimately opines that Ms. Herms' "condition appears nothing more than coincidental to her vaccination, and is, in [his] opinion, wholly insufficient to assign causation." *Id.*

#### ***D. The Special Master's Decision***

Ms. Herms filed her petition seeking compensation for her alleged vaccine injury on January 15, 2019. Pet., ECF No. 1. Per the parties' agreement, the Special Master resolved petitioner's case by ruling on the record rather than after an entitlement hearing. Joint Status Report of Feb. 6, 2023, ECF No. 129. Following briefing by the parties, the parties also stipulated to the following facts: petitioner received the DTaP vaccination at issue on June 18, 2017; "[t]wo days later, she experienced fever, muscle aches[,] and a feeling of being in a tunnel. She awoke and found she was deaf in her left ear. The following morning, she had tinnitus in her left ear." See Joint Submission of Mar. 24, 2023, at 1. The parties did, however, dispute the issue of causation. The Special Master issued her decision finding petitioner was not entitled to compensation on March 4, 2024. See *Entitlement Decision*, 2024 WL 1340669. Petitioner timely sought review of that decision on April 3, 2024. Pet'r's Mot.; see also Vaccine Rule 23(a) (providing that a motion for review must be filed "within 30 days after the date the [Special Master's] decision is filed").

The Special Master applied the well-established *Althen* framework. *Entitlement Decision*, 2024 WL 1340669, at \*1. The *Althen* framework requires that the petitioner establish by "preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." 418 F.3d at 1278.

The Special Master concluded that petitioner had "failed to establish by preponderant evidence that [the] DTaP vaccination she received caused her hearing loss and tinnitus." *Entitlement Decision*, 2024 WL 1340669, at \*27. Specifically, the Special Master concluded that petitioner had failed to establish by preponderant evidence any of the three *Althen* prongs. *Id.* at \*23, 26.

With respect to *Althen* prong one, the Special Master concluded petitioner "failed to provide preponderant evidence of a sound and reliable theory to explain how the DTaP vaccine can cause SNHL and tinnitus." *Entitlement Decision*, 2024 WL 1340669, at \*19. First, the Special Master concluded that Dr. Brawer provided opinions which were "not developed" and "conclusory in nature." *Id.* Specifically, the Special Master pointed to the fact that Dr. Brawer's initial expert report "does not explain SNHL, the pathogenesis of the illness, or provide evidence for his conclusions that it can be caused by vaccination." *Id.* Similarly, the Special Master noted that Dr. Brawer "does not explain how molecular mimicry explains hearing loss due to the DTaP vaccination." *Id.* In the same vein, the Special Master commented that although Dr. Brawer "provide[d] another long list of other mechanisms for autoimmune conditions," he did not "explain why this list is relevant or describe how any of the mechanisms can cause hearing loss after vaccination." *Id.*

The Special Master also found Dr. Kinsbourne's report unpersuasive, noting that the literature he cites considers viral infection but not vaccination, "as a trigger for immune-mediated hearing loss." *Entitlement Decision*, 2024 WL 1340669, at \*19-20. Moreover, the Special Master indicated that, although Dr. Kinsbourne explained that vaccines are meant to "elicit an immune reaction against the relevant antigen, like the immune reaction to the

corresponding infection,” *id.* at \*20 (quoting Pet’r’s Ex. 163 at 2), he did not “discuss the corresponding infection here” and thus failed to fully connect the causal theory. *Id.*

Conversely, the Special Master was persuaded by Dr. Kedl’s opinion that molecular mimicry was a “highly questionable” theory, and that “[b]ased on the current understanding of immune-mediated hearing loss as described in the literature filed herein, [p]etitioner’s proposed mechanisms fall short of sound and reliable, are conclusory in nature, and vague.” *Entitlement Decision*, 2024 WL 1340669, at \*20 (citing Resp’t’s Ex. A at 4). Although the Special Master did not require that petitioner identify any “specific antigenic trigger for an immune-mediated pathology,” she did conclude that “generally opining that molecular mimicry is a causal theory, without more, is insufficient,” and petitioner’s citations to case reports were largely irrelevant in establishing her claimed theory. *Id.* at \*20-21.

With respect to the second *Althen* prong, the Special Master concluded Ms. Herms failed to establish a logical connection between her vaccine and her ensuing condition. *Entitlement Decision*, 2024 WL 1340669, at \*23. As a threshold matter, although the Special Master noted that because Ms. Herms “failed to prove *Althen* prong one, it follows that she cannot prove *Althen* prong two,” the Special Master nevertheless assessed prong two. *Id.* The Special Master identified that Ms. Herms “did not have any significant response to the steroids” prescribed to her, even though “[t]he medical literature cited by the parties establishes that SNHL thought to be autoimmune is treated with corticosteroids.” *Id.* Moreover, the Special Master explained that Ms. Herms’ treating physicians seemed to provide either unreasoned explanations for their opinion regarding the cause of Ms. Herms’ condition, or explanations based on temporal association or the elimination of alternative causes. *Id.* at \*24-26. As such, the Special Master concluded that Ms. Herms did not establish “a logical sequence of cause and effect” connecting the vaccine to her condition. *Id.* at \*26.

Finally, the Special Master concluded that the temporal proximity between when Ms. Herms was vaccinated and when her symptoms began alone is insufficient to establish her burden under *Althen* prong three. *Entitlement Decision*, 2024 WL 1340669, at \*26. Specifically, the Special Master reasoned that Ms. Herms’ experts fail to explain how the onset of her symptoms falls within “a medically acceptable timeframe pursuant to the mechanisms discussed,” nor do they “provide any explanation of how [the timing of her symptom onset] is consistent with autoimmunity induced hearing loss.” *Id.* Accordingly, because Ms. Herms’ arguments regarding temporal proximity were “not developed within the context of a supportive theory of causation,” the Special Master concluded the third *Althen* prong had not been satisfied. *Id.* at \*26-27.

### STANDARDS FOR REVIEW

The Vaccine Act gives this court jurisdiction to review a Special Master’s decision regarding whether a petitioner who alleges they suffered a vaccine-related injury is entitled to compensation. 42 U.S.C. § 300aa-12(e)(1)-(2). Pursuant to the Vaccine Act, the court may: (1) “uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision”; (2) “set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law

and issue its own findings of fact and conclusions of law”; or (3) “remand the petition to the special master for further action in accordance with the court's direction.” 42 U.S.C. § 300aa-12(e)(2).

Ultimately, the court’s review of a Special Master’s decision is “uniquely deferential” and “on review, [this court] is not to second guess the Special Masters[’] fact-intensive conclusions.” *Hodges v. Sec’y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). Put differently, this court does not “reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses” as “these are all matters within the purview of the fact finder.” *Paluck ex rel. Paluck v. Sec’y of Health & Hum. Servs.*, 104 Fed. Cl. 457, 467 (2012) (quoting *Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011)). Rather, the court will uphold the Special Master’s determination as long as the findings are “based on evidence in the record that [is] not wholly implausible.” *Id.* (quoting *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1363 (Fed. Cir. 2000)). Moreover, the court’s deference in reviewing the decision of a Special Master “is especially apt in a case in which the medical evidence of causation is in dispute.” *Id.* (quoting *Hodges v. Sec’y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)). Ultimately, although the court’s review of a Special Master’s decision “is not a rubber stamp,” *Porter*, 663 F.3d at 1256 (O’Malley, J., concurring in part and dissenting in part), it is indeed a highly deferential one, as “reversible error will be extremely difficult to demonstrate” as long as “the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.” *Hines ex rel. Sevier v. Sec’y of Dep’t of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

## ANALYSIS

At issue is the Special Master’s finding that petitioner failed to establish causation. In *Althen*, the United States Court of Appeals for the Federal Circuit held that a petitioner seeking to prove causation in an off-table vaccine case must establish by a preponderance of the 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.

418 F.3d at 1278.

The Federal Circuit has further articulated, with respect to this causation framework, that “[a] persuasive medical theory is demonstrated by proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,] the logical sequence being supported by reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony.” *Althen*, 418 F.3d at 1278 (internal citation and quotation marks omitted). With respect to the petitioner’s burden of proof, the Federal Circuit has clarified that preponderant evidence is analogous to a showing of “more probable than not causation.” *Id.* at 1279 (internal citation and quotation marks omitted). The preponderant-evidence standard,

however, does not require a showing of “scientific certainty,” *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991), as establishing “causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is logical and legally probable, not medically or scientifically certain.” *Knudsen ex rel. Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994) (internal quotation marks omitted).

To establish causation by a preponderance of the evidence, the petitioner’s theory must be supported by either medical records or an opinion advanced by a medical doctor. *See* 42 U.S.C. § 300aa-13(a)(1). In assessing a theory of causation based on an expert witness’ medical opinion, “the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010). As the Federal Circuit has stated, “one factor in assessing the reliability of expert testimony is whether the theory espoused enjoys general acceptance within a relevant scientific community.” *Andreu ex rel. Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-97 (1993)).

In her motion for review, Ms. Herms lodges two main objections to the Special Master’s entitlement decision. Pet’r’s Mot. at 1-2. First, petitioner asserts “it is error to ignore the opinions of treating physicians that the DTaP was causative” because her injury is “consistent with an autoimmune attack,” “occur[red] within two days of a DTaP vaccination, a vaccine known to cause autoimmune injur[i]es,” and “no explanation for that injury exists except for the DTaP vaccination.” *Id.* Put differently, this would amount to “finding that the injury is idiopathic” in violation of 42 U.S.C. § 300aa-13(a)(2)(A). *Id.*<sup>4</sup> Second, petitioner asserts it is

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<sup>4</sup> This assertion takes the cited statutory sub-section out of context. Indeed, this sub-section refers to the fact that compensation shall be awarded if the Special Master determines “(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and where “the term ‘factors unrelated to the administration of the vaccine’” “does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.” 42 U.S.C. § 300aa-13(a)(1)-(2). This means that in instances where the petitioner successfully establishes a prima facie case, “the burden shifts to respondent to demonstrate by a preponderance of the evidence that a ‘factor unrelated’ to the vaccine ‘was the sole substantial factor in bringing about the injury.’” *Hammitt ex rel. Hammitt v. Sec’y of Health & Hum. Servs.*, 98 Fed. Cl. 719, 726 (2011), *aff’d sub nom. Stone v. Sec’y of Health & Hum. Servs.*, 676 F.3d 1373 (Fed. Cir. 2012) (quoting *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008)) (citing 42 U.S.C. § 300aa-13(a)). Here, the Special Master never found that petitioner had established a prima facie case, and thus such burden-shifting is inapposite.

And regardless, the Special Master made no such finding regarding idiopathy. While the Special Master did reference medical literature concluding that “the causal mechanism of

error to ignore an opinion offered by a treating physician who “is one of the top experts in his/her field,” where the opinion is “based upon his/her review of the case including all relevant tests, and after a full examination of the [p]etitioner,” and “no contrary evidence exists.” *Id.* at 2, 10-11. In support of her objections, Ms. Herms largely recapitulates the facts she presented in support of her original claim, including her symptoms, physician visits and corresponding impressions, and expert opinions and corresponding publications. *See generally id.* at 2-11 (detailing “[f]acts [a]pplicable to both [o]bjections”).

Overall, Ms. Herms’ motion for review revolves around the notion that the Special Master should have afforded more weight to the opinions of her treating physicians who, as petitioner pronounces, “have agreed that the vaccine caused this loss.” Pet’r’s Mot. at 7-8. Specifically, Ms. Herms avers that she has, contrary to the Special Master’s conclusion, established *Althen* prong one, as she “has provided a sound and reliable medical or scientific explanation that pertains specifically to this case.” *Id.* at 8. Specifically, Ms. Herms contends that she “can establish entitlement to compensation based upon the opinions of her treating physicians,” *id.* at 9 (citing 42 U.S.C. § 300aa-13(a)(1)),<sup>5</sup> as summarized in her motion for review, and “[t]he fact that these physicians’ diagnoses relied largely on the temporal proximity of Ms. Herm[s’] injuries to the administration of the vaccine is not disqualifying.” *Id.* (citing *Capizzano v. Sec’y of Dep’t of Health & Hum. Servs.*, No. 00-759V, 2004 WL 1399178, at \*25 (Fed. Cl. June 8, 2004)). To this effect, petitioner contends that her experts’ medical opinions are “quite probative” because the “close temporal proximity, combined with the finding that a vaccine can cause an autoimmune reaction which is a vaccine injury, demonstrates that it is logical to conclude that the vaccine was the cause of Ms. Herms[’] injury.” *Id.* Relatedly, petitioner suggests that the Special Master improperly elevated her burden of proof “beyond possibility,” by refusing to accept the conclusions of her treating physicians as evidence of causation and requiring her to identify a “perfect” causal theory in support of her condition. *See* Hr’g Tr. 20:10 to 21:9.

Ms. Herms also challenges the Special Master’s decisions to disregard “literature related to autoimmune studies that did not mention DTaP vaccine or similar events” as well as petitioner’s causal theory for “a lack of specific references to Ms. Herm[s’] situation.” Pet’r’s Mot. at 11. In support of her objection, Ms. Herms re-emphasizes that “[t]he record provides no explanation other than the presence of DTaP [of why] this damage occurred,” and that

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immune-mediated SNHL is unknown,” *Entitlement Decision*, 2024 WL 1340669, at \*20, this was by no means foundational to the Special Master’s causation analysis. Rather, the Special Master’s decision went on to reasonably critique the fact that petitioner failed to articulate a plausible causal theory or adequately support her claim that the DTaP vaccination caused her injuries. *Id.* at \*20-21; *see also* Hr’g Tr. 21:20 to 22:23. That the Special Master concluded petitioner did not sufficiently establish causation does not mean the Special Master ultimately determined petitioner’s condition was idiopathic.

<sup>5</sup> Petitioner cites 42 U.S.C. § 2000aa-13(a)(1), but as this provision is unrelated to the vaccine case at hand, the court reads this as a typographical error with respect to the sub-section cited.

“[i]gnoring the opinions of treating physicians” to this effect, and instead classifying Ms. Herms’ injuries as idiopathic, was erroneous. *Id.*<sup>6</sup>

Finally, petitioner disputes the conclusion that the steroidal taper of prednisone prescribed on June 29, 2017, was ineffective. *See* Hr’g Tr. 5:13 to 6:24, 10:1-17, 25:19 to 26:24; *see also* Pet’r’s Ex. 1 at 4. Specifically, petitioner indicated that both the experts and the Special Master seemed to ignore the fact that, weeks after the steroidal taper was prescribed, Ms. Herms experienced “good improvement of her speech discrimination.” Pet’r’s Ex. 1 at 20, as well as “improvement [of] 3 [kilohertz] [to] 8 [kilohertz] compared to” her hearing test on June 29, 2017. *Id.* at 16; *see also* Pet’r’s Ex. 163 at 1; Resp’t’s Ex. C at 4. Petitioner’s argument to this effect seems to be premised on the assumption that improvement following a steroidal taper treatment indicates an autoimmune reaction, and that the Special Master failed to identify that such improvement took place. *See, e.g., Entitlement Decision*, 2024 WL 1340669, at \*14 (noting that “Dr. Kinsbourne acknowledged ‘[o]ral steroids conveyed no benefit’ to [p]etitioner here”); *see also* Pet’r’s Ex. 163 at 5 (Dr. Kinsbourne’s explanation that “treatment with steroids would be appropriate if the mechanism of injury were autoimmune.”).

In response, the government contends that, contrary to petitioner’s assertions, “the Special Master applied the correct legal standards, considered all the relevant evidence, and articulated a rational basis for her [d]ecision.” Resp’t’s Resp. at 6. Accordingly, the Special Master “properly concluded that vaccine causation had not been proven, and there are no grounds upon which to disturb her [d]ecision.” *Id.* Ultimately, respondent asserts that “[p]etitioner’s arguments amount to a request that this [c]ourt reweigh the evidence and substitute its own judgment in order to reach a different conclusion than the Special Master reached,” but that petitioner makes this request without “showing that the Special Master erred.” *Id.* at 5-6.

Regarding *Althen* prong one, respondent asserts that “the Special Master applied the correct legal standard” regarding whether petitioner established a sound and reliable medical theory, and that her factual findings “were based on the evidence as a whole, were rationally explained, and were supported by the record.” Resp’t’s Resp. at 6-9. Specifically, respondent avers the Special Master correctly identified that the theory petitioner advanced—and the corresponding expert opinions provided in support—were overly general and failed to explain the particular pathogenesis of SNHL or how molecular mimicry could have triggered this condition in petitioner’s case. *Id.* at 7-9. Ultimately, respondent argues that the Special Master appropriately assessed the medical theory advanced by petitioner under *Althen* prong one, and rendered rational and supported factual findings to that effect. *Id.* at 9.

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<sup>6</sup> Ms. Herms, at several points in her motion, asserts that the Special Master erred by “ignoring the opinions of [her] treating physicians.” Pet’r’s Mot. at 2, 11. The court finds that, far from ignoring such opinions, the Special Master undertook a “meticulous review,” *Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1323 (Fed. Cir. 2010), of petitioner’s medical records, expert testimony, and record as a whole, in rendering her ultimate assessments.

Second, respondent asserts that the Special Master properly analyzed whether petitioner established a logical sequence of cause and effect connecting her claimed injury to the vaccine under *Althen* prong two, even though she “was under no obligation” to do so. Resp’t’s Resp. at 9-12. According to respondent, that petitioner disagrees with the Special Master’s findings is insufficient to disturb them under this court’s deferential review. *Id.* at 9-10. Relatedly, respondent contends petitioner’s argument that the Special Master “minimized the opinions of her treating physicians and erroneously elevated her burden of proof” represents “another inappropriate attempt to have this [c]ourt reweigh the evidence” on review. *Id.* at 10. Ultimately, respondent emphasizes that the Special Master’s assessment of the record was entirely reasonable, and the court should deny petitioner’s request to “reweigh evidence or substitute its judgment for that of the Special Master.” *Id.* at 10-12.

The court finds that the Special Master’s decision has a rational basis in the record and properly applied the relevant law. First, the Special Master properly concluded that, without more, a medical theory predicated predominantly on temporal proximity is insufficient to establish causation under *Althen* prong one. As this court has stated, “a temporal relationship alone will not demonstrate the requisite causal link.” *Veryzer v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 344, 356 (2011), *aff’d sub nom. Veryzer v. United States*, 475 F. App’x 765 (Fed. Cir. 2012). Instead, “the proximate temporal relationship prong” also “requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *de Bazan*, 539 F.3d at 1352. In this case, petitioner relies on the temporal proximity of her symptom onset without proffering a sufficiently particularized causal theory that is sound and reliable considering the specific etiology of her condition. As such, although it is the case that Ms. Herms’ treating physicians highlighted the close temporal proximity between her vaccination and the onset of her symptoms, it was reasonable for the Special Master to conclude that such proximity was insufficient to infer causation here, when petitioner did not advance an appropriately sound and reliable medical theory connecting her condition to the vaccine in this particular case. Accordingly, the Special Master gave due consideration to the timing of Ms. Herms’ injury in relation to her vaccination.

The Special Master also gave adequate consideration to the publications Ms. Herms cites for the proposition that the DTaP vaccine is “known to cause autoimmune injur[i]es.” Pet’r’s Mot. at 1. The Special Master noted many of the articles petitioner put forth to support her claim involved vaccinations other than the DTaP vaccination. *See, e.g.*, Pet’r’s Exs. 14-17; *see also Entitlement Decision*, 2024 WL 1340669, at \*19. Those that did involve the DTaP vaccination afforded at most weak support for petitioner’s claim. For instance, the De Marco publication concluded that the cause of the patient’s sudden hearing loss was, ultimately, “unknown.” Pet’r’s Ex. 11 at 2-3. Moreover, the Cabrera-Maqueda study covered the cases of two pregnant women who developed a different condition—optic neuritis—following a DTaP vaccination, and the authors concluded that there was “no definitive link” between the condition and the vaccination. Pet’r’s Ex. 20 at 2-3. And finally, the Baxter et al. case-centered study of the possible association between vaccination and sudden SNHL found no “statistically significant” association or increased risk between the DTaP vaccine and sudden SNHL. Indeed, it even cautioned against the “fallacy” “that if an event follows immunization, it is due to immunization,” because “some adverse events are bound to happen shortly after immunization,

due to *random chance alone*.” Pet’r’s Ex. 163-1 at 1, 5 (emphasis added); *see also* Pet’r’s Ex. 163-5 at 12 (identifying that although “[c]ases of SNHL have been reported in the literature after receipt of certain immunizations . . . a causal association has not been established”). As such, although Ms. Herms points to a multitude of publications involving vaccinations and resulting injuries generally, these articles mostly deal with different vaccinations, different conditions, or both. Those that do deal with the vaccination or conditions at issue in this case are inconclusive at best regarding causation. Therefore, the Special Master gave proper consideration to petitioner’s cited publications.

Moreover, the Special Master reasonably concluded that petitioner failed to demonstrate a sound and reliable medical theory in this case. “[T]he mere mention of [molecular mimicry] does not constitute satisfaction of the preponderant evidentiary standard,” as petitioner must actually demonstrate “that the mechanism likely does link the vaccine in question to the relevant injury.” *Loyd v. Sec’y of Health & Hum. Servs.*, 2021 WL 2708941, at \*31 (Fed. Cl. Spec. Mstr. May 20, 2021), *aff’d*, 2023 WL 1878572 (Fed. Cir. Feb. 10, 2023). Here, the Special Master found that petitioner’s contentions and expert reports described molecular mimicry at only a high level and failed to apply the theory with particularity to connect petitioner’s hearing loss to the DTaP vaccination specifically. *See Entitlement Decision*, 2024 WL 1340669, at \*19-20; *see also* Pet’r’s Ex. 10 at 3 (opining generally that “[i]t has been known for well over 20 years that there exists a cross reactivity between routinely used vaccine materials and self-antigens in the body”); Pet’r’s Ex. 164 at 2 (asserting broadly that “[l]ists of alternative mechanisms of autoimmunity continue to feature molecular mimicry”). The Special Master’s conclusion that petitioner’s medical theory was not sound and reliable is also supported by contrary evidence in the record. *See, e.g.*, Resp’t’s Ex. A at 3 (opining that “molecular mimicry is an outdated theory that fails to accommodate known parameters of immunology [and] is fundamentally flawed in its assumptions”); Resp’t’s Ex. C at 6 (identifying that “[t]he scientific community has rejected molecular mimicry as a basis for a reliable theory of vaccine causation”). Ultimately, the court concludes the Special Master’s analysis of petitioner’s molecular mimicry theory is adequately supported by the record.

The Special Master also properly concluded that there was insufficient circumstantial evidence to support petitioner’s medical theory. Although extrapolation from indirect or circumstantial evidence may be warranted in certain cases, *see K.O. v. Sec’y of Health & Hum. Servs.*, No. 13-472V, 2016 WL 7634491, at \*12 (Fed. Cl. Spec. Mstr. July 7, 2016), the Special Master rationally concluded that petitioner did not put forth sufficiently “transparent” or “persuasive” reasons to draw such extrapolations in this case. Indeed, petitioner did nothing to explain how such circumstantial evidence “could be extrapolated to the vaccines at issue here.” *Entitlement Decision*, 2024 WL 1340669, at \*21; *see also* Resp’t’s Resp. at 7-8.

The court also rejects Ms. Herms’ assertion that the Special Master erred by not finding causation considering alternative possible causes of Ms. Herms’ symptoms had been eliminated. Pet’r’s Mot. at 1-2. While Dr. Brawer opined that Ms. Herms’ condition was not attributable to another known cause, *see, e.g.*, Pet’r’s Ex. 10 at 5, eliminating alternative causes is insufficient on its own to establish causation. *Althen*, 418 F.3d at 1278; *see also Welch v. Sec’y of Health & Hum. Servs.*, No. 18-494V, 2019 WL 3494360, at \*13 (Fed. Cl. July 2, 2019) (“[M]erely eliminating possible alternative causes does not establish causation.”). As such, the Special

Master did not err in declining to find causation based on the elimination of alternate causes of Ms. Herms' condition.

In the circumstances, the court finds it was rational for the Special Master to find that petitioner failed to establish a sound and reliable medical theory under *Althen* prong one.

Although the Special Master was not obligated to do so, she proceeded to assess whether petitioner had satisfied *Althen* prong two. *Entitlement Decision*, 2024 WL 1340669, at \*23-26. Petitioner's argument under prong two focuses again on the Special Master's consideration of petitioner's treating physicians' diagnoses. Petitioner also contends the Special Master ignored evidence that her condition improved following treatment. Pet'r's Mot. at 2.<sup>7</sup>

While the opinions of treating physicians are generally given preferential weight, *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), such opinions are not "sacrosanct," *Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009). They are still assessed for their underlying reasonableness. *Welch v. Sec'y of Health & Hum. Servs.*, No. 18-494V, 2019 WL 3494360, at \*8 (Fed. Cl. Spec. Mstr. July 2, 2019). Here, the Special Master concluded that the treating physicians' conclusions were not sufficiently persuasive in light of the record as a whole, and in the absence of an underlying sound and reliable medical theory explaining petitioner's condition. *Entitlement Decision*, 2024 WL 1340669, at \*23-25. The Special Master's assessment is rational and this court may not re-engage in that assessment or reweigh the strength of those opinions on review.

The Special Master found evidence from petitioner's treating physicians unpersuasive because the treating physicians' opinions were relatively generic or seemed to be based primarily on temporal proximity. Although petitioner's treating physicians do attribute her condition to her vaccination, they do so in a conclusory manner. For instance, Dr. Shariati, Ms. Herms' primary care physician, posited that Ms. Herms' symptoms were "[p]robable side effects" and that her condition "was contributed from" the vaccine, but did not identify particular features of petitioner's condition supporting this statement. *See* Pet Ex. 1 at 1; Pet'r's Ex. 1-2 at 2; *see also* Pet'r's Ex. 1-2 at 6 (noting petitioner's condition was "presumably secondary" to her vaccination). The Special Master's decision to afford little weight to "statements of mere suspicion"—which "fall short of an opinion supporting a vaccine-causation of petitioner's condition"—was reasonable and within the discretion afforded to special masters in weighing the

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<sup>7</sup> Ms. Herms provides an excerpt of the credentials of one of her treating physicians, Dr. Selesnick, as well as a citation to a portion of *Richardson v. Perales*, 402 U.S. 389, 402 (1971), in which the Supreme Court discussed the evidentiary nature of a licensed physician's written report. Pet'r's Mot. at 6-7. As the Federal Circuit has previously stated, however, this court's deferential standard of review does not permit the court to "examine the probative value of the evidence or the credibility of the witnesses." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). And given that the citation to Dr. Selesnick's credentials would, if anything, go to his credibility, it is not pertinent to the court's analysis at this time. Likewise, petitioner's citation to the Supreme Court's decision in *Richardson*, 402 U.S. at 402, is inapposite as it deals primarily with admissibility considerations surrounding a physician's report that are not at issue here.

evidence in the record before them. *See Robertson v. Sec’y of Health & Hum. Servs.*, No. 18-554V, 2022 WL 17484980, at \*17 (Fed. Cl. Spec. Mstr. Dec. 7, 2022); *see also Whitecotton v. Sec’y of Health & Hum. Servs.*, 81 F.3d 1099, 1108 (Fed. Cir. 1996) (“Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence.”).

Moreover, the explanations provided by petitioner’s treating physicians seem to primarily revolve around the temporal proximity between vaccination and symptom onset, without offering much by way of causal explanation. *See, e.g.*, Pet’r’s Ex. 1 at 27 (opining “it is likely that the vaccine is at least in some way responsible” for Ms. Herms’ condition “[d]ue to the close time proximity” between vaccination and symptom onset). Such statements, without more, are insufficient to establish causation. *Veryzer*, 100 Fed. Cl. at 356. As such, it was reasonable for the Special Master to determine that these statements by petitioner’s treating physicians failed to establish causation.

Further, the court disagrees with petitioner’s suggestion that the Special Master erroneously elevated her burden of proof “beyond possibility” by requiring her to establish a “perfect” medical theory in support of causation. Hr’g Tr. 20:10 to 21:9. Indeed, the Special Master herself stated that “[p]etitioner need not make a specific type of evidentiary showing or require identification of a specific antigenic trigger for an immune-mediated pathology” because such proof “would require scientific certainty, which is a bar too high” “[g]iven the state of current scientific knowledge.” *Entitlement Decision*, 2024 WL 1340669, at \*20. As such, the Special Master did not require a scientifically certain, or “perfect” causal theory in support of petitioner’s condition. Rather, as evidenced by the foregoing, the Special Master rationally concluded that petitioner failed to provide preponderant evidence in support of her causal theory. *Id.* at \*22-23.

Finally, petitioner has suggested—for the first time during oral argument in this court’s motion hearing—that the Special Master overlooked the improvement in petitioner’s audiological test results between her first hearing test on June 29, 2017, and her second on July 18, 2018. *See* Hr’g Tr. 5:13 to 6:24, 10:1-17, 25:19 to 26:24. Specifically, in analyzing the second *Althen* prong, the Special Master articulated that “[t]he medical literature cited by the parties establishes that SNHL thought to be autoimmune is treated with corticosteroids” and “the experts agree that [p]etitioner did not have any significant response to the steroids” she was prescribed. *Entitlement Decision*, 2024 WL 1340669, at \*23 (citing Pet’r’s Ex. 163 at 1; Pet’r’s Ex. 10 at 1; Resp’t’s Ex. C at 4). Contrary to petitioner’s argument, however, the Special Master specifically identified that “[p]etitioner’s hearing test, performed July 18, 2017,” following petitioner’s steroidal taper, “showed ‘good improvement of her speech discrimination[.]’” *Id.* at \*4 (emphasis added).<sup>8</sup> In her assessment of *Althen* prong two, the Special Master concluded not that Ms. Herms had no response at all to the steroids, but that she did not have “any significant

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<sup>8</sup> Moreover, the Federal Circuit has indicated that there is a presumption that a Special Master has considered all evidence in the record, unless there is an indication to the contrary. *Hazlehurst v. Sec’y of Health & Hum. Servs.*, 604 F.3d 1343, 1352 (Fed. Cir. 2010). Here, far from being selective in her review, the Special Master was quite thorough in assessing the record before her, as outlined in her thirty-five-page decision.

response.” *Id.* at \*23 (emphasis added) (quoting Pet’r’s Ex. 1 at 18-20). This indicates the Special Master was aware of some improvement to Ms. Herms’ condition.

Moreover, notwithstanding the ambiguity surrounding the possible improvement to petitioner’s condition following steroids, the Special Master also included a citation to the record which explains that “a treatment response or its failure is not in itself diagnostic of SNHL” and therefore that “treatment or treatment response” had not been utilized “towards the fulfillment of the SNHL case definition.” *See* Pet’r’s Ex. 163-5 at 12; *see also Entitlement Decision*, 2024 WL 1340669, at \*23. So, even if the Special Master overlooked evidence that Ms. Herms’ condition did improve following her steroidal treatment, she still could have rationally concluded, based on the record, that causation had not been established. As such, the court finds no error in the Special Master’s consideration of evidence that petitioner’s steroidal treatment improved some of her symptoms.

Relatedly, the court identifies a possible inconsistency in the factual record regarding whether Ms. Herms suffered a “local destructive inflammatory response” that could indicate an “inflammatory or immune-related medical incident.” Resp’t’s Ex. C at 4. According to Dr. Kedl, Ms. Herms’ symptoms arose too quickly after vaccination to be attributable to an immune response. *Id.* at 4. Dr. Kedl found the immune-response mechanism even less plausible based on “the complete absence of any clinical signs of a local destructive inflammatory response.” *Id.* But, Ms. Herms’ medical records indicate her III through XII cranial nerves “were grossly intact with the *exception* of the left VIII[] cranial nerve.” Pet’r’s Ex. 1 at 27 (emphasis added). In his first expert report, Dr. Kedl confirmed that he reviewed petitioner’s medical records. *See* Resp’t’s Ex. A at 2. It is possible that Dr. Kedl identified the aberration to Ms. Herms’ left, eighth cranial nerve, and simply concluded it did not amount to a “clinical sign[] of a local destructive inflammatory response.” Resp’t’s Ex. C at 4. Alternatively, Dr. Kedl may have overlooked this fact. Regardless, the Special Master did not. She expressly identified that petitioner’s medical records indicated that her left, eighth cranial nerve had been damaged. *Entitlement Decision*, 2024 WL 1340669, at \*5 (citing Pet’r’s Ex. 1 at 27). With this fact in mind, the Special Master found Dr. Kedl’s reasoning persuasive. *Id.* at \*16 (citing Resp’t’s Ex. C at 3-4). This was reasonable because Dr. Kedl explained other features of Ms. Herms’ condition that undermined the immune response theory, namely that she suffered “complete hearing loss, in only one ear.” Resp’t’s Ex. C at 4. Accordingly, even if respondent’s expert and the Special Master had both identified a local destructive inflammatory response in petitioner’s left ear, the Special Master nonetheless could have reasonably ruled out petitioner’s medical theory based on all the evidence taken together.

As such, neither evidence that the steroidal taper administered to Ms. Herms caused some improvement nor evidence of a local destructive inflammatory response provides sufficient grounds for this court to disturb the Special Master’s rational decision.

## CONCLUSION

Based on the foregoing, petitioner’s motion for review of the Special Master’s March 4, 2024, entitlement ruling is **DENIED** and the Special Master’s entitlement ruling is **AFFIRMED**. The Clerk is **DIRECTED** to enter judgment in accordance with this opinion.

It is so **ORDERED**.

s/ Charles F. Lettow

Charles F. Lettow

Senior Judge