

In the United States Court of Federal Claims

No. 21-2343V

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SIMON LEGAULT,
 Petitioner,
 v.
 SECRETARY OF HEALTH AND
 HUMAN SERVICES,
 Respondent.

* * * * *

Courtney C. Jorgenson, Siri & Glimstad, LLP, Phoenix, AZ, for petitioner.

Mark K. Hellie, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent. With him were **Colleen C. Hartley**, Assistant Director of the Torts Branch, Civil Division, United States Department of Justice, Washington, DC; **Heather L. Pearlman**, Deputy Director of the Torts Branch, Civil Division, United States Department of Justice, Washington, DC; **C. Salvatore D'Alessio**, Director of the Torts Branch, Civil Division, United States Department of Justice, Washington, DC; and **Yaakov M. Roth**, Acting Assistant Attorney General, United States Department of Justice, Washington, DC.

OPINION

On December 29, 2021, Simon Legault filed his National Vaccine Injury Compensation Program (Vaccine Program) petition for compensation under the National Vaccine Injury Compensation Act of 1986, 42 U.S.C. § 300aa-10 *et seq.* (2018) (the Vaccine Act), for an alleged off-Table vaccine injury resulting from an influenza (flu) vaccine that he received on November 19, 2019. Mr. Legault alleged that the stress response theory explained his vaccine-induced sudden sensorineural hearing loss

¹ This Opinion was issued under seal on June 27, 2025. The parties did not propose any redactions to the June 27, 2025 Opinion, and the court, therefore, issues the Opinion without redactions for public distribution.

(SSNHL)² and tinnitus. On January 2, 2025, Chief Special Master Brian H. Corcoran issued a decision finding that “[p]reponderant evidence does not support petitioner’s causation theory. Accordingly, he is not entitled to compensation.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 27 (Fed. Cl. Spec. Mstr. Jan. 2, 2025) (alteration added). Following receipt of the Chief Special Master’s decision, petitioner filed a Motion for Review of the Chief Special Master’s decision in the United States Court of Federal Claims. Thereafter, the Motion for Review was fully briefed and oral argument was held. After careful review of the Chief Special Master’s decision, the parties’ briefs, and the record before the court, the court’s issues the following Opinion.

FINDINGS OF FACT

Petitioner Simon Legault was born on August 1, 1982. Petitioner alleged that, before receiving the flu vaccine in 2019, he was healthy, he went running a few times a week and did weight training on a consistent basis. Petitioner’s medical records reflect that he did have a history of anxiety and depression, but the record also reflects that he was not being treated for either anxiety or depression at the time of his vaccination. Petitioner alleged he worked long hours at an aerospace company as a consultant engineer before he was laid off in September of 2019. Petitioner then began to look for new work elsewhere. In his petition before the Office of the Special Masters, petitioner alleged that the time off was welcome after having consistently worked “so many hours for more than 3 years.”

On November 19, 2019, petitioner received a flu vaccine at a CVS pharmacy in Georgia with the vaccine administered in his left arm. Petitioner alleged that approximately three to four days after receiving the flu vaccine, he began to experience intense ringing in both ears, accompanied by an increasing pain within the inner ear. Petitioner alleged that the pain, although present in both ears, was worse in the left ear. Petitioner further alleged that over the following two to three weeks, the ringing and pain worsened to the point where it hurt to speak or be around any noise. Petitioner also alleged that he began to experience dizziness and had difficulty concentrating while sitting at a computer. The record before the Chief Special Master reflects that about one month after receiving the flu vaccine, on December 17, 2019, petitioner saw Dr. Tyler DeBlieux, an ear, nose, and throat (ENT) specialist. The petitioner’s medical record for the December 17, 2019 visit indicated the following:

Chief Complaint: bilateral tinnitus

History of Present Illness: LEGAULT, SIMON is a 37 years [sic] male who presents with and plans [sic] bilateral tinnitus. He states that approximately 1 month ago he developed myalgias and general malaise but no significant sinonasal symptoms. He associated this with a viral infection after which she [sic] developed tinnitus in both ears. He notes that he might have had slight dizziness at that time, but it was very mild. Since then he has traveled

² Sudden sensorineural hearing loss, or SSNHL, is used to describe hearing loss when it is unclear whether the cause is sensory or neural in nature.

to Mexico and back without significant issue, but relates that he still has a feeling of general malaise and bilateral tinnitus. Tinnitus is constant, nonpulsatile. It is worse in quiet areas. He [sic] often keeps him from sleeping at night. He endorses bilateral aural fullness, with the left being slightly worse on [sic] the right. He however notes that his hearing appears intact and functional. Denies a history of headaches and migraines. Denies any significant vertigo. Denies a history of otitis or otalgia. Denies history of otologic surgery.

Does have a history of anxiety and depression and has been previously treated, but currently not treated. He recently lost his job at Gulfstream, but does not fill [sic] stressed about this. Does relate having poor sleep and insomnia.

(capitalization and emphasis in original; alterations added). During the December 17, 2019 visit, Dr. DeBlieux conducted a hearing test and diagnosed petitioner with “bilateral tinnitus” and “left mild sensorineural hearing loss– high frequency” on petitioner’s left side. Dr. DeBlieux explained to petitioner that hearing loss also can be associated with anxiety, stress, depression, and insomnia. Dr. DeBlieux discussed with petitioner the “possibility of this being a viral induced tinnitus.” Since there were no significant balance symptoms present and because the tinnitus was bilateral, Dr. DeBlieux and petitioner elected to defer on conducting magnetic resonance imaging (MRI) at that time. Dr. DeBlieux prescribed petitioner a course of steroids and antivirals in the hope that it might resolve the issues, but Dr. DeBlieux was doubtful there would be a “significant benefit” from the medication one month after the start of petitioner’s symptoms. Petitioner indicated he found some relief from the steroids, however, petitioner alleged that the symptoms returned once the course of steroids was finished. By late December 2019, petitioner alleged that he was experiencing “extreme sensitivity to noise and constant headaches” and that the headaches felt “as though my brain was literally vibrating with the worst pain coming from the left side of my head near my ear.” During this time, petitioner claimed he was looking for work, but ultimately gave up looking after Christmas in 2019, alleging that he felt too unwell to even consider employment.

On January 10, 2020,³ petitioner had another visit with Dr. DeBlieux. At the January 10, 2020 visit, the chief complaint listed in the medical record was “[b]ilateral aural pressure, intermittent.” (alteration added). The January 10, 2020 medical record stated the following:

LEGAULT, SIMON is a 37 years [sic] male who presents today for follow-up. He was seen back in December 17 for evaluation of bilateral tinnitus, general malaise, and aural pressure that he relates to viral infection. At that

³ In petitioner’s sworn statement included with his petition to the Office of the Special Masters, Mr. Legault claimed that he visited Dr. DeBlieux on January 15, 2020. The medical records provided to the court, however, reflect that the visit occurred on January 10, 2020.

time he was noted to have a slight decrease in hearing on the left that was sensorineural related, otherwise normal ear exam. He states that since the visit he has been [sic] continue to have intermittent bouts of aural pressure, postnasal drip at times as well as general myalgias, malaise, and fatigue. He is concerned that there is a persistent viral infection that is causing the symptoms. He was prescribed a course of steroids which he did take that temporarily improved his symptoms, but he did have side effects such as increased insomnia when taking the medicine. He also took a course of acyclovir, which did not change his symptoms. He otherwise denies any significant vertigo or dizziness or other balance problems. Denies any fevers or chills. States that his tinnitus did improved [sic] temporarily, but it has returned.

(capitalization in original; alterations added). At the January 10, 2020 visit, Dr. DeBlieux diagnosed petitioner with “[b]ilateral tinnitus,” “[l]eft mild sensorineural hearing loss,” and “[i]ntermittent aural pressure.” (alterations added). Dr. DeBlieux told petitioner that he did “not know of a viral etiology that would cause his constellation of symptoms to persist in this manner.” Dr. DeBlieux “reviewed that his otologic examination^[4] [was] by and large normal.” (alteration and footnote added). Dr. DeBlieux also “discussed that other types of etiologies that could present similarly would be headache and migraine disorders, but they would not necessarily account for his experience of myalgias and general malaise, and fatigue.” During this visit Dr. DeBlieux discussed the option to obtain an MRI and a computerized tomography scan (CT scan) of the temporal bone to rule out any masses or growths that could account for the symptoms.⁵ Dr. DeBlieux did not prescribe a new course of medication, but did suggest to petitioner that he “follow up with his family medicine practitioner for age on [sic] assessment and consideration for further blood work to rule out other systemic etiologies.” (alteration added).

On January 31, 2020, petitioner alleged in his sworn statement included with his petition to the Office of the Special Masters that he went to an urgent care clinic because he was experiencing even more pain and that his ears were “fully blocked.”⁶ Petitioner alleged that at the urgent care he was diagnosed with inflammation in his ear that was not allowing the ear to drain properly through the Eustachian tube. Petitioner alleged that the urgent care gave petitioner an allergy medication and Sudafed, which petitioner

⁴ An otologic examination, also known as an otoscope exam, is an exam used to “assess the condition of the external auditory canal (EAC), tympanic membrane (TM), and the middle ear.” Nicholas L. Mankowski and Black S. Raggio, Otoscope Exam, National Library of Medicine: National Center for Biotechnology Information, <https://www.ncbi.nlm.nih.gov/books/NBK553163> (last visited July 30, 2025).

⁵ The record before this court does not reflect that petitioner underwent an MRI or CT scan subsequent to this visit.

⁶ The record before this court, however, does not contain a record documenting this visit.

alleged that he took for two weeks, although petitioner claims that neither medication was effective.

In January of 2020,⁷ petitioner was told that his previous employer would re-hire him and on March 9, 2020, petitioner went back to work with his previous employer. Petitioner alleged he had difficulty working due to the ringing in his ears, strong headaches, dizziness, and inability to focus, and that he experienced daily panic and performance anxiety during this time. Around March 16, 2020, petitioner alleged that he went to his primary care physician.⁸ On May 1, 2020, petitioner, once again was laid off, this time because of COVID 19. By June of 2020, petitioner alleged that physical activity was a struggle due to “the pain and dizziness” and that he had gained twenty-five pounds. Petitioner also alleged that his sleep had been impacted and that he was only sleeping three to four hours a night.

On June 9, 2020, petitioner saw Dr. James Ryon Poston, a neurologist, after a referral from his primary care physician, Dr. Russell Lake. The medical record listed tinnitus, dizziness, headache, and hearing loss as the reason for the appointment. At the June 9, 2020 visit, the medical record lists the following history:

37-year-old man who received a flu shot in around November 2019 and approximately 1 week later began noticing bilateral ear ringing that was worse on the left side that became constant, not exposed to loud noises at work. Around Christmas 2019 he was noting some left ear pain internally and sensitive to noise on that side and sometimes would hurt when he would speak. Dizzy and nausea [sic] when he would try to concentrate that improved over time. Saw [an] ENT in January and was told of some sensorineural hearing loss on the left side has some aural pressure. Patient concerned about new headaches in the posterior head since December describes a constant ache in the posterior head. Denies tension and tightness in the neck. Tylenol and Advil were no help. Prednisone caused more side effects than benefit.

(alterations added). Dr. Poston conducted a neurologic exam, the results of which were normal. Dr. Poston diagnosed petitioner with “[h]earing loss of the left ear, unspecified hearing loss type,” “[t]innitus of both ears,” and “[n]ew onset headache.” (alterations added). Dr. Poston determined that “given the severity of the symptoms and their persistent nature he [Mr. Legault] needs [an] MRI of the brain with and without contrast

⁷ In petitioner’s sworn statement included with his petition to the Office of the Special Masters, he states that it was in January of 2019 that he was told that his previous employer would re-hire him, however, plaintiff was still working for his employer in January 2019, and was not laid off until September 2019.

⁸ The medical record from the January 10, 2020 visit with Dr. DeBlieux mentions that Dr. DeBlieux plans to see petitioner again in March 2020, “sooner as needed,” but there is no medical record of this March 2020 visit in the record before the court.

with special cuts through the internal auditory canals.” (alterations added). Dr. Poston told petitioner that “there is no specific medication I can give him for the hearing loss and tinnitus.” Dr. Poston mentioned in the treatment notes from this visit that, “I do think its [sic] possible he could have some type of viral induced tinnitus after the flu shot but we have no way of confirming this. My hope is that this would improve over the coming months.” (alteration added). Petitioner was prescribed Alprazolam. Petitioner elected not to undergo an MRI due to not having health insurance that would cover the MRI. Petitioner also elected not to take the medication prescribed to him by Dr. Poston due to an alleged fear of the long-term effects and consequences of taking the medication.

On June 29, 2020, petitioner once again was re-hired by his previous employer. Despite alleging that he was still experiencing symptoms, petitioner accepted the position. In November of 2020, petitioner was treated for a COVID 19 infection.⁹ In May 2021, petitioner saw an acupuncturist for his ear pain and headaches. Nearly two years after the November 2019 flu vaccination, on September 29, 2021, petitioner saw his primary care physician, Dr. Lake, to get an exemption from the COVID 19 vaccine due to concern about a vaccine reaction. The medical record’s “Reason for Appointment” reflects that petitioner “noticed severe ringing in ears, It [left] ear congestion, headaches he states noticed 3 days after getting a flu shot in 2019. Symptoms has [sic] worsened over period since then he wants to be referred to allergy/immunology[.]” (alterations added). In the petitioner’s medical record it was further noted:

He [petitioner] reminds me that he had what he believes to have been a reaction to a flu vaccine in 2019 which manifested as some ear and neurologic symptoms. He saw an ENT who found he had some hearing loss but also was worried about his neurologic symptoms.

He ended up seeing a neurologist who felt the vaccine activated his immune response. To this day he still has headaches, ear ringing, and trouble concentrating. Dr. Poston order an MRI, however, he was unable to have this done[.]

He is from Canada and has been unable to go there or do anything in Canada[.]

If, however, he has a medical vaccine exemption he would have a lot more liberties.

While he would like to get the vaccine he is more afraid of the vaccine than he is of the virus, even though he does not want to get sick either.

He also tells me has an active litigation case being adjudicated [sic] for the vaccine injury fund.

(alterations added). The medical record’s “Assessments” lists: “Adverse effect of vaccine, sequela – T50.Z95S (Primary).” Dr. Lake also provided petitioner with a COVID 19 vaccine exemption due to “a history of adverse reactions to immunizations.” In the clinical notes section, Dr. Lake indicated: “We will try to get him in with an immunologist to discuss

⁹ Petitioner has not alleged that the COVID 19 infection is related to his alleged injuries in this case.

further. I have asked him to look into academic institutions as I think this would be his best fit.”

On October 7, 2021, petitioner saw Dr. Jack R. Eades, an immunologist. The chief complaint noted in the medical record for this visit was “[v]accine reaction.” (alteration added). The medical record of the October 7, 2021 visit noted the following:

Very pleasant 39-year-old gentleman who had an influenza vaccine in November of 2019 and following the shot, without [sic] about three or four days, he had bilateral tinnitus, which gradually worsened on the left side. He had . . .^[10] congestion and then left-sided pain. He has had dull, aching pain, kind of a headache, on the left side, decreased hearing, and scintillating scotomas. He has been evaluated by an ear, nose, and throat physician, Dr. Tyler Deblieux, [sic] who noted that he had about 40% hearing loss on the left side and treated him with prednisone to no avail. He was subsequently seen by a neurologist, Dr. [James] Ryon Poston [petitioner’s neurologist], who thought that he had had an adverse reaction with the influenza vaccine. Based on the description by Mr. Legault, I think that Dr. Poston was thinking that he could have had Guillain-Barre [sic] syndrome or a variant thereof. I would tend to favor that diagnosis as well. Understandably Mr. Legault is worried about receiving the Covid-19 vaccine. Fortuitously for him, he believes he has had Covid and had full recovery.

(alterations, omission, and footnote added). In the “IMPRESSION/PLAN” section of the medical record for the October 7, 2021, Dr. Eades stated:

Guillain-Barre [sic] syndrome subsequent to influenza vaccine.^[11] I have offered him a second opinion and will offer a neurologic referral if necessary. Obvious concern about receiving subsequent vaccines. I have discussed with him that Guillain-Barre [sic] syndrome can be seen with live attenuated vaccines as well as live virus vaccines and obviously in the aftermath of a viral syndrome. He has a concern about taking the Covid-19 vaccines, which is messenger RNA [ribonucleic acid]. He has currently [sic] a vaccine exemption from his primary care physician. I have mentioned that he might

¹⁰ The word before “congestion” was illegible in the copy of the record submitted to the court.

¹¹ It is not clear that petitioner ever had Guillain-Barré syndrome. Dr. Eades is the only physician in the record before this court who suggests petitioner could have had Guillain-Barré syndrome. Dr. Eades’ diagnosis also was made nearly two years after the November 2019 flu vaccination and petitioner’s alleged symptoms began. Moreover, petitioner does not allege in his petition that he suffered Guillain-Barré syndrome as a result of his flu vaccination.

want to obtain a second opinion from an academic medical center such as the Allergy & Immunotherapy Department at Medical College of Georgia.

(capitalization in original; footnote and alterations added). Dr. Eades also assessed petitioner with “[v]accine reaction.” (alteration added).

At the time of the filing of his petition with the Office of the Special Masters, on December 29, 2021, petitioner alleged he was still experiencing symptoms. Petitioner stated he “believe[s] they [the symptoms] will never go away or even improve at this point. Everything in life is a struggle and less enjoyable than before, friendships and relationships have fallen apart [sic] and no one understands when I explain what I’m dealing with because it seems unbelievable and to them, I look fine physically.” (alterations added).

Petitioner also filed a number of medical records with the Office of the Special Masters dated after his petition was filed, to support the allegations in his case, including an April 2, 2022 COVID 19 vaccine exemption from Dr. Poston, which stated that “patient is at high risk for negative outcome if he receives future vaccinations including the Covid vaccination,” and records from a May 17, 2023 visit with Dr. Lake, for a “routine physical exam and to discuss his ongoing concerns of neurologic symptoms.” As reflected above, petitioner also had a COVID 19 vaccination exemption issued prior to the filing of his petition with the Office of the Special Masters, issued on September 29, 2021 by Dr. Lake, which was provided due to “a history of adverse reactions to immunizations,” as noted in petitioner’s medical record.

After December 29, 2021, when petitioner filed his petition with the Office of Special Masters, the case was assigned to Chief Special Master Corcoran.¹² Petitioner filed a motion for a Ruling on the Record and a Brief in Support of Entitlement, together with petitioner’s expert report from Dr. Alexander Arts and supporting medical literature. Petitioner argued to the Chief Special Master that “[i]n Mr. Legault’s case, it is vaccination that abnormally activates the cellular stress pathways, resulting in SSNHL.” (alteration added).

The government then filed its response to the motion for a Ruling on the Record, along with the government’s expert reports from Dr. Jay Rubinstein and Dr. You-Wen He, together with supporting medical literature. Petitioner followed with the filing of a rebuttal expert report from Dr. Arts and a reply to the government’s response to the motion for a Ruling on the Record.

In his decision, Chief Special Master Corcoran included a recitation of the factual background of petitioner’s case, the contents of both expert reports filed by petitioner’s expert, Dr. Arts, petitioner’s accompanying medical literature, the contents of the expert reports filed by the government’s experts, Dr. Jay Rubinstein and Dr. You-Wen He, and the government’s accompanying medical literature. See Legault v. Sec’y of Health &

¹² The case was subsequently reassigned to Special Master Danial T. Horner and then reassigned back to Chief Special Master Corcoran.

Hum. Servs., No. 21-2343V, Slip Op. at 2-11. In his decision, the Chief Special Master also offered a discussion of the applicable legal standards governing a petitioner's burden of proof in Vaccine Program cases, including the three prongs of the Althen test, see Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005), and analyzed the facts of Mr. Legault's case in light of those legal standards. See Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 14-20.

Chief Special Master Corcoran noted that "Petitioner generally argues he has met all three prongs of the test set by the Federal Circuit in Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005) for causation claims. Regarding the first prong, Petitioner puts forth a stress response theory to explain his post-vaccination SSNHL." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 12. Chief Special Master Corcoran in his analysis of petitioner's claim under Althen prong one noted that "[p]rogram claimants have frequently argued that SSNHL and/or tinnitus could be attributable to a vaccine. Far more often than not, such claims have not succeeded." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 20 (alteration added). The Chief Special Master further noted that "[i]n most such cases, the fact of post-vaccination SSNHL was not disputed, but the claimants could not demonstrate the vaccine was causal." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 21 (emphasis in original; alteration added). The Chief Special Master also discussed a number of decisions he had issued in other Vaccine Program cases, including Vanore v. Secretary of Health & Human Services, No. 21-870V, 2024 WL 3200287 (Fed. Cl. Spec. Mstr. May 31, 2024), M.R. v. Secretary of Health & Human Services, No. 16-1024, 2023 WL 4936727 (Fed. Cl. Spec. Mstr. June 30, 2023), and Schilling v. Secretary of Health & Human Services, No. 16-527V, 2022 WL 1101597 (Fed. Cl. Spec. Mstr. March 17, 2022). In his January 2, 2025 decision, Chief Special Master Corcoran also addressed the arguments made in Madigan v. Secretary of Health & Human Services, No. 14-1187V, 2021 WL 3046614 (Fed. Cl. Spec. Mstr. June 25, 2021), which resulted in an entitlement decision by Special Master Horner, in which Special Master Horner found that a vaccination could cause SSNHL under the stress response theory. See Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22.

As indicated above, Chief Special Master Corcoran concluded that in petitioner's case, Mr. Legault had failed to preponderantly demonstrate "that the flu vaccine can cause SSNHL and/or tinnitus." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23 (emphasis in original). The Chief Special Master determined that, "[a]s in prior cases, Petitioner repeats the argument that a vaccine-caused, cytokine-driven process can cause inflammation sufficient to create a favorable environment for sudden hearing loss." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23 (citing M.R. v. Sec'y of Health & Hum. Servs., 2023 WL 4936727, at *27; Inamdar v. Sec'y of Health & Hum. Servs., No. 15-1173V, 2019 WL 1160341, at *17 (Fed. Cl. Spec. Mstr. Feb. 8, 2019)) (alteration added). The Chief Special Master further determined that "Petitioner invokes the same specific proinflammatory cytokines (IL-6 and TNF) that I have addressed (and found wanting) in previous cases." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23 (citing Inamdar v. Sec'y of Health & Hum. Servs., 2019 WL 1160341, at *17).

Regarding Althen prong two, Chief Special Master Corcoran determined that the medical record in Mr. Legault's case "offers scant support for the 'did cause,' second Althen prong." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 25. The Chief Special Master determined that petitioner could "only point to his post-vaccination onset of tinnitus and left-sided hearing loss as evidence of a 'logical sequence of cause and effect' – even though the [Vaccine] Program clearly recognizes that a bare temporal relationship does not prove a vaccine caused a subsequent injury." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 25 (citing Bulman v. Sec'y of Health & Hum. Servs., No. 19-1217V, 2023 WL 5844348, at *14 (Fed. Cl. Spec. Mstr. Aug. 16, 2023)) (emphasis in original; alteration added). The Chief Special Master found it significant that "Petitioner did not even seek treatment until about a month post-vaccination," which, in the Chief Special Master's view, undermined petitioner's claim to a close-in-time onset between vaccination and petitioner's symptoms. See Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 25. In sum, the Chief Special Master found in Mr. Legault's case that "there is an overall lack of reliable or trustworthy treater opinion evidence favoring causation." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26.

Although Chief Special Master Corcoran did not separately address Althen's third prong in his decision, the Chief Special Master noted in a footnote: "I need not resolve Petitioner's success in establishing the third prong, since the failure to establish just one of the three Althen prongs of the causation test is sufficient grounds for dismissal." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 25 n.13 (citing Dobrydnev v. Sec'y of Health & Hum. Servs., 566 F. App'x 976, 980 (Fed. Cir. 2014) (emphasis and omission in original; alterations added)).

After reviewing the record before him, Chief Special Master Corcoran issued his decision on January 2, 2025, in which he ruled that "[p]reponderant evidence does not support petitioner's causation theory. Accordingly, he is not entitled to compensation." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 27 (alteration added). After the Chief Special Master issued his decision, petitioner filed a Motion for Review of the decision on January 30, 2025 in the United States Court of Federal Claims. The government filed a response to petitioner's Motion for Review, following which petitioner filed his reply to the response to the Motion for Review. After the Motion for Review was fully briefed, the court held oral argument.

DISCUSSION

In order for compensation to be awarded under the Vaccine Program, a Special Master or court must find that, based on the record as a whole,

- (A) that the petitioner has demonstrated by 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.

42 U.S.C. § 300aa–13(a)(1)(A)-(B) (2024). As the United States Court of Appeals for the Federal Circuit explained in Althen v. Secretary of Health & Human Services:

The Act provides for the establishment of causation in one of two ways: through a statutorily prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table (“Table Injury”), see 42 U.S.C. § 300aa–14(a); or where the complained -of injury is not listed in the Vaccine Injury Table (“off-Table injury”) by proving causation in fact, see 42 U.S.C. §§ 300aa–13(a)(1), –11(c)(1)(C)(ii)(I).

Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1278; see also Milik v. Sec’y of Health & Hum. Servs., 822 F.3d 1367, 1379 (Fed. Cir. 2016); Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1341-42, 1346 (Fed. Cir. 2010); Walther v. Sec’y of Health & Hum. Servs., 485 F.3d 1146, 1149 (Fed. Cir. 2007); Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir.), reh’g and reh’g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007); Exum v. Sec’y of Health & Hum. Servs., 175 Fed. Cl. 681, 701 (2025); Record v. Sec’y of Health & Hum. Servs., 175 Fed. Cl. 673, 676 (2025); Gonzalez v. Sec’y of Health & Hum. Servs., 173 Fed. Cl. 728, 734 (2024); Flowers v. Sec’y of Health & Hum. Servs., 173 Fed. Cl. 613, 621-22 (2024). The United States Supreme Court also has explained:

Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation. No showing of causation is necessary; the Secretary bears the burden of disproving causation. A claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation.

Bruesewitz v. Wyeth LLC, 562 U.S. 223, 228-29 (2011) (footnotes omitted). As mentioned, the burden of proof for Table and Non-Table claims under the Vaccine Program is by preponderance of the evidence. See 42 U.S.C. § 300aa–13(a)(1)(A). The preponderance of the evidence standard required by the Vaccine Act is “one of proof by a simple preponderance, of ‘more probable than not causation.’” Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1279-80 (citing Hellebrand v. Sec’y of Health & Hum. Servs., 999 F.2d 1565, 1572–73 (Fed. Cir. 1993) (Newman, J. concurring)).

In the case currently before the court, there is no dispute that the injuries petitioner alleges he suffered as a result of the flu vaccination are not included on the Vaccine Injury Table. See 42 U.S.C. § 300aa–14. Petitioner, therefore, must proceed under an off-Table theory of recovery as noted by the Chief Special Master. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 14. The United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health & Human Services specified a three-prong test which a petitioner must meet. in order to establish causation in an off-Table injury case:

To meet the preponderance standard, she [petitioner] must “show a medical theory causally connecting the vaccination and the injury.” Grant v. Sec’y of Health & Hum. Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). 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[.]” Grant, 956 F.2d at 1148. Althen may recover if she shows “that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface[] [v. Sec’y of Health & Hum. Servs.], 165 F.3d 1344, 1352–53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, Althen’s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1278 (first alteration added); see also Winkler v. Sec’y of Health & Hum. Servs., 88 F.4th 958, 961-62 (Fed. Cir. 2023); Sanchez by and through Sanchez v. Sec’y of Health & Hum. Servs., 34 F.4th 1350, 1353 (Fed. Cir. 2022); Demore v. Sec’y of Health & Hum. Servs., 175 Fed. Cl. 756, 761 (2025); Exum v. Sec’y of Health & Hum. Servs., 175 Fed. Cl. at 702; Flowers v. Sec’y of Health & Hum. Servs., 173 Fed. Cl. at 622; Hoffman v. Sec’y of Health & Hum. Servs., 172 Fed. Cl. 477, 492 (2024).

To prove the first Althen prong, petitioner must provide “a reputable medical theory,” that shows that the vaccine petitioner received can cause the type of injury alleged. See Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d at 1355-56; see also Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010); Andreu ex rel. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009). The Federal Circuit has explained: “We have consistently rejected theories that the vaccine only ‘likely caused’ the injury and reiterated that a ‘plausible’ or ‘possible’ causal theory does not satisfy the standard.” Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1360 (Fed. Cir. 2019) (quoting Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d at 1322); see also LaLonde v. Sec’y of Health & Hum. Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014) (“in the past we have made it clear that simply identifying a ‘plausible’ theory of causation is insufficient for a petitioner to meet her burden of proof”).

Althen’s first prong permits the petitioner to offer medical opinion as proof of their injury but does not require petitioner to demonstrate “objective confirmation” obtained from medical literature. See Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1279.

Indeed, the United States Court of Appeals for the Federal Circuit determined in Simanski v. Secretary of Health & Human Services:

Although a finding of causation “must be supported by a sound and reliable medical or scientific explanation,” causation “can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms.” Knudsen v. Sec’y of the Dep’t of Health & Human Servs., 35 F.3d 543, 548–49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner’s injury, as long as the petitioner can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. Moberly [v. Sec’y of Health & Hum. Servs.], 592 F.3d at 1325; Andreu v. Sec’y of Health & Human Servs., 569 F.3d [at] 1378.

Simanski v. Sec’y of Health & Hum. Servs., 671 F.3d 1368, 1384 (Fed. Cir. 2012) (alterations and omissions in original); see also Andreu ex rel. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d at 1378 (“Requiring ‘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.” (quoting Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1325-26 (Fed. Cir. 2006))) (omissions in original); Knudsen by Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d at 549 (“to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.”); Shapiro v. Sec’y of Health & Hum. Servs., 105 Fed. Cl. 353, 358-59 (2012). Althen’s first prong does not require the petitioner to provide a theory that is “medically or scientifically certain,” the theory need only be “legally probable.” Moberly ex. rel Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d at 1322 (quoting Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d at 548-59).

The second prong of the Althen test requires the petitioner to demonstrate “a logical sequence of cause and effect, showing that the vaccination was the reason for the injury” by a preponderance of the evidence. See Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1278; see also Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d at 1326 (“‘A logical sequence of cause and effect’ means what it sounds like—the claimant’s theory of cause and effect must be logical.”). The United States Court of Appeals for the Federal Circuit has held that causation-in-fact for Vaccine Act purposes is the same as the “legal cause” in the general torts context. See Shyface v. Sec’y of Health & Hum. Servs., 165 F.3d at 1351-52; see also Walther v. Sec’y of Health & Hum. Servs., 485 F.3d at 1150; Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d at 1355. The Federal Circuit has ruled that “the vaccine is a cause-in-fact when it is ‘a substantial factor in bringing about the harm.’” de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1351 (Fed. Cir.), reh’g and reh’g en banc denied (Fed. Cir. 2008) (quoting Restatement (Second) of Torts § 431(a)); see also Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs., 717 F.3d 1363, 1367 (Fed. Cir.) (“To prove causation, a 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.’” (quoting Shyface v. Sec’y of Health & Hum. Servs., 165 F.3d at 1352-53)), reh’g and reh’g en banc denied (Fed. Cir. 2013). A temporal association alone is not sufficient to establish causation in fact under the second prong of Althen. See Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d at 1326 (finding “if close temporal proximity, combined with the finding that hepatitis B vaccine can cause RA [rheumatoid arthritis], demonstrates that it is logical to conclude that the vaccine was the cause of the RA (the effect), then medical opinions to this effect are quite probative” (alteration added)). The logical sequence of events can be supported by “reputable medical or scientific explanation” or “evidence in the form of scientific studies or expert medical testimony.” Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1278 (quoting Grant v. Sec’y of Health & Hum. Servs., 956 F.2d at 1148).

The Federal Circuit also has held that Special Masters should consider the opinions of treating physicians when making a determination as to Althen prong two. See Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d at 1326 (finding “the chief special master erred in not considering the opinions of the treating physicians” and “medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether ‘a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’” (quoting Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1280)); see also Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993) (finding “[m]edical records, in general, warrant consideration as trustworthy evidence . . . [t]hese records are also generally contemporaneous to the medical events” (alterations and omission added)). Medical records and medical opinion testimony, however, are not binding on the Special Master. See 42 U.S.C. § 300aa–13(b)(1) (“Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.”).

The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of the evidence, “a proximate temporal relationship between vaccination and injury.” Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1278. As noted by the United States Court of Appeals for the Federal Circuit in Pafford v. Secretary of Health & Human Services, “without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.” Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d at 1358. The Federal Circuit also has determined that “the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d at 1352; see also Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d at 1358; Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1281.

The Federal Circuit additionally ruled in Capizzano v. Secretary of Health & Human Services that evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d at 1326 (“We see no reason why evidence used to satisfy one of the Althen III prongs cannot overlap to satisfy another prong.”). If the petitioner satisfies all three prongs laid out by Althen by a preponderance of the evidence, the petitioner is “entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.” Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1278 (quoting Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d at 547 (alteration in original; citation omitted)); see also Stone v. Sec’y of Health & Hum. Servs., 676 F.3d 1373, 1379-80 (Fed. Cir. 2012); de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d at 1352; Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d at 1355; Rus v. Sec’y of Health & Hum. Servs., 129 Fed. Cl. 672, 680 (2016) (citing 42 U.S.C. § 300aa–13(a)(1)(B)). It has additionally been determined that “regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case.” Rus v. Sec’y of Health & Hum. Servs., 129 Fed. Cl. at 680 (citing Stone v. Sec’y of Health & Hum. Servs., 676 F.3d at 1379); see also de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d at 1353.

When reviewing a Special Master’s decision, the assigned Judge of the United States Court of Federal Claims shall:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusions 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
- (C) remand the petition to the special master for further action in accordance with the court’s decision.

42 U.S.C. § 300aa-12(e)(2). The legislative history of the Vaccine Act states: “The conferees have provided for a limited standard for appeal from the [special] master’s decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made.” H.R. Rep. No. 101–386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120 (alteration added). The standard of review under the Vaccine Act was articulated in Markovich v. Secretary of Health & Human Services, by the United States Court of Appeals for the Federal Circuit which wrote, “the Court of Federal Claims reviews the Special Master’s decision to determine if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.’ 42 U.S.C. § 300aa–12(e)(2)(B).” Markovich v. Sec’y of Health & Hum. Servs., 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 522 U.S. 816 (2007); see also Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d at 1358 (citing LaLonde v. Sec’y of Health & Hum. Servs., 746 F.3d at 1338); Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs., 717 F.3d at 1366 (“we ‘perform[] the same task as the Court of

Federal Claims and determine[] anew whether the special master's findings were arbitrary or capricious.” (quoting Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))) (alterations in original); Hibbard v. Sec’y of Health & Hum. Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d at 1321 (citing Munn v. Sec’y of Health & Hum. Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992) de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1350 (Fed. Cir.), reh’g and reh’g en banc denied (Fed. Cir. 2008); Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1277; Dodd v. Sec’y of Health & Hum. Servs., 114 Fed. Cl. 43, 47 (2013); Taylor v. Sec’y of Health & Hum. Servs., 108 Fed. Cl. 807, 817 (2013)). Therefore, this court may only set aside a Special Master’s decision if the court determines that the “findings of fact or conclusion of law of the special master . . . [are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 42 U.S.C. § 300aa–12(e)(2)(B) (omissions and alteration added); see also Lombardi v. Sec’y of Health & Hum. Servs., 656 F.3d 1343, 1350 (Fed. Cir. 2011) (citing Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d at 1324); Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d at 1321; Markovich v. Sec’y of Health & Hum. Servs., 477 F.3d at 1356-57; Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d at 1360. The standard of review applied in Vaccine Program cases is “uniquely deferential for what is essentially a judicial process.” Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); see also Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d at 1345 (“Thus, although we are reviewing as a matter of law the decision of the Court of Federal Claims under a non-deferential standard, we are in effect reviewing the decision of the special master under the deferential and capricious standard on factual issues.” (quoting Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d at 1369 (Plager, J., dissenting))); Munn v. Sec’y of Health & Hum. Servs., 970 F.2d at 869 (“The findings of fact and conclusions of law of the special master may be set aside only if found violative of the standard of review set forth in the statute, a standard of review which is highly deferential to the factual findings of the special master.”); Hines on Behalf of Sevier v. Sec’y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991) (“‘arbitrary and capricious’ is a highly deferential standard of review” in vaccine cases). Indeed, the United States Court of Appeals for the Federal Circuit has noted:

Congress assigned to a group of specialists, the special masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the special masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs., 717 F.3d at 1366-67 (quoting Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d at 961) (omission and alteration in original); see also Hibbard v. Sec’y of Health & Hum. Servs., 698 F.3d at 1363.

A Special Master has discretion to determine the relative weight of evidence presented, including between contemporaneous medical records and oral testimony. See Hibbard v. Sec’y of Health & Hum. Servs., 698 F.3d 1355, 1368-69 (Fed. Cir. 2012) (finding that it was not arbitrary or capricious for the Special Master to weigh conflicting treating physicians’ conclusions against each other); see also Burns v. Sec’y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (finding the Special Master had discretion whether to hold evidentiary hearings or not and determining that the Special Master gave thorough and careful consideration to the record). Further, a Special Master is “not required to discuss every piece of evidence or testimony in [his or] her decision.” Snyder ex. rel. Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. 706, 728 (2009) (alteration added); see also Paluck ex rel. Paluck v. Sec’y of Health & Hum. Servs., 104 Fed. Cl. 457, 467 (2012) (“while the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec’y of Health & Hum. Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010)], he cannot dismiss so much contrary evidence that it appears that he ‘simply failed to consider genuinely the evidentiary record before him.’”) (quoting Campbell v. Sec’y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011) (alteration added)); Snyder by Snyder v. Sec’y of Health & Hum. Servs., 36 Fed. Cl. 461, 466 (1996) (“The special master need not discuss every item of evidence in the record so long as the decision makes clear that the special master fully considered a party’s position and arguments on point.”), aff’d, 117 F.3d 545 (Fed. Cir. 1997). The United States Court of Appeals for the Federal Circuit has further explained that on review, 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— these are all matters within the purview of the fact finder.” Porter v. Sec’y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011); see also Lozano v. Sec’y of Health & Hum. Servs., 958 F.3d 1363, 1368 (Fed. Cir. 2020); Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d at 1349 (citing Munn v. Sec’y of Health & Hum. Servs., 970 F.3d at 871); Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d at 1363); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d at 961 (finding “on review the Court of Federal Claims is not to second guess the Special Masters fact-intensive conclusions”). The Federal Circuit has also held that “[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.” Hines on Behalf of Sevier v. Sec’y of Health & Hum. Servs., 940 F.2d at 1528 (alteration added); see also Porter v. Sec’y of Health & Hum. Servs., 663 F.3d at 1253-54; Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d at 1338; Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d at 1360; Dodd v. Sec’y of Health & Hum. Servs., 114 Fed. Cl. at, 56-57. So long as “the special master’s conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.” Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs., 717 F.3d at 1367 (quoting Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d at 1363) (alterations in original); see also Hibbard v. Sec’y of Health & Hum. Servs., 698 F.3d at 1363 (citing Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

The United States Court of Appeals for the Federal Circuit has additionally determined that, “[u]nder the Vaccine Act, Special Masters are accorded great deference in determining the credibility and reliability of expert witnesses. Indeed, we have held that a Special Master’s ‘credibility determinations are virtually unreviewable.’” Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d at 1347 (quoting Hanlon v. Sec’y of Health & Hum. Servs., 191 F.3d 1344, 1349 (Fed. Cir. 1999) (alteration added)); see also Porter v. Sec’y of Health & Hum. Servs., 663 F.3d at 1253-54 (“‘reversible error will be extremely difficult to demonstrate’ where the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision’”) (quoting Hines on Behalf of Sevier v. Sec’y of Health & Hum. Servs., 940 F.2d at 1528); Lombardi v. Sec’y of Health & Hum. Servs., 656 F.3d at 1353; Anderson v. Sec’y of Health & Hum. Servs., 131 Fed. Cl. 735, 752 (2017); Holt v. Sec’y of Health & Hum. Servs., 132 Fed. Cl. 194, 199 (2017).

When both petitioner and respondent offer one or more experts “[t]he special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories. As such, the special master’s credibility findings ‘are virtually unchallengeable on appeal.’” Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d at 1347 (quoting Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d at 1362) (alteration added); see also Milik v. Sec’y of Health & Hum. Servs., 822 F.3d 1367, 1381-82 (Fed. Cir. 2016) (finding that the Special Master was not arbitrary and capricious when determined that the government’s expert’s specific medical qualifications made his testimony more reliable than testimony of petitioner’s expert); Porter v. Sec’y of Health & Hum. Servs., 663 F.3d at 1250 (“[S]pecial masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act.” (alteration added); Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d at 1325-26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations,” and the Special Master may analyze credibility of experts). Additionally, nothing requires a special master to accept an expert’s conclusion “only by ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” Snyder ex rel. Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. at 473 (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997))). The Special Master also may inquire into the scientific reliability of expert testimony and make determinations as to whether the proffered science is sufficiently reliable in light of any submitted medical literature of epidemiological studies. See Copenhaver v. Sec’y of Health & Hum. Servs., 129 Fed. Cl. 176, 183 (2014); Tompkins v. Sec’y of Health & Hum. Servs., 117 Fed. Cl. 713, 719 (2014); Holmes v. Sec’y of Health & Hum. Servs., 115 Fed. Cl. 469, 490-91 (2014); Locane v. Sec’y of Health & Hum. Servs., 99 Fed. Cl. 715, 727 (2011), aff’d, 685 F.3d 1375 (Fed. Cir. 2012).

Finally, the United States Court of Appeals for the Federal Circuit has ruled, “[a] Special Master is not bound to follow the opinions of other Special Masters.” Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d at 1358 (quoting Boatmon v. Sec’y of Health & Hum. Servs., 138 Fed. Cl. 566, 571 (2018)) (alteration in original); see also Snyder ex rel. Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. at 720 (finding “special masters

were free to reach different conclusions based on the same evidence); Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998) (“Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand.”), aff'd, 191 F.3d 1344 (Fed. Cir. 1999); Sharpnack v. Sec'y of Health & Hum. Servs., 27 Fed. Cl. 457, 461 (1993) (noting that Special Masters have the “discretion to evaluate the utility of [evidence] differently in light of all facts relevant in a specific claim,” and “[s]uch variations in the analyses of the special masters are within [Vaccine] Program standards.” (alterations added)). Special Masters, however, may rely upon Vaccine Program case law as an analytical tool to aid them in their decision making. See Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1366-67 (quoting Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d at 961) (“Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims.”); see also Soto Galvan v. Sec'y of Health & Hum. Servs., 151 Fed. Cl. 789, 796 (2021) (finding “the Special Master correctly considered case law and the Vaccine Act’s legislative history”).

In petitioner’s Motion for Review in this court, Mr. Legault argues the Chief Special Master’s determination that petitioner did not satisfy his burden under Althen prong one and Althen prong two was arbitrary and capricious and the Chief Special Master’s January 2, 2025 decision finding petitioner was not entitled to compensation should be reversed. Regarding Althen prong one, Mr. Legault alleges that the Chief Special Master improperly raised petitioner’s burden of proof by imposing a new requirement that personal stress must exist in the petitioner in order to prevail under the stress response theory, thus, imposing a “novel, heightened standard” to petitioner’s burden of proof beyond the typical standard of showing preponderant evidence of causation, as required by the Vaccine Act and Althen v. Secretary of Health & Human Services, 418 F.3d at 1278; that the Chief Special Master did not give proper weight to evidence given by petitioner’s expert and supporting medical literature; and that the Chief Special Master also improperly relied on prior vaccination cases for his decision. Regarding Althen prong two, petitioner alleges that the Chief Special Master arbitrarily and capriciously reduced petitioner’s theory under Althen prong two to “a bare temporal relationship” that was not supported by the evidence from the record because petitioner alleges that there was sufficient evidence in the record to preponderantly meet Althen’s second prong and that the Chief Special Master forced petitioner to show demonstrated signs of an immunological process that is not required under the stress response theory and, thus, impermissibly elevated petitioner’s burden of proof under Althen prong two.¹³

¹³ Although petitioner also did not directly address Althen’s third prong before this court, in a footnote in petitioner’s Motion for Review, petitioner “maintains he succeeds in meeting his burden of proof under Althen Prong 3.” As noted above, the Chief Special Master did not address Althen’s third prong in his decision because he found the first two Althen prongs had not been met. The Chief Special Master stated: “I need not resolve Petitioner’s success in establishing the third prong, since the failure to establish just one of the three Althen prongs of the causation test is sufficient grounds for dismissal.” Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 25 n.13 (citing Dobrydnev v. Sec'y of Health & Hum. Servs., 566 F. App'x at 980).

Regarding Althen prong one, petitioner specifically argues that “[w]hile the stress response theory discusses various types of stressors that can converge to cause SSNHL, the Chief Special Master imposes a new requirement that personal stress must exist in the Petitioner in order to prevail under this theory.” (emphasis in original; alteration added). Petitioner states that “there is nothing in Dr. Arts’ initial expert report that states a Petitioner must experience personal stress under the stress response theory. He merely explains that “[i]t is generally accepted that stress (psychological, physical, biological) causes weakness in the immune system.” (alteration added by petitioner). Petitioner argues that personal stress as a requirement for establishing the stress response theory is “unsupported by the expert reports of Dr. Arts as well as the medical literature,” and is not addressed by respondent’s experts in their expert reports. Petitioner further argues that the submitted medical literature “discusses the convergence of multiple factors in the cause of sensorineural hearing loss but does not require an individual to experience personal stress.” At oral argument in this court on petitioner’s Motion for Review, when asked if vaccination alone under the stress response theory would be enough to entitle petitioner to vaccine compensation under the Vaccine Act, petitioner’s counsel confirmed that petitioner’s position is “[i]f it’s just vaccination alone, under the Masuda article that talks about the convergence of multiple factors, I would say no. . . . So just vaccination alone, based upon the stress response theory, I would say no.” (alteration and omission added). Petitioner’s counsel also argued at the oral argument that, “based upon the medical literature that has been produced about sensorineural hearing loss and the stress response theory, the test is a convergence of multiple factors.”

Petitioner relies on the Madigan case extensively in his Motion for Review to support his argument that the stress response theory does not require personal stress to meet the causation requirements under Althen’s first prong. At oral argument in the case before this court, petitioner’s counsel argued that “based on the reading of Madigan, there is nothing in Madigan that indicated that personal stress is required because, in Legault, we have vaccination plus infection.”

In the Madigan decision, Special Master Horner accepted the petitioner’s expert’s “reliance on the stress response theory as a sound and reliable explanation of the pathophysiology underlying SSNHL.” Madigan v. Sec’y of Health & Hum. Servs., 2021 WL 3046614, at *12. The stress response theory accepted by Special Master Horner in Madigan relied upon an acceptance of a great deal of the same literature as presented in the case currently before this court.¹⁴ In Madigan, Special Master Horner noted:

¹⁴ The following literature was discussed in Madigan v. Secretary of Health & Human Services, 2021 WL 3046614, and was also submitted in this case to the Chief Special Master: Saamil N. Merchant, Joe C. Adams & Joseph B. Nadol, Jr., Pathology and Pathophysiology of Idiopathic Sudden Sensorineural Hearing Loss, 26, OTOLOGY & NEUROTOLOGY 151, 151-60 (2005); J.C. Adams, et. al., Selective Activation of Nuclear Factor Kappa Beta in the Cochlea By Sensory and Inflammatory Stress, 160 NEUROSCIENCE 530, 530-39 (2009); Masatsugi Masuda & Jin Kanzaki, Cause of idiopathic sudden sensorineural hearing loss: The stress response theory, 3(3) WORLD J.

Obviously, however, not everyone who experiences stress will lose their hearing. The stress response theory posits that the above-discussed process operates in connection with innate factors, such as polymorphisms or vascular tone, as well as possibly minor pre-existing subclinical damage to the inner ear. ([Masuda, & Kanzaki, The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 51].) Based on the specific findings of prior studies it does not appear to be the case that infection alone can cause sufficient NF- κ B activation to result in the type of fibrocyte damage that causes hearing loss[.] The process proposed by the stress response theory operates when multiple stressors combine synergistically to result in elevated IL-6. This does not require a full clinical infection and may involve subclinical infection or other immune disturbance.

Madigan v. Sec'y of Health & Hum. Servs., 2021 WL 3046614, at *12 (internal citations omitted, alterations added). In Madigan, even though Special Master Horner found that the petitioner had satisfied the first Althen prong by demonstrating through his medical record the convergence of pre-existing stress and vaccination under the stress response theory, Special Master Horner also stated:

Petitioner also advanced a theory of reactivation of a latent HSV-1 infection. In fact, Dr. Hicks¹⁵] hypothesized a role for viral reactivation within the context of the stress response theory. However, Dr. Hicks explained that his proposed theories could operate alone as well as in combination. Because I have accepted Dr. Hicks's reliance on the stress response theory in itself, I do not reach the question of whether petitioner's HSV-1 reactivation theory satisfies his burden of proof under Althen prong one.

Madigan v. Sec'y of Health & Hum. Servs., 2021 WL 3046614, at *17 (internal citations omitted; footnote added).

Special Master Horner in Madigan appears to have based his acceptance of the stress response theory under Althen prong one on a totality of the circumstances, including on Mr. Madigan's pre-existing background stress in his medical history. See Madigan v. Sec'y of Health & Hum. Servs., 2021 WL 3046614, at *17 ("For all of the reasons discussed above, petitioner has met his burden of proof with respect to Althen prong one by presenting a sound and reliable explanation through Dr. Hicks of how a flu vaccine can cause SSNHL via the stress response theory."). In Madigan, by way of background, Special Master Horner explained:

OTORHINOLARYNGOLOGY 42, 42-57 (2013); Masatsugu Masuda, et. al., Correlations of Inflammatory Biomarkers with the Onset and Prognosis of Idiopathic Sudden Sensorineural Hearing Loss, 33 OTOLOGY & NEUROLOGY at 1142-50; and Baxter et. al., Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis, 155 Otolaryngology – Head and Neck Surgery 81, 81-86 (2016).

¹⁵ Dr. Hicks was the Madigan petitioner's expert.

Prior to December 15, 2011, petitioner did not complain about hearing loss to his primary care physician, Dr. Michael S. Wein. Petitioner had a colonoscopy in December 2010 and had four polyps removed. Petitioner's previous medical history included a five-day headache of unclear etiology, elevated levels of glucose and cholesterol, low levels of MPV [Mean Platelet Volume], and hyperlipidemia. On January 17, 2011, petitioner had a follow-up visit with Dr. Wein regarding hypertension and hypercholesterolemia. Petitioner denied having any side effects to taking Lipitor and his blood pressure was elevated at this visit. Dr. Wein started petitioner on lisinopril. At petitioner's next follow-up visit on February 17, 2011 with Dr. Wein, petitioner's "blood pressure has improved after starting lisinopril." On March 16, 2011, petitioner saw Dr. Wein with a complaint of pain which occurred after tripping over his dog and falling onto his wrist. Petitioner had pain and swelling on the dorsum of his wrist at this visit, but no pain in his hand or elbow. Dr. Wein prescribed petitioner a lace up wrist brace and recommended ice and NSAIDs [Nonsteroidal Anti-inflammatory Drugs]. Petitioner saw Dr. Wein for an annual physical on June 17, 2011. Petitioner complained of some osteoarthritic changes in his hands, but his physical examination was normal. He received a Zostavax vaccination at his visit. Petitioner's laboratory results were unremarkable.

Prior to vaccination, petitioner raised the issue of stress multiple times with Dr. Wein. During his 2010 annual exam on April 23, 2010, petitioner indicated that he had recently undergone a period of financial strain that had caused him to lose insurance and delay medical care. He indicated that his stress had reduced by that time; however, he again raised the issue of stress on January 17, 2011, in connection with a follow-up regarding hypertension and hypercholesterolemia. He attributed his stress to managing his mother's estate. Shortly thereafter, petitioner began to suspect he had low testosterone, though he had no "significant symptoms or concerns." Subsequent testing revealed borderline low testosterone and petitioner was referred to Dr. Rudin, an endocrinologist. Upon review of repeat testing showing normal testosterone levels, Dr. Rudin recommended against testosterone therapy. Subsequently, however, on September 25, 2011, petitioner reported to Barry Erner, D.O. that he was experiencing "reduced energy [and] sexual interest, can't seem to loose [sic] weight, general malaise." Petitioner saw Dr. Erner on November 7, 2011 for low back pain, myalgia, and muscle spasm. During 2011 Dr. Erner prescribed both testosterone and Valium.

Madigan v. Sec'y of Health & Hum. Servs., 2021 WL 3046614, at *3-4 (internal citations and footnote omitted; first two alterations added). Special Master Horner also noted that the Madigan petitioner testified "to having a history of cold sore presentation." Id. at *19. Special Master Horner, therefore, found the following in Madigan:

Petitioner's clinical history is also significant for additional sources of stress that could hypothetically contribute to the synergistic effect anticipated by the stress response theory. Accord Shyface v. Sec'y of Health & Human

Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). First, petitioner's medical records suggest some degree of chronic stress and/or depression during the years and months leading up to his hearing loss. Specifically, petitioner raised the issue of stress with Dr. Wein in both 2010 and 2011. By September 25, 2011, petitioner was being referred for treatment for symptoms of reduced energy and general malaise, though no diagnosis or resolution of these complaints is reflected in the medical records. More acutely, Dr. Erner suggested that petitioner's folliculitis may have contributed an increased inflammatory state. However, none of these factors have been cited as constituting any independent alternative cause of petitioner's SSNHL.

Dr. Hicks also combined his discussion of the stress response theory with the additional idea that petitioner's flu vaccine may have reactivated a latent HSV-1 infection that contributed to the inflammatory conditions within the ear. HSV-1 infection has been separately associated with SSNHL and Dr. Hicks opined that it can be reactivated by innocuous genotoxic stressors or infection. As noted above, I did not find it necessary to reach that aspect of Dr. Hicks's opinion . . . Dr. Hicks specifically opined that petitioner's folliculitis alone would not have been the cause of petitioner's SSNHL under his stress response theory.

Madigan v. Sec'y of Health & Hum. Servs., 2021 WL 3046614, at *19 (internal citations omitted; omission added).

Petitioner quotes the following from Madigan in his Motion for Review in order to demonstrate what is required to rely on the stress response theory in support of petitioner's argument under Althen prong one:

"The stress response theory is viewed as a good candidate for explaining the clinical characteristics of idiopathic sudden hearing loss, including its unilateral presentation and prevalence in adulthood. (Masuda & Kanzaki, [Cause of idiopathic sudden sensorineural hearing loss: The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 51]).) Obviously, however, not everyone who experiences stress will lose their hearing. The stress response theory posits that the above-discussed process operates in connection with innate factors, such as polymorphisms or vascular tone, as well as possibly minor preexisting subclinical damage to the inner ear. Based on the specific findings of prior studies it does not appear to be the case that infection alone can cause sufficient NF- κ B activation to result in the type of fibrocyte damage that causes hearing loss. The process proposed by the stress response theory operates when multiple stressors combine synergistically to result in elevated IL-6. This does not require a full clinical infection and may involve subclinical infection or other immune disturbance.

(quoting Madigan v. Sec'y of Health & Hum. Servs., 2021 WL 3046614, at *12 (internal citations omitted; alteration added)). Petitioner also quotes the following from Madigan in his Motion for Review:

“The stress response theory posits a ‘synergistic’ effect whereby circulating cytokines converge with a stress-related abnormal immune response to trigger the above-discussed feedback loop. (Masuda & Kanzaki, [Cause of idiopathic sudden sensorineural hearing loss: The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 51]).) The theory does not require an active clinical infection, but may include subacute infection or other immunologic stressors.”

(quoting Madigan v. Sec'y of Health & Hum. Servs., 2021 WL 3046614, at *15 (internal citation omitted; alteration added)).

In petitioner’s Motion for Review, petitioner conceded that the “facts of Madigan and Legault differ, including the Petitioners’ levels of personal stress as reflected in the medical chart.” Therefore, respondent states “petitioner agrees that the facts of his case are different from the petitioner in Madigan,” and claims “the Chief Special Master’s finding that petitioner’s expert failed to preponderantly establish that the flu vaccine could cause SSNL and tinnitus through the proposed stress response theory was not arbitrary or capricious.” Despite the differences in the kinds and degrees of stress present in Mr. Madigan’s case and Mr. Legault’s case, petitioner, nonetheless, argues that “the Chief Special Master has imposed a new requirement that personal stress is a requirement of the stress response theory,” which petitioner claims is not supported by the ruling in Madigan or by Dr. Arts’ explanation of the stress response theory. (emphasis in original). Petitioner challenges the Chief Special Master’s interpretation of Madigan in his Motion for Review, by alleging that the Chief Special Master’s decision in Legault specifically holds that Madigan “requires proof that the vaccinated individual was under demonstrated amounts of excessive stress.” (quoting Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22-23 (emphasis in original)).

In his Legault decision, Chief Special Master Corcoran discussed the personal stress of the Madigan petitioner and noted that the Madigan petitioner’s demonstrated multiple varieties and degrees of medically documented personal stress. See Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22-23. The Chief Special Master wrote:

As Petitioner has noted, a different reasoned decision resulted in an entitlement decision favorable to a vaccine-SSNHL associated. See Madigan, 2021 WL 3046614, at *1, 4 (flu vaccine caused adult petitioner’s SSNHL). The Madigan petitioner relied on a stress response theory and/or reactivation of a latent HSV-1 infection (although the latter did not play into the case’s resolution). Madigan, 2021 WL 3046614, at *9-10, 17. As observed in Madigan, the stress response theory had not been offered in prior adverse decisions, like Kelly [v. Secretary of Health & Human Services], No. 16-878, 2021 WL 5276373 (Fed. Cl. Spec. Mstr. Oct. 18,

2021), motion for review denied, 2022 WL 2314746 (Fed. Cl. Apr. 13, 2022)]. The theory as presented in Madigan placed special emphasis on an immune pathway's stimulation by vaccination, causing inflammation elsewhere in the body sufficient to impact the ear. Id. at *9, 12. Indeed, it was deemed a "good candidate for explaining the clinical characteristics of idiopathic sudden hearing loss," and accepted as reasonable by Respondent's expert (although he did not also believe the flu vaccine could trigger it). Id. at *13.

The special master in Madigan further accepted the petitioner's argument, supplemented by literature, that vaccination can increase circulating cytokine levels that could travel to the ear and cause harm, rejecting Respondent's expert's invocation of Baxter [Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis, 155 Otolaryngology – Head and Neck Surgery at 81-86] on the grounds that (a) its findings with respect to a lack of vaccine association were less robust for longer time intervals, (b) its onset determinations had not (in the estimation of Petitioner's expert) been sufficiently confirmed, and (c) it had other methodologic limitations. Madigan, 2021 WL 3046614, at *15-17. Also notable in Madigan was the fact that vaccine causation had treater support, and other lab work findings were consistent with the stress response theory. Id. at *18-19.

Most importantly for present purposes, however, it was clearly established by the medical record in Madigan that the claimant was under significant, demonstrated stress prior to vaccination, raising concerns about the impact of his personal stress "multiple times" with a treater. Madigan, 2021 WL 3046614, at *4. The Madigan petitioner was also able to document a number of sources of the stress, including (a) financial strain resulting in the loss of insurance coverage, and (b) management of a parent's estate. Id. He also manifested the stress in other physiologic ways, reporting a loss of energy, weight gain, and reduced sex drive, among other things. Id.

Madigan provides some support for Petitioner's argument, but it remains an outlier (especially since it involved proof of a degree of stress as a causal factor absent here). And I otherwise do not deem the theory presented to be especially persuasive or reliable, in light of the majority of cases rejecting vaccination as a hearing loss cause. The stress response theory mainly attempts to transmute the expected reaction to a vaccine (which inherently stimulates some short-lived cytokine production) into pathology. Dean v. Sec'y of Health & Hum. Servs., No. 13-808V, 2017 WL 2926605, at *17 (Fed. Cl. Spec. Mstr. June 9, 2017). And (importantly for present purposes) it requires proof that the vaccinated individual was under demonstrated amounts of excessive stress.

Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22-23 (emphasis in original; alterations added).

In his discussion of Althen prong one in Legault, the Chief Special Master, however, never states that personal stress was required to successfully prove entitlement to compensation under the stress response theory. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22-23. The Chief Special Master determined that the stress response theory, accepted in Madigan as satisfying Althen prong one, requires the petitioner to prove that the “vaccinated individual was under demonstrated amounts of excessive stress.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22-23 (emphasis in original). The Chief Special Master does not define how much “demonstrated amounts of excessive stress” would be required under the stress response theory. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22-23. The Chief Special Master, however, concluded that Madigan “involved proof of a degree of stress as a causal factor absent” in Mr. Legault’s case. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22. The Chief Special Master concluded that “the record does not support the application of the stress response theory as embraced in Madigan to this case. There is no proof that Mr. Legault was in fact experiencing levels of stress significant enough to encourage an immune-mediated injury of hearing loss (in comparison to the Madigan petitioner).” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26. Additionally, the Chief Special Master commented that “the record suggests, if anything, the opposite,” because petitioner had stated he was not stressed about being laid off prior to his vaccination and welcomed the time off of work. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26. The Chief Special Master found that the petitioner “acknowledges that he was not suffering from psychological stress pre-vaccination, but argues that this ‘only serves to bolster [his] argument that a biological triggering event was responsible for the acute onset of hearing loss.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26 (alteration and emphasis in original). The Chief Special Master noted that petitioner

also maintains that the Madigan petitioner did not argue that he suffered SSNHL “simply as a result of external, psychological stress.” But this in fact was a central factor embraced in Madigan’s construction of the stress response theory. Madigan, 2021 WL 3046614, at *12 (“[t]he process proposed by the stress response theory operates when multiple stressors combine synergistically to result in elevated IL-6”).

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26 (alteration and emphasis in original; internal citations omitted). The Chief Special Master determined that without the multiple stressors present preceding petitioner’s vaccination to utilize the stress response theory embraced in Madigan “what is left is the contention that ‘biologic stress’ brought on by the immune system’s response to vaccination is enough - precisely the kind of causation theory I, and many other special masters,^[16] have repeatedly

¹⁶ The cases referred to and cited by the Chief Special Master included his own decisions, some of which are discussed in depth below: Vanore v. Secretary of Health & Human Services, 2024 WL 3200287 (Fed. Cl. Spec. Mstr. May 31, 2024) (flu vaccine not shown to be causal of SSNHL); M.R. v. Secretary of Health & Human Services, 2023 WL 4936727 (Fed. Cl. Spec. Mstr. June 30, 2023) (evidence supported the conclusion that petitioner’s acoustic neuroma/vestibular schwannoma was the “factor unrelated” cause

rejected as unreliable.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26 (emphasis in original; footnote added).

Therefore, contrary to petitioner’s suggestion, the Chief Special Master’s statements in Legault are consistent with how Special Master Horner ruled in Madigan; i.e., that some confluence of background stress, either viral or psychological, converged and worked synergistically with the immune response from the vaccination and must have been present to cause a petitioner’s SSNHL. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 22-23; see also Madigan v. Sec’y of Health & Hum. Servs., 2021 WL 3046614, at *12. That Special Master Horner found the stress response theory to be persuasive in the case before him in Madigan, which included different facts, including the Madigan petitioner’s medical history, is not binding on the Chief Special Master’s decision in Mr. Legault’s case. See Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d at 1358; Snyder ex rel. Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. at 720; Hanlon v. Sec’y of Health & Hum. Servs., 40 Fed. Cl. at 630; Sharpnack v. Sec’y of Health & Hum. Servs., 27 Fed. Cl. at 461. That Special Master Horner in Madigan found much of the same medical literature persuasive to validate the stress response theory also does not necessitate that the Chief Special Master find the same medical literature persuasive in Mr. Legault’s case. Because no two Vaccine Program cases are factually identical, individual Special Masters can reach different conclusions in different cases based upon the same or similar documentation of the medical science presented, including the medical literature offered into evidence in each case. See Snyder ex rel. Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. at 720; Sharpnack v. Sec’y of Health & Hum. Servs., 27 Fed. Cl. at 461. Moreover, the Chief Special Master, in Mr. Legault’s

of his SSNHL); Kelly v. Secretary of Health & Human Services, No. 16-878V, 2021 WL 5276373, at *23 (Fed. Cl. Spec. Mstr. Oct. 18, 2021), motion for review denied, 2022 WL 2314746 (Fed. Cl. Apr. 13, 2022) (petitioner failed to establish any preexisting condition, leading to hearing loss, that was aggravated by the flu vaccine); Inamdar v. Secretary of Health & Human Services, No. 15-1173V, 2019 WL 1160341, at *16 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (referencing multiple prior negative decisions involving SSNHL or hearing loss); Donica v. Secretary of Health & Human Services, No. 8-625V, 2010 WL 3735707, at *1, *10 (Fed. Cl. Spec. Mstr. Aug. 31, 2010) (flu vaccine not demonstrated to cause adult hearing loss); and Hopkins v. Secretary of Health & Human Services, Nos. 00-745V & 00-746V, 2007 WL 2454038, at *13 (Fed. Cl. Spec. Mstr. Aug. 10, 2007) (noting that the specific onset of hearing loss in child siblings after receipt of several vaccines could not be established).

In addition to the Chief Special Master’s own decisions, the Chief Special Master also cited to a vaccine case decided by Special Master Nora Beth Dorsey, Herms v. Secretary of Health & Human Services, No. 19-70V, 2024 WL 1340669 (Fed. Cl. Mar. 4, 2024) (Tdap vaccine not causal of tinnitus and left-sided hearing loss), as well as a vaccine case decided by Special Master Katherine E. Oler, Henry v. Secretary of Health & Human Services, No. 17-721V, 2022 WL 2301321 (Fed. Cl. Spec. Mstr. May 2, 2022) (flu vaccine did not likely cause claimant’s right-sided tinnitus).

case, not only examined the stress response theory, but also devoted a significant portion of this decision to compare the facts in Legault as opposed to in Madigan.

Petitioner separately argues in his reply brief in this court that he was experiencing pre-existing stress when he received the vaccine due to his recent layoff. Petitioner had earlier argued in his Reply to his Brief to Entitlement filed with the Chief Special Master that it was the vaccination alone that had abnormally activated the cellular pathways in Mr. Legault's ear which resulted in his SSNHL, stating "Respondent's pointing out Mr. Legault was not suffering psychological stress pre-vaccination only serves to bolster Petitioner's argument that a biological triggering event was responsible for the acute onset of hearing loss." In his reply brief to his Motion for Review in this court, petitioner now states that "the medical chart does make mention of Mr. Legault's anxiety and depression." Petitioner also points to the December 17, 2019 doctor visit to Dr. DeBlieux, and the medical record which stated: "Deos [sic] have a history of anxiety and depression and has been previously treated, but not currently treated. He recently lost his job at Gulfstream, but does not [feel] stressed about this. Does relate having poor sleep and insomnia." (second alteration added by petitioner). Petitioner tries to argue that the "language of this record does not portray Mr. Legault as an individual completely free of stress." In addition, petitioner quotes from one of the articles among the medical literature submitted by Dr. Arts to argue that: "All persons under stress do not suffer from ISHL [Idiopathic Sudden Sensorineural Hearing Loss]. Therefore, there must be innate factors for ISHL onset, probably including polymorphisms of genes encoding coagulation factors, vascular tone, and [sic] cytokines, among others (Table 1). Even individual personality is likely be involved in differential stress response." (quoting Masuda, & Kanzaki, The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 51 (alterations added). Petitioner argues that "Masuda correctly notes that individual personality would be involved in different responses to stress." (citing Masuda & Kanzaki, The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 51). Petitioner also argues that "[t]he loss of a job could induce an extraordinary amount of stress in one Petitioner, but far less stress in another." (alteration added). Petitioner alleges that "[r]equiring the demonstration of 'personal stress' is going to add a highly subjective component into the analysis of the validity of SSNHL cases within the Vaccine Program because individual personality is involved in different responses to stress." (alteration added). Petitioner consequently argues that personal stress may be taken into consideration under the stress response theory, but that personal stress "cannot be a pre-requisite for demonstrating vaccine-induced SSNHL" under Althen's first prong.

In addition, although not urged before the Chief Special Master, but now urged in this court, petitioner argues that based on his medical record, "perhaps a viral infection is a stress factor that converged with Mr. Legault's vaccination" to cause petitioner's SSNHL. Petitioner states that, "[i]f Mr. Legault suffered from a viral infection at the time of vaccination, it is arguable that that infection would be supportive of vaccine-induced SSNHL under the stress response theory" and points to the December 17, 2019 doctor visit to Dr. DeBlieux, the record of which states "that approximately 1 month ago he developed myalgias and general malaise but no significant sinonasal symptoms. He associated this with a viral infection after which [he] developed tinnitus in both ears. (second alteration added by petitioner). Respondent, however, argues that petitioner's

original argument is that “only one stressor, such as a vaccine, is needed to trigger the stress response theory,” and that the Chief Special Master had determined that “without another stressor, petitioner’s stress response theory was the same as multiple deficient cases that merely show SSNHL might be an immune-mediated condition and vaccines stimulate the immune system.”

In petitioner’s reply brief, he repeats his arguments and quotes heavily from the Masuda article to try again to explain his view on the stress response theory and personal stress:

“The word ‘stress’ refers to a constellation of physical and psychological stimuli including systemic viral and bacterial illness, systemic inflammatory disorders, and physical, mental or metabolic stress. Numerous studies have demonstrated adverse effects of systemic stress on health. Stress causes changes in the immune system and cytokine network through activation of the hypothalamus-pituitary-adrenal axis and the sympathetic nervous system. Several types of catecholamine and cytokine receptors are in the cochlea cells other than capillary cells, and then they can respond to systemic stressors. However, there are few studies examining how systemic stress is associated with cochlear dysfunction. The stress response theory addresses this question. In the theory, a variety of stressors and risk factors contribute to the onset of ISHL in varying degrees. The lateral wall of the cochlea has very unique responses to systemic stressors. It plays a critical role in causing ISHL. Systemic stressors converge at the lateral wall and trigger pathological activation of nuclear factor kappa-light-chain-enhancer of activated B cells, a transcriptional factor known as a stress sensor. This activation enhances local expression of genes associated with immune and inflammatory system, resulting in cochlear dysfunction. We review the original stress response theory advocated by [J.C.] Adams et al[., Selective Activation of Nuclear Factor Kappa Beta in the Cochlea By Sensory and Inflammatory Stress, 160 NEUROSCIENCE 530, 530-39 (2009)] and the integrative stress response theory that integrates our knowledge about the etiologies of ISHL so far.”

(quoting Masuda & Kanzaki, The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 42 (alterations added)). Petitioner also quotes the following in his reply brief from the Masuda article, discussing psychological stress:

“IL-1 is a potent pro-inflammatory cytokine, and is produced centrally and periphery following exposure to immunological and psychological stressors. It directly activates the HPA axis and central nervous system, and can even cause depressive symptoms. IL-1 is also known to induce IL-6 strongly. IL-6 is induced by stress as well as by IL-1. Stress induced increases in IL-6 are a robust finding, and increases are typically higher in adverse psychological conditions. Work stress is associated with an enhancement

of IL-6 production by leukocytes before and after infectious stressor and with a lower capacity of GC to suppress IL-6 production.”

(quoting Masuda & Kanzaki, The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 46). Petitioner further quotes from the Masuda article discussing personal stress:

“There is an anecdotal hypothesis about the onset of ISHL, in which so-called ‘stress’ (i.e., psychological and physical stressors) may be associated with the onset of ISHL. It is reported that fatigue, stressful life events, inability to cope with stress, and shortness of sleep are involved in the onset of ISHL. However, this hypothesis has a contradictory survey, as the other hypotheses do (Table 1 and see Merchant et al). According to a survey by Japanese Ministry of Health, Labor and Welfare in 1975, rates of ISHL patients complaining of psychological and physical stress were unexpectedly low, 13.7% and 22.5%, respectively. This may suggest that a subjective scale of stress is different among individuals and it is difficult to analyze individual stress just by questionnaires.”

(quoting Masuda & Kanzaki, The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 49 (emphasis added by petitioner)). Petitioner further quotes from the following explanation from the Masuda article also in his reply brief:

“A quest for a single definitive cause of ISHL does not seem to be reasonable after reviewing the literature. The basic and critical concept of the stress response theory is that ISHL must not result from a specific single and local cause in the inner ear. Moreover, ISHL should encompass several causes contributing to different degrees of severity and prognosis. Synchronism of different types of factors and different degrees of contribution of each factor could result in the individual ISHL case. Some of these factors must occur rarely, and each factor must occur in a temporally appropriate order to trigger pathological NF-κB activation in the cochlear lateral wall. Therefore, ISHL does not recur frequently, even in the same individual.”

(quoting Masuda & Kanzaki, The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 51).

Although suggested by petitioner in his reply on his Motion for Review, the Chief Special Master’s decision, as indicated above, did not require petitioner to demonstrate “personal stress” before the Chief Special Master would accept the stress response theory as a medical theory causative of petitioner’s SSNHL under Althen’s first prong in Mr. Legault’s case. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23-25. Instead, the Chief Special Master determined that the stress response theory presented by petitioner and his expert was insufficient in petitioner’s case to explain the cause of petitioner’s SSNHL under Althen prong one. The Chief Special Master deemed

the contention “that the ‘NF-κB’ protein complex could play a role in encouraging allegedly autoimmune-mediated injuries, including hearing loss” unpersuasive in petitioner’s case. Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 21. The Chief Special Master explained why he did not find the science proffered by this petitioner and the conclusions of petitioner’s expert compelling:

I do not take issue with Petitioner’s success in establishing that hearing loss might be immune mediated in some contexts. But this does not mean a vaccine’s general/systemic stimulation of the immune system is likely pathogenic. Such an argument rests on faulty reasoning common to unsuccessful Program cases: if vaccines stimulate the immune system, and there is a possible immune-mediated pathogenic explanation for an injury, then, as many claimants posit, the expected immune process could become pathogenic in susceptible individuals. But this kind of causal theory has too many “broken links” to find it reliable overall. In order for such a theory to rise above mere plausibility, a petitioner would need to connect it with evidence that suggests that at least the analogs for a vaccine’s antigenic components might be capable of triggering such a process. The fact that vaccines generally impact the immune system (and cause localized inflammation or stimulate cytokines that can initiate inflammation elsewhere in the body) is only the starting point for a successful theory.

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23 (emphasis in original).

The court notes that when this case was before the Office of the Special Masters, petitioner explicitly argued in his Reply to his Brief to Entitlement that it was the vaccination alone “that abnormally activate[d] the cellular stress pathways, resulting in [Mr. Legault’s] SSNHL.” (alterations added). Petitioner made this argument even though petitioner relied on the decision in Madigan, in which Special Master Horner held that the stress response theory explains an occurrence of SSNHL when a variety of previous background stressors combine synergistically with the vaccine to induce SSNHL. See Madigan v. Sec’y of Health & Hum. Servs., 2021 WL 3046614, at *12. Some of petitioner’s submitted supporting medical literature also held that the stress response theory can explain an occurrence of SSNHL when a variety of previous background stressors combine synergistically with a triggering event, such as a vaccine. See, e.g., Masuda & Kanzaki, The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 42, 50-51; Hitoshi Kanzaki & Masatsugu Masuda, Social Medical Problems Related to Hearing “Considerations on Stress and Sensorineural Deafness – Especially the Relationship with Sudden Deafness,” 56 AUDIOLOGY JAPAN 137, 140-45, 148-49 (2013); Masuda, Correlations of Inflammatory Biomarkers with the Onset and Prognosis of Idiopathic Sudden Sensorineural Hearing Loss, 33 OTOLOGY & NEUROLOGY at 1142, 1147-49.

Also as indicated above, at oral argument in this case on petitioner’s Motion for Review, petitioner’s counsel confirmed that his position is that the test for determining whether a vaccine caused SSNHL under the stress response theory is “a convergence of multiple factors,” whether that be vaccination in conjunction with pre-vaccination personal

stress, infection, subclinical infection, or genetic polymorphisms. Petitioner's counsel additionally confirmed at oral argument in this court that a showing of vaccination alone as the cause of SSNHL under the stress response theory is not sufficient to entitle a petitioner to compensation under the Vaccine Act, a petitioner would have to demonstrate other factors such as personal stress, infection, subacute infection, or genetic polymorphisms. Neither petitioner, nor Dr. Arts in his expert reports for petitioner, argue that petitioner was either suffering from a background viral infection, subclinical or otherwise, or suffering from personal stress that converged with an immune response from the received flu vaccine, which then caused petitioner's SSNHL. Indeed, it was respondent's expert, Dr. He, who first suggested that petitioner's SSNHL may have been virally induced.

Although the record before this court reflects that petitioner had some history of anxiety and depression, as documented by Dr. DeBlieux, the record before this court does not demonstrate that it was an active, acute, or ongoing concern for petitioner in close proximity to when petitioner received his flu vaccination. It also was noted in petitioner's medical records that he was not actively being treated for either anxiety or depression around the time of his vaccination. Petitioner additionally did not identify his anxiety or depression as the causal factor that combined with his vaccine to cause his SSNHL under the stress response theory when this case was before the Chief Special Master. Although the record reflects that petitioner had recently lost his job prior to being vaccinated, the record provides that petitioner did "not fill [sic] stressed about this." (alteration added). Petitioner himself in his sworn statement included with his petition to the Office of the Special Masters stated that "[t]he time off was welcome after working so many hours for more than 3 years," at the crucial time before vaccination. (alteration added). After Mr. Legault received the flu vaccine he was rehired by his employer before he was laid off again, but any stress from these events, based on the record before this court, would not appear to be a contributing factor to petitioner's post-vaccine SSNHL under the stress response theory because the stress response theory involves preexisting stress to a vaccination that can synergistically combine with the body's immune response to a vaccination. The record before this court also reflects that petitioner was struggling to sleep, but petitioner in his briefs to the Chief Special Master did not suggest that this was the stress factor that combined with the vaccine caused his SSNHL.

The record also reflects that petitioner thought that he might have had a viral infection prior to his vaccination, which caused petitioner to experience myalgias and general malaise. Petitioner alleges for the first time in this court, however, that "perhaps a viral infection is a stress factor that converged with Mr. Legault's vaccination" to cause his post-vaccination SSNHL. Notably, neither petitioner nor Dr. Arts argued to the Chief Special Master that petitioner's possible viral infection was a likely, or even possible, cause of petitioner's post-vaccine SSNHL, either independently of or under the stress response theory. Moreover, none of petitioner's doctors tested for, or diagnosed petitioner with, a viral infection prior to or immediately after vaccination. The Chief Special Master noted in his discussion of the facts of this case that petitioner "did not otherwise relate his hearing symptoms [sic] onset to his vaccination, instead reporting that he thought his symptoms were associated with is prior viral illness." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 2 (alteration added). The Chief Special Master also

specifically rejected petitioner’s argument that “‘biologic stress’ brought on by the immune system’s response to vaccination is enough” to explain how the flu vaccine can cause SSNHL. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26. After his review, the Chief Special Master determined that:

There are several deficiencies in this claim making it impossible to render an entitlement decision in Petitioner’s favor. First – and most importantly – it has not been preponderantly demonstrated that the flu vaccine can cause SSNHL and/or tinnitus. As noted above, theories in support of arguments that the flu vaccine can cause SSNHL/tinnitus have consistently been found to be unreliable and/or unpersuasive.

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23 (emphasis in original). The Chief Special Master determined that petitioner had failed to make a demonstrated connection between the flu vaccine administered to petitioner and an SSNHL diagnosis. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23.

In this court, petitioner also appears to argue that the Chief Special Master impermissibly based his rejection of petitioner’s argument based on the stress response theory on the decisions made in multiple other prior Vaccine Program cases, including the Chief Special Master’s own decisions. Petitioner argues, for example, that the “Chief Special Master’s statement that ‘[m]y recent determination in Vanore provides a useful overview of the logic behind these kinds of claims—as well as why the routinely fail’ is a statement that combines SSNHL cases that have both relied and not relied upon the stress response theory.” (alteration added by petitioner). Petitioner further argues that Vanore v. Secretary of Health & Human Services is not applicable in this case because Vanore is “immediately distinguishable from Legault as the date of onset was three weeks post-vaccination, as opposed to days post-vaccination.” (citing Vanore v. Sec’y of Health & Hum. Servs., 2024 WL 3200287, at *1). Petitioner quotes the following from the Chief Special Master’s decision in Vanore v. Secretary of Health & Human Services to support his argument that the Chief Special Master is biased against a vaccine/SSNHL association:

“Madigan unquestionably offers positive parallels for Petitioner herein. But I do not find the causation theory therein offered, or the decision embracing it, to be compelling, reliable, or persuasive. I have on many occasions considered theories asserting a vaccine-caused stimulation of the innate (and hence immediate) immune process led to injury, but have repeatedly deemed such theories wanting, absent evidence connecting the process (no matter how scientifically plausible it might be) with additional proof sufficient to render it “more likely than not” that the immune process outlined could be rendered pathogenic by introduction of a vaccine.”

(quoting Vanore v. Sec’y of Health & Hum. Servs., 2024 WL 3200287, at *18). In addition, petitioner argues that M.R. v. Secretary of Health & Human Services, 2023 WL 4936727, at *1, also relied on by the Chief Special Master in his Legault decision, is likewise

distinguishable from petitioner's case because the petitioner in M.R. had an acoustic neuroma.

Petitioner additionally argues that a string cite used by the Chief Special Master in his Legault decision to justify his decision to dismiss the vaccine/SSNHL causation theory, includes cases that do not utilize the stress response theory as presented in Madigan and Legault.¹⁷ Petitioner contends that "based on the decisions rendered in the past few years, it is clear that SSNHL victims in this Program are going to experience vastly different decisions simply based upon the Special Master randomly drawn."

In his decision, the Chief Special Master did note that, "[a]s in prior cases, Petitioner repeats the argument that a vaccine-caused, cytokine-driven process can cause inflammation sufficient to create a favorable environment for sudden hearing loss." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23 (alteration added). The Chief Special Master also stated that "[t]o explain this theory, Petitioner invokes the same specific proinflammatory cytokines (IL-6 and TNF) that I have addressed (and found wanting) in previous cases." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23 (citing Inamdar v. Sec'y of Health & Hum. Servs., 2019 WL 1160341, at *17) (alteration added). Finally, the Chief Special Master explained "Petitioner also invokes the theory that the pathologic activation of NF-kB can lead to ear/hearing dysfunction, but as I explained in M.R., this theory has not been sufficiently corroborated."

¹⁷ The string citation offered by the Chief Special Master in his Legault decision is as follows:

Vanore v. Sec'y of Health & Hum. Servs., No. 21-0870V, 2024 WL 3200287 (flu vaccine not shown to be causal of SSNHL); Herms v. Sec'y of Health & Hum. Servs., No. 19-70V, 2024 WL 1340669 (Tdap vaccine not causal of tinnitus and left-sided hearing loss) (S.M. Dorsey); M.R. v. Sec'y of Health & Hum. Servs., No. 16-1024, 2023 WL 4936727 (evidence supported the conclusion that Petitioner's acoustic neuroma/vestibular schwannoma was the "factor unrelated" cause of his SSNHL); Henry v. Sec'y of Health & Hum. Servs., No. 17-721V, 2022 WL 2301321 (flu vaccine did not likely cause claimant's right-side tinnitus) (S.M. Oler); Kelly v. Sec'y of Health & Hum. Servs., 2021 WL 5276373, at *23 (petitioner failed to establish any preexisting condition, leading to hearing loss, that was aggravated by the flu vaccine); Inamdar v. Sec'y of Health & Hum. Servs., 2019 WL 1160341, at *16 (referencing multiple prior negative decisions involving SSNHL or hearing loss); Donica v. Sec'y of Health and Hum. Servs., 2010 WL 3735707, at *1, 10 (flu vaccine not demonstrated to cause adult hearing loss); Hopkins v. Sec'y of Health & Hum. Servs., 2007 WL 2454038, at *13 (noting that the specific onset of hearing loss in child siblings after receipt of several vaccines could not be established).

Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 20-21 (emphasis in original).

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23. (citing M.R. v. Sec’y of Health & Hum. Servs., No. 16-1024, 2023 WL 4936727, at *32).

Chief Special Master Corcoran stated that he had “previously been tasked with considering the contention that the ‘NF-kB’ protein complex could play a role in encouraging allegedly autoimmune-mediated injuries, including hearing loss.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 21 (citing M.R. v. Sec’y of Health & Hum. Servs., 2023 WL 4936727, *1, *30-32. In M.R. v. Secretary of Health & Human Services, also decided by the Chief Special Master, the Chief Special Master noted:

Items of literature more specific to the ear, like [Masatsugi] Masuda [& Jin Kanzaki, Cause of idiopathic sudden sensorineural hearing loss: The stress response theory, 3(3) WORLD J. OTORHINOLARYNGOLOGY at 42-57], Merchant, [Pathology and Pathophysiology of Idiopathic Sudden Sensorineural Hearing Loss, 26, OTOLOGY & NEUROTOLOGY 151, 151-60 (2005)], and [Joe C.] Adams[, Clinical Implication of Inflammatory Cytokines in the Cochlea: A Technical Note, 23 ONTOLOGY & NEUROTOLOGY 316, 316-22 (2002)], did not establish that [S]SNHL is only or predominantly mediated by disruption of the NF-kB pathway, did not evaluate the extent to which a viral infection could cause this kind of immune interference (let alone vaccination), and were forthright in acknowledging their speculative or hypothetical aspects.

M.R. v. Sec’y of Health & Hum. Servs., 2023 WL 4936727, *32 (alterations added).¹⁸ In another decision by the Chief Special Master, Schilling v. Secretary of Health & Human Services, No. 16-527V, 2022 WL 1101597, the Chief Special Master explained

the best Dr. Steinman [the Schilling petitioner’s expert] could do was to muster up some literature, like Youssef, suggesting that the NF-kB immune signaling pathway can cause upregulation of specific cytokines that the VZV infectious process succeeds in suppressing—concluding from this that the opposite was possible as well, and that vaccination could also stimulate this pathway to “un-suppress” a latent VZV infection. But the articles cited do not in the least stand for this speculative contention, and instead merely explore ways to make vaccination more effective in promoting immune memory, especially in elderly recipients. See, e.g., Haralambieva. They also seem more focused on the immune response to an active and progressing VZV infection, as opposed to what is relevant here—when the infection becomes latent, and what might in turn cause subsequent reactivation. Thus, articles like El Mjiyad make reliable scientific observations about how

¹⁸ All three items of literature cited in M.R. by the Chief Special Master are items of literature relied upon by Mr. Legault’s expert, Dr. Arts, in the Legault case before the Chief Special Master.

an active VZV infection will initially inhibit NF-kB activity—but not that stimulation of the same pathway later on can cause reactivation.

Schilling v. Sec’y of Health & Hum. Servs., 2022 WL 1101597, at *19 (emphasis in original; alteration added). In both M.R. v. Secretary of Health & Human Services and Schilling v. Secretary of Health & Human Services, the Chief Special Master determined that he did not deem the “sub-contention” of NF-kB playing a role in allegedly autoimmune-mediated injuries persuasive. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 21. The Chief Special Master noted in his decision in Legault:

In M.R. (the case more directly on point), I noted that even if the description of the NF-kB pathway were correct, and its association with immune processes accepted, it was speculative to leap from that to the conclusion that a vaccine could aberrantly stimulate NF-kB to cause hearing loss (noting also that there – as here – the petitioner relied on Merchant in part for this aspect of the causations theory.

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 21 (citing M.R. v. Sec’y of Health & Hum. Servs., 2023 WL 4936787, at *32-33).

The Chief Special Master also discussed one of his earlier vaccine cases, Vanore v. Secretary of Health & Human Services, 2024 WL 3200287, which was criticized by petitioner, to offer what the Chief Special Master described as “a useful overview of the logic behind these kinds of claims [vaccine caused SSNHL and/or tinnitus] – as well as why they routinely fail.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 21 (citing Vanore v. Secretary of Health & Human Services, 2024 WL 3200287, at *20) (alteration added). Chief Special Master Corcoran stated:

First the proposition that sudden hearing loss may be immune-mediated does not mean that a vaccine’s general stimulation of the immune system can turn pathogenic and cause SSNHL. Vanore, 2024 WL 3200287 at *20. The fact that vaccines cause localized inflammation or stimulate cytokines is only a starting point for a successful causation theory, and as concluded by Respondent’s experts in Vanore, “it is not likely that the limited systemic inflammatory effect of an unadjuvanted flu vaccine would result in a cascading, pathologic process specific to the inner ear.” Id. Furthermore, the petitioner in Vanore was unable to establish that SSNHL is solely or predominantly mediated by an immune process. Id. Thus, I found the immune-mediated theory to be evidentiarily insufficient to meet the preponderance standard. Id.

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 21 (citing Vanore v. Sec’y of Health & Hum. Servs., 2024 WL 3200287, at *20) (emphasis in original).

The Chief Special Master, in his Legault decision, reviewed the facts of Mr. Legault’s case, while also reviewing the determinations and reasonings in other Vaccine

cases, but found that Mr. Legault has not met his burden under the first Althen prong under the Vaccine Act to prove entitlement to compensation. See Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 23. As discussed above, a Special Master is permitted to consider existing Vaccine Program case law as an analytical tool to aid him in his decision making. See Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1366-67 (quoting Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d at 961); see also Soto Galvan v. Sec'y of Health & Hum. Servs., 151 Fed. Cl. at 795; Nunez v. Sec'y of Health & Hum. Servs., 144 Fed. Cl. 540, 548 (2019). A Special Master, however, must examine each case before him or her based on the particular facts of the case under review. See Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. at 720; see also Sharpnack v. Sec'y of Health & Hum. Servs., 27 Fed. Cl. at 460.

In the case now before the court, petitioner also argues that the Chief Special Master relied “heavily upon ‘the probative value of Baxter,’ despite the serious concerns raised” by both petitioner’s expert Dr. Arts and also petitioner’s expert in Madigan v. Secretary of Health & Human Services, 2021 WL 3046614, at *17 (quoting Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 24), regarding the Baxter study. Petitioner further contends that Dr. Arts explained the limitations of the Baxter study in his expert report, and, thus, petitioner argues, the Baxter study does not undermine petitioner’s position. Petitioner quotes from Dr. Arts’ expert report in his Motion for Review that with regards to the Baxter study:

“They reviewed only 50 cases of sudden sensorineural hearing loss, occurring within 28 days of vaccination (25 patients) vs. within 9 months to 28 days (25 patients). Using a statistically complex case-centered method, they found an increase in odds-ratio of being vaccinated in the sudden hearing loss patients vaccinated within the first 28 days vs. the earlier (9 months—28 days) groups. This does not at all constitute robust evidence that there is no relationship between influenza immunization and sudden sensorineural hearing loss.”

(citing Baxter, Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis, 155 Otolaryngology – Head and Neck Surgery at 82-83) (emphasis added by petitioner). Petitioner also quotes from Special Master Horner’s decision in Madigan in his Motion for Review to support the proposition that the Baxter study does not undermine petitioner’s argument that the flu vaccine could cause petitioner’s SSNHL:

“[T]he authors noted that a limitation of their study is that only medically attended cases of SSNHL would have been captured. Additionally, those cases that were included were not individually reviewed to confirm diagnosis and/or onset date. Also significant, the authors considered the date of onset to be the date on which any hearing-related diagnosis was given. Dr. Hicks explained, however, that delay in treatment is a major problem in the clinical care of SSNHL. see also Massachusetts Eye and Ear, Diseases and Conditions: Sudden Deafness (noting that delay in diagnosis is the “greatest clinical problem in SSNHL.”) Because SSNHL

symptoms can be confused with benign issues like wax impaction or congestion, patients often wait days or weeks before seeking medical evaluation and then may be treated symptomatically for a period before being referred for diagnosis. (Massachusetts Eye and Ear) Thus, in light of Dr. Hicks's testimony, these study limitations appear to be especially meaningful to the identification of cases of SSNHL temporally proximate to flu vaccination. This suggests a need to interpret the study cautiously, particularly given that the study included an equivocal finding of an association even with these limitations.”

(quoting Madigan v. Sec’y of Health & Hum. Servs., 2021 WL 3046614, at *17) (internal citations omitted; alteration added).

Respondent answers:

The Chief Special Master acknowledged that “even though no epidemiologic study can ever fully rebut the possibility of a rare instance of vaccine causation happening,” the Baxter study “reached statistically-reliable results, and observed that a flu-vaccinated population’s incidence of hearing loss was not higher than a comparable unvaccinated group.” [Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op.] at 24. The Chief Special Master further found that “Dr. Arts’s [petitioner’s expert] attempt to undermine Baxter was unpersuasive” because Dr. Arts “ignore[d] the millions of vaccination events in the greater sample, and thus misapprehends the thrust of Baxter’s conclusion – that the risk of incurring SSNHL due to the flu vaccine is incredibly low, regardless of when hearing loss-related symptoms manifest.” Id.; see also Grant v. Sec’y of Health & Hum. Servs., 956 F.2d 1144, 1149 (Fed. Cir. 1992) (“considerable weight [is] due to epidemiological studies in the absence of direct evidence of actual causation[.]”) (alterations added by respondent); cf. Tullio v. Sec’y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *10-11 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (“One of the [] arguments—that epidemiology is not relevant to individual cases—has been rejected for being inconsistent with both law and medicine.”). Based on the applicable caselaw, the consideration the Chief Special Master gave to the Baxter study was not arbitrary and capricious. Henry v. Sec’y of Health & Hum. Servs., No. 17-721V, 2022 WL 2301321, at *33 (Fed. Cl. Spec. Mstr. May 2, 2022) (finding that the Baxter article constitutes “persuasive evidence” that there is no association between the flu vaccine and autoimmune inner ear disease).

(first alteration added; subsequent alterations made by respondent; emphasis in original).

In Legault, the Chief Special Master determined there was “evidence in this case [Mr. Legault’s] directly undercutting a vaccine-SSNHL association – a large-scale epidemiologic study, Baxter [et. al., Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis, 155 OTOLARYNGOLOGY – HEAD AND NECK

SURGERY at 83], that reached statistically-reliable results, and observed that a flu-vaccinated population’s incidence of hearing loss was not higher than a comparable unvaccinated group,” and “that the risk of incurring SSNHL due to the flu vaccine is incredibly low.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 24 (emphasis in original; alterations added). The Chief Special Master stated that he had previously noted the probative value of the Baxter study in other cases, despite the fact that “no epidemiologic study can ever fully rebut the possibility of a rare instance of vaccine causation happening.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 24 (citing Vanore v. Sec’y of Health & Hum. Servs., 2024 WL 3200287, at *21; M.R. v. Sec’y of Health & Hum. Servs., 2023 WL 4936727, at *32) (emphasis in original). The Chief Special Master further stated:

And (as noted in Madigan) Baxter does not wholly “close the door” on a vaccine-SSNHL relationship; no doubt an even more methodologically-sound study is possible. But epidemiologic evidence is not embargoed from my consideration merely because claimants are never compelled to offer it to prove causation. See Perekotiy v. Sec’y of Health & Hum. Servs., No. 16-997V, 2020 WL 12904810, at *13 (Fed. Cl. Spec. Mstr. Apr. 20, 2020), mot. for review den’d, No. 16-997V, 2020 WL 5887548 (Fed. Cl. 2020) (citing Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1378–79 (Fed. Cir. 2009)). While Baxter alone does not rebut Petitioner’s causation theory, its existence greatly undercuts it. See Henry v. Sec’y of Health & Hum. Servs., No. 17-721V, 2022 WL 2301321, at *33 (Fed. Cl. Spec. Mstr. May 2, 2022) (S.M. Oler) (finding that the Baxter article constitutes “persuasive evidence” that there is no association between the flu vaccine and autoimmune inner ear disease).

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 24 (emphasis in original). The Chief Special Master also found that petitioner’s expert Dr. Arts focused “on the relatively small number of instances of post-flu vaccine SSNHL observed from the sample,” and ignored “the millions of vaccination events in the greater sample, and thus” misapprehended “the thrust of Baxter’s conclusion – that the risk of incurring SSNHL due to the flu vaccine is incredibly low, regardless of when hearing loss-related symptoms manifest.” Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 24 (citing Baxter, Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis, 155 OTOLARYNGOLOGY – HEAD AND NECK SURGERY at 83) (emphasis in original). The Chief Special Master determined that Dr. Arts’ attempts to undermine the Baxter study were unpersuasive. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 24.

As indicated above, a Special Master is permitted to enquire into the scientific reliability of submitted medical literature and the credibility of the expert testimony, including contradictory expert testimony, and then to make a determination as to what the Special Master finds credible and applicable. See Terran ex rel. Terran v. Sec’y of Health & Hum. Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999); see also Holmes v. Sec’y of Health & Hum. Servs., 115 Fed. Cl. at 490-91; Locane v. Sec’y of Health & Hum. Servs., 99 Fed.

Cl. at 727. Moreover, the Chief Special Master is not required to agree with an expert's opinion simply because it is the opinion of an expert, especially if the "analytical gap between the data and the opinion proffered" by the expert is great. See Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. at 743 (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)); see also Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d at 1339.

That the Chief Special Master weighed the credibility and reliability of some of the same medical literature including the Baxter study, submitted in other cases when reviewing Mr. Legault's case does not automatically lessen the credibility and reliability of the conclusions the Chief Special Master reached in petitioner's case. Regardless of whether Special Master Horner found the Baxter study limited in its reliability and the stress response theory credible in Madigan, does not mean that the Chief Special Master is bound to find the Baxter study unreliable and the stress response theory credible. See Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d at 1358 (quoting Boatmon v. Sec'y of Health & Hum. Servs., 138 Fed. Cl. at 571); see also Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. at 720; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. at 630; Sharpnack v. Sec'y of Health & Hum. Servs., 27 Fed. Cl. at 461. Instead, it appears that the Chief Special Master plausibly evaluated the Baxter study in the case before him, based on the facts in Mr. Legault's case.

As discussed above, the second Althen prong requires the petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278; see also Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d at 1326. The logical sequence of events under the second prong of Althen can be supported by "reputable medical or scientific explanation" or "evidence in the form of scientific studies or expert medical testimony." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278 (quoting Grant v. Sec'y of Health & Hum. Servs., 956 F.2d at 1148).

With regards to petitioner's argument that "[t]he Chief Special Master arbitrarily and capriciously reduces Petitioner's theory under Althen prong two, [that the November 19, 2019 flu vaccine caused Mr. Legault's SSNHL] to 'a bare temporal relationship.'" (alteration added). Petitioner states:

Dr. Poston did not merely speculate. He clearly states "I do think its [sic] possible he could have some type of viral induced tinnitus after the flu shot but we have no way of confirming this." Dr. Poston's statement that there is no way of confirming tinnitus after the flu shot aligns perfectly with the explanation of Petitioner's expert Dr. Arts. Dr. Arts explains that "[r]esearch in the human ear is limited by our inability to visualize or biopsy the inner ear during life without resultant profound hearing loss." Additionally, Dr. Arts states "[g]iven that the inner ear is not accessible for biopsy or microscopic imaging during life, clear scientific evidence of causation is not possible in humans." In other words, Dr. Poston's statement merely reflects the scientific reality that the inner ear is not accessible for testing or biopsy.

(emphasis and last two alterations added by petitioner; internal references omitted). Petitioner also argues that the following three medical records constitute support for

petitioner's claim that the petitioner had suffered SSNHL caused by a vaccination reaction: (1) Dr. Lake's assessment at the September 29, 2021 visit of petitioner with "[a]dverse effect of vaccine, sequela – T50.Z95S (Primary);" (2) Dr. Eades' assessment at the October 7, 2021 visit that petitioner had "Guillain-Barre [sic] syndrome subsequent to influenza vaccine,"¹⁹ and "Vaccine reaction," and (3) Dr. Poston's April 4, 2022 COVID 19 vaccine exemption issued to petitioner because petitioner "was seen due to the new onset of multiple symptoms including hearing loss, tinnitus, headache that presented in the immediate aftermath of having a flu vaccination in late [November 19,] 2019," and that petitioner "is at high risk for negative outcome if he receives future vaccinations including the Covid vaccination." (alterations added). In response to the Chief Special Master's finding that petitioner did not "seek treatment until about a month post-vaccination, somewhat undermining his complaints of a close-in-time onset," Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 25, petitioner maintains that he "sought treatment after a reasonable amount of time had passed in which he waited to see if his symptoms would go away on their own." Petitioner additionally argues

Mr. Legault is clear in his under-oath affidavit that his symptoms began approximately three to four days after receiving the shot, and he explains "[a]fter realizing these symptoms were not going away, I made an appointment with an ENT specialist and received an appointment on December 17, 2019." Mr. Legault sought treatment after a reasonable amount of time had passed in which he waited to see if his symptoms would go away on their own.

(alteration added by petitioner; internal references omitted).²⁰ Petitioner, therefore, argues that "the Chief Special Master's assertion that 'there is an overall lack of reliable or trustworthy treater opinion evidence favoring causation,' is arbitrary and capricious" (quoting Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26).

¹⁹ Petitioner did not allege he suffered from Guillain-Barré syndrome as a result of his November 2019 flu vaccination in his petition filed with the Office of the Special Masters.

²⁰ The Vaccine Act does not permit a petitioner to prove entitlement to compensation based on petitioner's testimony alone. Findings of fact must be substantiated by medical records or medical opinion. See 42 U.S.C. § 300aa-13(a)(1); see also LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d at 1341 ("In Vaccine Act cases, petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard."); Althen v. Sec'y of Health & Hum. Servs., 418 at 1278 ("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[.]'" (quoting Grant v. Sec'y of Health & Hum. Servs., 956 F.2d at 1148) (alterations in original)).

Regarding Althen prong 2, respondent argues that the Chief Special Master “thoroughly and thoughtfully evaluated the evidence.” Respondent also argues that “[w]hile petitioner clearly disagrees with the Chief Special Master’s findings, that is not grounds to disturb [the Chief Special Master’s] conclusion that the flu vaccine did not cause his SSNHL and tinnitus, where his findings are supported by the record.” (alterations added). Respondent further argues that “[b]ecause his [the Chief Special Master’s] well-supported findings are not ‘wholly implausible,’ this court is compelled to uphold the findings as not arbitrary and capricious.” (quoting Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d at 1338) (alterations added).

Although the Chief Special Master’s decision in petitioner’s case demonstrates a thorough review of the record before him, the Chief Special Master is “not required to discuss every piece of evidence or testimony” in his decision. See Paluck ex rel. Paluck v. Sec’y of Health & Hum. Servs., 104 Fed. Cl. at 467; Snyder ex. rel. Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. at 728; Snyder by Snyder v. Sec’y of Health & Hum. Servs., 36 Fed. Cl. at 466. Although the Chief Special Master did not discuss the 2022 COVID 19 vaccine exemption from Dr. Poston in depth in his analysis of petitioner’s case, he did mention it in the factual background of his decision. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 3. The court also notes that the 2022 COVID 19 vaccine exemption from Dr. Poston was provided to petitioner well after petitioner had filed his petition with the Office of the Special Masters.

The Chief Special Master properly used his discretion to weigh the evidence presented and found it to be insufficient to find entitlement under the Vaccine Program. See Hibbard v. Sec’y of Health & Hum. Servs., 698 F.3d at 1368-69; see also Burns v. Sec’y of Health & Hum. Servs., 3 F.3d at 417. Special Masters should consider the medical information provided by treating physicians when making a determination as to Althen prong two, however, he or she need not accept that information without question. See Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d at 1326; see also 42 U.S.C. § 300aa–13(b)(1); Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d at 1528. Moreover, the Vaccine Act makes clear that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court” and must be evaluated within the context of the facts in the case under review. See 42 U.S.C. § 300aa–13(b)(1) (alteration added). The Chief Special Master’s decision demonstrated that he properly weighed the evidence presented, including contemporaneous medical records and testimony, in Mr. Legault’s case. The Chief Special Master determined that

the record in this case (which is somewhat limited, and characterized by large gaps in treatment) offers scant support for the “did cause,” second Althen prong. Petitioner can only point to his post-vaccination onset of tinnitus and left-sided hearing loss as evidence of a “logical sequence of cause and effect” – even though the Program clearly recognizes that a bare temporal relationship does not prove a vaccine caused a subsequent injury.

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 24-26 (citing Bulman v. Sec’y of Health & Hum. Servs., 2023 WL 5844348, at *14 (footnote omitted)). Medical records are considered trustworthy evidence when the medical records are contemporaneous to the medical event, however, the medical records cited by petitioner

from his medical history are not contemporaneous to the onset of petitioner's symptoms. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d at 1528. The Chief Special Master noted that the closest contemporaneous medical record was a month after vaccination and symptom onset and, thus, the Chief Special Master found the submitted medical records not trustworthy evidence or conclusive for purposes of entitlement under the Vaccine Program. In petitioner's case, the Chief Special Master determined that the opinions of Dr. Poston and Dr. Eades that petitioner's SSNHL was, or could be, vaccine related were not reliable evidence or dispositive in favor of causation under the second Althen prong because the record from Dr. Eades "reflects Dr. Eades's erroneous speculation that Petitioner had also experienced GBS, undermining the reliability of any causal opinion there set [sic] (since there is no way on this record to conclude that Petitioner ever likely had GBS)," and "Dr. Eades referred to Dr. Poston's purported opinion of vaccine causation from June 2020 – yet that record reveals that Dr. Poston himself did little more than speculate that vaccine causation could be explanatory." Legault v. Sec'y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 26 (emphasis in original; alteration added). The Chief Special Master used his discretion to weigh the evidence in the record before him and rationally explained why he did not find the later in time medical opinions of Dr. Poston and Dr. Eades to be persuasive and reliable. The Chief Special Master did not ignore the opinions of petitioner's treating physicians, rather, he considered and evaluated the medical opinions but found them unpersuasive. See Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1253-54; see also Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d at 1338; Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1360; Hines on Behalf of Sevier v. Sec'y of Health & Hum. Servs., 940 F.2d at 1528; Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. at 56-57.

Petitioner separately argues that the Chief Special Master improperly elevated petitioner's burden of proof under the second Althen prong by "forcing" him to demonstrate "clinical signs of an immunological process," that are not otherwise required under the stress response theory as advanced by petitioner. As discussed above, petitioner quotes Special Master Horner in Madigan in his Motion for Review discussing the Madigan petitioner's expert's view on the clinical signs evaluated when diagnosing SSNHL:

"Inner ear disorders are by their nature very difficult to investigate because the inner ear cannot be penetrated in an ordinary clinical setting. Moreover, Dr. Hicks stressed the delicacy of the inner ear to minute changes and did not suggest that the stress response theory would lead to outward clinical signs of inflammation beyond the manifestations of SSNHL itself. For example, Dr. Hicks indicated that lab results are generally not beneficial in assessing SSNHL. Instead, diagnosis is usually based on history, examination, and MRI,^[21] with 90 percent of the diagnosis being the history. Accordingly, further clinical findings beyond the fact of petitioner having

²¹ The court notes it was recommended to petitioner that he receive an MRI to aid in diagnosing his ear problem, however, the record before the court does not reflect that Mr. Legault ever received an MRI for his hearing problems contemporaneously to receipt of the flu vaccine or subsequently.

otherwise unexplained sudden hearing loss temporally proximate to his vaccination are not necessarily expected. As noted above, 85-90% of SSNHL cases remain idiopathic despite investigation in the course of care.”

(quoting Madigan v. Sec’y of Health & Hum. Servs., 2021 WL 3046614, at *18 (internal citations omitted; footnote added)). Petitioner alleges, based on a reading of the above quote from Madigan that “hearing loss may be the only clinical finding,” and, thus, the Chief Special Master should not have required a demonstration of clinical signs of an immunological process that is not required by the stress response theory.

As discussed above, after reviewing the record before him, the Chief Special Master did not accept the science underpinning petitioner’s stress response theory as reliable or persuasive. See Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 24-25. Removing the stress response theory as a reliable explanation of causation and without strong treater support in the record to explain petitioner’s SSNHL, the Chief Special Master determined regarding Althen prong two:

There is otherwise no evidence from the record (beyond the fact of injury itself) that Petitioner experienced an unusual or suspect immunologic process (for example, characterized by inflammation manifesting in other ways) leading to the symptoms he reported a month after vaccination, or ever yielded testing results consistent with an immune-mediated process that could have been initiated by the November 2019 vaccination. . . . There is no discernible evidence of any other aberrant immune response to the vaccine corroborative of his theory (beyond the fact of hearing loss symptoms and tinnitus – although to point to them as evidence of a “logical sequence of cause and effect” is to engage in circular reasoning). And Petitioner first posited, at the first two instances he sought treatment for his hearing-related concerns (December 2019 and January 2020) that he associated his onset with a viral infection – making no mention of vaccination. While I do not purport on this record to determine what alternative cause the evidence supports (and Dr. Rubinstein himself did not do so either), the medical record does not preponderantly support vaccination as causal in this case (and that matter is Petitioner’s affirmative burden to establish).

Legault v. Sec’y of Health & Hum. Servs., No. 21-2343V, Slip Op. at 25-26 (emphasis in original; omission added). The Chief Special Master did not rule that the stress response theory required petitioner to demonstrate some unusual immunological process. The Chief Special Master concluded that without reliable, persuasive medical records, and without evidence of a suspect immunological response to the vaccination, petitioner has not demonstrated under Althen prong two a logical sequence of cause and effect to establish that the November 19, 2019 flu vaccination was the reason for the medical issues petitioner claimed were the result of his receiving a flu vaccination, and, thus, petitioner was unsuccessful. See Legault v. Sec’y of Health & Hum. Servs., No. 21-

2343V, Slip Op. at 25-26. The Chief Special Master's determination regarding Althen prong two was not arbitrary or capacious.

The Chief Special Master considered all the relevant evidence in the record before him, including the expert reports of petitioner and the expert reports of the government, as well as the assessments of petitioner's treating physicians, as demonstrated throughout the Chief Special Master's discussion of the record in his decision. The Chief Special Master drew plausible inferences from the record before him and articulated a rational conclusion for the basis of his decision when he determined that petitioner had not met his burden of proof under the Vaccine Act and Althen prongs one and two. See Hines on Behalf of Sevier v. Sec'y of Health & Hum. Servs., 940 F.2d at 1528; see also Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1253-54; Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d at 1338; Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1360; Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. at 56-57. The Chief Special Master did not accept the stress response theory petitioner advocated to establish Vaccine Act compensation eligibility under Althen prong one. Moreover, while reviewing the record, the Chief Special Master did not impose a new requirement or raise petitioner's burden to require that personal stress must exist in the petitioner's history prior to vaccine administration in order to prevail under Althen prong one using the stress response theory. Furthermore, the Chief Special Master did not accept that petitioner had met his burden to prove a logical sequence of cause and effect under Althen prong two. The Chief Special Master's findings and legal conclusions under Althen prong one and Althen prong two were not arbitrary or capricious.

As discussed above, this court will only set aside the Chief Special Master's decision if it determines that the findings of fact and conclusions of law are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. See 42 U.S.C. § 300aa-12(e)(2)(B); see also Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d at 1358; Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1366; Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d at 1350 (citing Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d at 1324); Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d at 1321; Markovich v. Sec'y of Health & Hum. Servs., 477 F.3d at 1356-57; Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1360. Respondent argues in response to the Motion for Review that petitioner is attempting to relitigate the case before this court and that petitioner is requesting that this court reweigh the evidence and substitute its own judgment of the facts in place of the Chief Special Master's conclusions. Respondent states that "petitioner argues that the Chief Special Master's findings were arbitrary and capricious because the Chief Special Master did not accept petitioner's expert's proposed stress response theory of alleged vaccine causation." As indicated above, this court may not reweigh the factual conclusions of the Chief Special Master except to determine if the findings of fact were arbitrary and capricious. See Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1249 and 42 U.S.C. § 300aa-12(e)(2)(B); see also Lozano v. Sec'y of Health & Hum. Servs., 958 F.3d at 1368; Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1366 (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1360); Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d at 1349; Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d at 1321(citing Munn v. Sec'y of Health & Hum. Servs.,

970 F.2d at 870 n.10). So long as “the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.” Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs., 717 F.3d at 1367 (quoting Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d at 1363) (alterations in original). The Chief Special Master plausibly determined that petitioner had not proven a medical theory causally connecting the vaccination and the injury, nor proven a logical sequence of cause and effect, by a preponderance of the evidence under either Althen prong one or Althen prong two.

C O N C L U S I O N

For the reasons described above, the Chief Special Master’s decision was not arbitrary or capricious. The Motion for Review is **DENIED**. The Clerk of the Court shall enter **JUDGMENT** consistent with this Opinion.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge