In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-1173V
(not to be published)

MAHESHCHAN INANDAR, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Corcoran Filed: February 8, 2019 Entitlement; Ruling on Record; Influenza ("flu") Vaccine; Sudden Sensorineural Hearing Loss ("SNHL"); Onset; Alternative Cause

Howard S. Gold, Gold Law Firm, LLC, Wellesley Hills, MA, for Petitioner.

Claudia B. Gangi, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On October 9, 2015, Maheshchan Inamdar filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] In it, Mr. Inamdar alleged that the influenza ("flu") vaccine he received on September 12, 2013, caused him to develop bilateral, sudden sensorineural hearing loss ("SNHL"). Petition (ECF No. 1) at 1.

Following a fact hearing, the filing of expert reports, and my review of the record as a whole, I determined that this case was best resolved on the papers rather than by hearing. To that end, Petitioner filed a Motion for Ruling on the Record and brief in support of his claim, dated August 5, 2018 (ECF No. 41) ("Mot."). Respondent thereafter opposed Petitioner's entitlement to a damages award by brief dated September 7, 2018 (ECF No. 42) ("Opp."). Petitioner also filed a

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

reply on September 14, 2018 (ECF No. 43) ("Reply"). Having completed my review of the evidentiary record and the parties' filings, I hereby **DENY** Petitioner's request for compensation, for the reasons stated below.

I. Factual Background

A. *Medical Records*

On September 12, 2013, Mr. Inamdar received the flu vaccine at the Harvard Vanguard office of his primary care physician ("PCP"), Dr. Madu A. Wahi, in Sudbury, Massachusetts. Ex. 3 at 1. Petitioner was eighty years-old at the time of vaccine administration. *Id.* Records indicate that he previously received the flu vaccine in 2009, 2011, and 2012, without any noted complications. *Id.* at 2.

At the time of the vaccination, Petitioner's health history was significant for sudden vision loss in 2006 and *existing* mild hearing loss. Ex. 4 at 30 (noting vision problems in right eye), 32 (noting hearing loss); Ex. 5 at 30. Office notes taken during the September 12th visit in fact indicate that on the day he received the flu vaccine, Petitioner requested a hearing test to follow-up on these earlier-in-time symptoms. *Id.* at 30. Petitioner was otherwise noted to be feeling well and had no active complaints. *Id.* A physical examination was normal. Exam notes indicated that he was currently taking Atenolol (for hypertension/coronary artery disease), a multivitamin, Flomax (for urinary retention), Albuterol (for breathing troubles), and using topical ointment for a rash. *Id.* at 30-31.

Petitioner's records prior to vaccine administration also indicate that he was diagnosed with bronchitis on September 3, 2013 (nine days prior to his receipt of the flu vaccine). Ex. 4 at 39-42. Petitioner had presented to Dr. Wahi, but was assessed by Dr. Peter Britton. *Id.* at 40. He complained of symptoms including recurring productive cough, fatigue, shortness of breath, and a fever. *Id.* at 40-41. Upon exam, Dr. Britton noted that Petitioner appeared "mildly fatigued, but comfortable." *Id.* at 41. Treatment notes indicated that Petitioner was prescribed a course of Azithromycin[3] (or a "Z pack") to treat his bronchitis symptoms. *Id.* at 41; Ex. 5 at 30. He was directed to take two tablets on the day of the visit, then one tablet daily for the next four days. Ex. 4 at 41.

On September 13, 2013 (one day post-vaccination), Petitioner had a consultation with audiologist Patricia Weil-Lefkovith at Harvard Vanguard. Ex. 4 at 28-29. Petitioner reported having experienced sudden, diminished hearing loss in both ears when "he [a]woke [that] morning." *Id.* at 28. An examination was conducted, and testing revealed moderate sensorineural hearing loss in the right ear, along with severe-to-profound SNHL in the left ear. *Id.* at 29.

[3] Azithromycin is an antibiotic that inhibits bacterial protein synthesis. It is effective against a wide range of bacteria and is used to treat mild to moderate infections. *See Dorland's Medical Dictionary* 187 (32nd ed. 2012) (hereinafter "*Dorland's*").

Petitioner was referred to a Harvard Vanguard ENT specialist, Dr. Henri Tannas, for further evaluation. *Id.*

The record next reveals that Petitioner saw Dr. Tannas later that same day. Ex. 4 at 25. Dr. Tannas was informed[4] that Petitioner had experienced an onset of sudden hearing loss and tinnitus within the last 24 hours. *Id.* His health history indicated an onset of bronchitis within the last week or two, but a normal wellness exam the day prior. *Id.* at 26-27. Following an audiogram, Dr. Tannas diagnosed Petitioner with sudden idiopathic hearing loss of both ears. *Id.* at 27. Mr. Inamdar's left ear was noted to be in the moderate-to-severe range of loss (between 55dB and 75 dB, with 28% speech discrimination). *Id.* at 29. His right ear was in the moderate-to-severe range, but with non-testable discrimination. *Id.* He prescribed high dose steroids for two weeks followed by a rapid taper. *Id.* at 27. Dr. Tannas also ordered an MRI to rule out retrococlear pathology, though he noted such a diagnosis would be "very unlikely as [hearing loss] is bilateral." *Id.*

On September 16, 2013 (four days post-vaccination), Petitioner was evaluated by Dr. Ronald de Venecia, an ENT specialist with the Massachusetts Eye and Ear Infirmary ("MEEI"). Ex. 5 at 30. Petitioner reported that the day after he received the flu vaccine, he noticed an acute decline in hearing in both ears that occurred over a period of hours (with accompanying tinnitus). *Id.* Dr. de Venecia also noted that Petitioner was "currently being treated for bronchitis with a Z pack." *Id.* Examination revealed that Petitioner could not detect a tuning fork with the right ear. *Id.* at 30. His speech reception threshold, however, was difficult to determine due to a language barrier. *Id.* Exam notes also indicated that Petitioner's facial nerve function was normal, and there was no spontaneous nystagmus or ataxia. *Id.* Dr. de Venecia diagnosed Petitioner with "[b]ilateral sudden sensorineural hearing loss that occurred within 24 hours after receiving a flu shot." *Id.* He explained to Petitioner, however, that a vaccine-induced reaction would be "very unusual" given the nature of the injury. *Id.* Dr. de Venecia instructed Petitioner to continue his current 19-day course of oral steroids and return for follow-up testing upon completion. *Id.*

Petitioner returned to Dr. de Venecia for two follow-up appointments on September 23, 2013, and October 2, 2013, respectively. Ex. 5 at 25-26, 27-28. During the September 23rd evaluation, it was noted that Petitioner was not responding to oral steroid therapy and no improvement was noted. *Id.* at 28. The audiogram from the October 2nd appointment indicated a nearly flat sensorineural hearing loss on the left, and profound sensorineural hearing loss on the right. *Id.* at 26. Exam notes from October 2nd indicated that Petitioner had a modest response to a 19-day course of oral steroid therapy (Prednisone) on the left, and no response to steroid therapy on the right. *Id.* It was noted that Petitioner felt that hearing in his left ear had improved. *Id.* An MRI previously conducted on September 21, 2013, was interpreted as showing no evidence of

[4] Although Petitioner is conversant in English, it is not his first language. During a fact hearing conducted in March 2017, it was revealed that (due to the language barrier, as well as his age), Petitioner's wife or daughter typically accompanied him to most medical visits. *See* Fact Ruling, dated April 27, 2017 (ECF No. 31) at 3. It is thus not evident that Petitioner necessarily informed treaters himself of his condition, as opposed to his wife or daughter, and the records themselves do not consistently identify which individual provided the medical history at any given appointment.

abnormal enhancement in the brain. *Id.* at 29, 36. Based on the above, Dr. de Venecia concluded that there were "no findings to explain sensorineural hearing loss" based on the MRI imaging results. *Id.* at 28.

Over the course of the next month, Petitioner received four intratympanic steroid injections in his left ear with noticeable improvement. Ex. 5 at 22-24. Petitioner had a follow-up visit with Dr. de Venecia on October 21, 2013, and November 8, 2013. *Id.* at 9, 21. Petitioner reported improvement in both ears during the October 21st appointment. *Id.* at 21. An audiogram completed that day demonstrated a 10dB improvement in the left ear and a 10-30 dB improvement in the right. *Id.* at 20. Blood work collected during the visit indicated a low white blood cell count and elevated sedimentation rate. *Id.* at 17-19. An autoimmune disease panel (including testing for autoantibodies, thyroid function, and Lyme disease) was negative. *Id.* at 9, 10-16. During the November 8th consultation, Dr. de Venecia recommended that Petitioner schedule an appointment with an immunologist or infectious disease physician who specializes in vaccines. *Id.* at 9. Dr. de Venecia expressed some concern that Petitioner had experienced an adverse reaction to the flu vaccine. *Id.* (noting "this appears to be a very unusual and unexpected reaction to the flu vaccine"). It does not appear, however, that Mr. Inamdar ever acted on this advice.

Approximately two months later, on January 16, 2014, Petitioner returned to Dr. de Venecia for an additional follow-up exam. Ex. 5 at 3. His hearing loss in the left ear had improved somewhat following steroid therapy, but he continued to experience profound sensorineural hearing loss on the right. *Id.* Dr. de Venecia noted that MRI scans and autoimmune disease testing results were negative, however. *Id.* Repeat bloodwork revealed a normal white blood count, and a slightly elevated sedimentation rate. *Id.* Petitioner's head and neck examination (except for the hearing loss) was normal. *Id.* A repeat audiogram from April 1, 2014, showed that Petitioner's hearing in his right ear had improved, while hearing in the left ear was stable (when compared to the audiogram completed in October 2013). *Id.* at 2.

There is a subsequent nine-month gap in Petitioner's ENT records. On September 22, 2014, Petitioner returned for a follow-up appointment with Dr. de Venecia for monitoring of his condition. Ex. 5 at 1. Dr. de Venecia noted that Petitioner had obtained hearing aids for both ears, which resulted in improved hearing. *Id.* Those same treatment notes also indicated, however, that Petitioner was still experiencing decreased hearing in both ears (with the right ear still worse than the left), although overall his prior decline had stabilized. *Id.* Dr. de Venecia's impression remained "[b]ilatral symmetric sensorineural hearing loss with history of sudden hearing loss after flu vaccine." *Id.* Following the appointment, Dr. de Venecia recommended that Petitioner continue using hearing aids in both ears and return for a follow-up "as necessary." *Id.*

Petitioner has also filed various treatment records for ailments unrelated to hearing loss. *See* Ex. 4 at 22-24 (1/15/2014 treatment for mild asthma); Ex. 4 at 6-7 (3/6/2014 treatment for shortness of breath), Ex. 6 at 41-43 (5/30/2014 treatment for chronic dyspnea, progressive wheezing, and obstructive lung disease); Ex. 4 at 1-5 (11/8/2014 medical-prevention visit for planned trip to

India); Ex 6 at 91-92 (3/6/2015 diagnosis of shingles). These remaining records make no mention of hearing complaints.

B. *Petitioner's Affidavits*

In addition to the medical records discussed above, Petitioner offered two affidavits detailing the course of his treatment and health history following his receipt of the flu vaccine. *See* Affidavit, filed as Ex. 2, dated October 1, 2015 (ECF No. 8-1) ("Aff."); Supplemental Affidavit, filed as Ex. 8, dated December 7, 2016 (ECF No. 21-1) ("Supp. Aff.").

The majority of Petitioner's statements contained in his first affidavit are consistent with the medical facts discussed above. Mr. Inamdar asserted therein that he experienced diminished hearing in both ears with sudden onset one day following his receipt of the flu vaccine. Aff. at 1. Currently, in his own estimation, his left ear is "completely unable to detect language" and his right ear functions at "twenty-five (25%)." *Id.* at 2. Petitioner stated that his hearing loss has negatively impacted his life in many ways. *Id.* at 1-2. Due to this "marked decline" in hearing, Mr. Inamdar obtained hearing aids in both ears, and can no longer enjoy certain activities (such as listening to music or watching television). *Id.* at 2. Petitioner also stated he is unable to communicate well with family members and can no longer comfortably babysit his grandchildren. *Id.* Petitioner's affidavits make no mention of his preexisting hearing loss (described at times in the medical record as mild or age-appropriate).

Petitioner's second affidavit was filed to clarify certain inconsistencies in the record involving his use of Azithromycin to treat his pre-vaccination bronchitis diagnosis. Supp. Aff. at 1-2. In the supplemental affidavit, Petitioner acknowledged that he was diagnosed with bronchitis on September 3, 2013. *Id.* at 1. He indicated, however, that he did not take Azithromycin (or any other antibiotic) for treatment purposes prior to his receipt of the flu vaccine. *Id.* at 1.

C. *April 28, 2017 Fact Ruling*

On March 20, 2017, I held a fact hearing on an issue relevant to the disposition of this case: whether, at the time of his receipt of the flu vaccine, Petitioner had been taking Azithromycin (a medication that has been associated with hearing loss). On April 28, 2017, I issued a fact ruling in which I determined that Petitioner more likely than not had taken Azithromycin prior to administration of the flu vaccine despite witness testimony to the contrary. Fact Ruling, dated Apr. 28, 2017 (ECF No. 31) ("Ruling").

As the Ruling indicates, Petitioner and his caretakers provided persuasive evidence that Petitioner's Azithromycin prescription was not likely filled at his mostly commonly used pharmacy location. Ruling at 10 (citing Ex. 7; Ex. 10). Petitioner's medical records, however, made several contemporaneous references to Petitioner's bronchitis diagnosis and Azithromycin treatment. It was unrebutted that Petitioner was indeed *prescribed* the medication, and medical visits thereafter acknowledged that Petitioner was "currently" taking the medication for the above-noted

respiratory symptoms (and was likely told this by Petitioner or his caretakers). *Id.* (citing Ex. 5 at 30; Ex. 4 at 27). My analysis thus placed significant weight on the medical record evidence suggesting the medication was taken. *Id.* at 10-12.

My Ruling similarly deemed significant the testimony of Petitioner's daughter (Medha Inamdar). She testified that she typically accompanied her father to doctor's visits in order provide both familial support and language assistance, and was present at the above-noted visits where both Petitioner's use of Azithromycin and associated illness were discussed. Ex. 5 at 30. Ms. Inamdar's testimony was somewhat equivocal on the topic of Petitioner's Azithromycin use. Ruling at 10-11. After initially denying knowledge of both Petitioner's bronchitis diagnosis and Azithromycin use, she later allowed for the possibility that she *might* have relayed the information regarding the illness and the prescription to Petitioner's treaters (who definitively noted the "use" of the medication – not that it merely had been prescribed). *Id.* at 11. She also made statements corroborating a logical reason for why she would have known about the treatment: awareness that Azithromycin had in the past made Petitioner feel ill. *Id.*

Upon weighing the proof, I determined that the totality of the evidence best supported the conclusion that Petitioner likely took the medication for his prior-in-time bronchitis diagnosis. Ruling at 10-12. In so determining, I placed great emphasis on the contemporaneous medical records (as Program case law affords), and less weight on the lack of evidence suggesting the prescription was not filled, and also deemed it likely that Ms. Inamdar had known her father was not only prescribed Azithromycin but had taken it as well.

II. Expert Reports

A. *Petitioner's Expert—Dr. David Axelrod*

Dr. Axelrod submitted two written reports in this case. *See* Expert Report, dated November 7, 2016, filed as Ex. 9 (ECF No. 19-1) ("First Axelrod Rep."); Expert Report, dated August 17, 2017, filed as Ex. 11 (ECF No. 34-1) ("Second Axelrod Rep."). According to Dr. Axelrod, Petitioner's SNHL was due to the flu vaccine. Axelrod First Rep. at 1-2.[5]

Dr. Axelrod graduated from the University of Michigan Medical School in 1974 (after obtaining his bachelor's degree at Michigan as well). Ex 9-B (ECF No. 19-2) ("Axelrod CV") at 1. He completed two residencies in internal medicine, one at the University of Toronto and one at William Beaumont Hospital, followed by additional residencies with a fellowship in allergy, immunology, and rheumatology at McGill University. Axelrod CV at 1. He then served as a fellow

[5] Dr. Axelrod's report also characterizes Petitioner's SNHL as a "significant worsening of" pre-existing hearing loss. First Axelrod Rep. at 2; Second Axelrod Rep. at 3. Despite the above, it does not appear that Petitioner alleges a significant aggravation of his hearing loss, but rather categorizes his pre-existing hearing loss as "age-appropriate" or "mild hearing loss" (with "no testing indicating significant loss"). *See* Pre-hearing Brief at 1, 5; Pet. at 1-2. Apart from the statements noted above, Dr. Axelrod's reports do not further explain or theorize that Petitioner experienced a "significant aggravation" of a pre-existing injury under Program standards.

for the National Institutes of Health in the Clinical Immunology Laboratory. *Id.* Dr. Axelrod holds board certifications in allergy and immunology, adult rheumatology, and medical laboratory immunology. *Id.* He currently works in private practice, with the vast majority of his patients having allergies, immunologic conditions, or autoimmune rheumatic diseases. *Id.* He does not appear, however, to have conducted research in immunologic matters that bear on SNHL specifically (or hearing loss conditions generally).

Dr. Axelrod's report proposed two related biologic processes by which the flu vaccine could cause sudden onset of SNHL. First Axelrod Rep. at 1-2, 9. First, he opined that the flu vaccine could cause the production of proinflammatory cytokines immediately upon vaccine administration. First Axelrod Rep. at 2, 5; L. Christian, et al., *Serum Proinflammatory Cytokine Response to Influenza Virus Vaccine Among Women During Pregnancy Versus Non-Pregnancy*, 70 Am. J. Reprod. Immunol. 1 (2013), filed as Ex. 9-D (ECF No. 19-4) ("Christian"). The Christian study was conducted to comprehensively describe inflammatory responses to the trivalent influenza virus vaccine ("TIV") among pregnant women as compared to non-pregnant women. Researchers in Christian compared the levels of proinflammatory cytokine levels in the sera of 28 pregnant women to that of 28 non-pregnant women, finding slightly elevated levels of two specific cytokines (TNF-alpha and IL-6) in *both* groups within 24 hours post-vaccination. *Id.* at 1, 5. Despite the observed increase, researchers concluded that the overall inflammatory response to the TIV flu vaccination was "mild, transient, and generally similar" in pregnant and non-pregnant women. *Id.* The study did not implicate the production of proinflammatory cytokines as pathologically harmful to either group.

Dr. Axelrod also cited to two other studies that he maintained establish that cytokines (including IL-6, TNF-alpha, and IL-1 beta) have been shown to be elevated in the sera of patients with sensorineural hearing problems. First Axelrod Rep. at 2; *see* J. Kuemmerle-Deschner, et al., *NLRP3 E311K Mutation in a Large Family with Muckle-Wells Syndrome—Description of a Heterogenous Phenotype and Response to Treatmen*t, 12 Arthritis Research & Therapy 1, 5 (2011), filed as Ex. 9-F (ECF No. 19-6) ("Kuemmerle-Deschner"); S. Pathak, et al., *Innate Immune Recognition of Molds and Homology to the Inner Ear Protein, Cochlin, in Patients with Autoimmune Inner Ear Disease*, 33 J. Clin. Immunol. 1 (2013), filed as Ex. 9-G (ECF No. 19-7) ("Pathak"). Kuemmerle-Deschner was a 42-patient (single family) study aimed at analyzing the clinical spectrum and patterns of inflammatory parameters (along with treatment) in Muckle-Wells Syndrome ("MWS"), an inherited autoinflammatory disease characterized by a gene mutation. Kuemmerle-Deschner at 1. Of the thirteen patients determined to have MWS, twelve also suffered from SNHL as part of their disease course. *Id.* at 5. In addition, lab testing conducted during the study revealed elevated levels of IL-6 (in five patients) and TNF-alpha (in seven patients). *Id.*

Pathak examined the peripheral blood of twenty Autoimmune Inner Ear Disease ("AIED") patients to determine if exposure to mold could possibly exacerbate the disease. Pathak at 1. Researchers determined that exposure to mold resulted in an up-regulation of IL-1 beta as well as IL-6 cytokine levels. *Id.* at 1-2. Notably, however, the medical record does not support any

contention that the Petitioner in this case suffers from MWS (or was exposed to mold prior to symptom onset). More significantly, both studies in no way implicate a vaccination as being causal of the elevated cytokine levels in a patient with SNHL.

Dr. Axelrod's theory next proposed that increased cytokine levels (here, purportedly attributable to vaccination) could damage the ganglion neurons and Schwann cells[6] in the Corti organ[7] of the ear. First Axelrod Rep. at 2; *see* J. Levine, et al., *Influenza A Virus Infection of Human Schwann Cells In Vitr*o, 123 Acta Otolaryngol. 41 (2003), filed as Ex. 9-E (ECF No. 19-5) ("Levine"). In attempts to link the influenza A virus to sensorineural hearing loss (and other adverse nerve conditions), researchers in Levine exposed Schwann cell tissue from one donor (in vitro) to the virus. Levine at 41. Following exposure, researchers concluded that Schwann cells could be infected as early as 24 hours post-inoculation. *Id.* The article also references investigative studies finding evidence for proinflammatory cytokine production in Schwann cells following direct trauma or infection. *Id.* All in all, however, Levine does not implicate the flu *vaccine* as capable of increased cytokine production or resulting damaged to cells in the ear. At best, it suggests that the flu *virus* could be capable of triggering damage to Schwann cells via direct infection (a triggering event wholly distinguishable from vaccination).

As an alternative to proinflammatory cytokine harm as the vaccine-induced cause for SNHL, Dr. Axelrod's theory also identified a vaccine-specific component as having the potential to cause injury. First Axelrod Rep. at 4-5. Specifically, Dr. Axelrod posited that flu vaccine component antigens were structurally homologous with ganglioside receptors on the neuronal myelin contained in the inner ear tissue, and that antibodies generated in response to the vaccine could also cross-react with the self myelin, resulting in tissue damage. *Id.* at 4. To establish this alleged cross-reactivity potential, however, Dr. Axelrod relied on literature discussing mimicry in the context of the anti-GM_1 antibody and its relationship to a different autoimmune disease, Guillain-Barré syndrome. *Id.* at 2; *see also* I. Nachamkin, et al., *Anti-Ganglioside Antibody Induction by Swine (A/NJ/1976/H1N1) and Other Influenza Vaccines: Insights Into Vaccine-Associated Guillain-Barre Syndrome*, 198 J. Infect. Diseases 226 (2008), filed as Ex. 9-P (ECF No. 19-15) ("Nachamkin"); P. Csurhes, et al., *Increased Circulating T Cell Reactivity to GM1 Ganglioside in Patients With Guillain-Barré Syndrome*, 12 J. Clin. Neurosci. 409 (2005), filed as Ex. 9-Q (ECF No. 19-16).[8]

Based upon the above, Dr. Axelrod reasoned, the antibody attack on the "homologous structures" (the neuronal gangliosides in the ear) could cause damage to the surrounding tissues and allow for the development of a damaging immune response to other structures of the neurons. First

[6] Schwann cells produce the myelin sheath around the neuronal axon. *Dorland's* at 323.

[7] The Corti or "organum spirale" is the receptor organ in the inner ear responsible for hearing. *Dorland's* at 1333, 1335.

[8] Dr. Axelrod's report also filed literature relating to cross-reactivity in the context of yet another different autoimmune disease, multiple sclerosis. *See* S. Markovic-Plese, et al., *High Level of Cross-Reactivity in Influenza Virus Hemagglutinin-Specific CD4+ T-Cell Response: Implications for the Initiation of Autoimmune Response in Multiple Sclerosis*, 169 J. Neuroimmunol. 169 (2005), filed as Ex. 9-M (ECF No. 19-12) ("Marcovic-Plese").

Axelrod Rep. at 5. This could also occur in a secondary manner, through the mechanism of epitope spreading, which Dr. Axelrod described as the continuing and "persistent damage (physiologic or anatomic)" to the neuronal ear tissue (via T or B cell recognition of non-cross-reactive structures). *Id.*; *see* A. Vojdani, et al., *A Potential Link Between Environmental Triggers and Autoimmunity*, Autoimmune Diseases 1, 6 (2014), doi:10.1155/2014/798029, filed as Ex. 9-R (ECF No. 19-17) ("Vojdani") (discussing epitope spreading in the context of an infectious agent, but not implicating a vaccination). His first report suggested that Petitioner's *prior* flu vaccines could be the basis for such a response, but he offered no supporting literature directly discussing how vaccinations (in the *years prior* to injury) could, in combination with a more recent vaccination, result in an SNHL injury in this way. First Axelrod Rep. at 5.

In addition, Dr. Axelrod's first report briefly noted that Petitioner's "pre-existing neurologic disease" increased the likelihood of his developing a more "severe disease" following flu vaccine administration. First Axelrod Rep. at 2; A. Wilking, et al., *Central Nervous System Manifestations in Pediatric Patients with Influenza A H1N1 Infection During the 2009 Pandemic*, 51 Pediatric Neuro. 370 (2014), filed as Ex. 9-C (ECF No. 19-3) ("Wilking"). The report, however, does not identify what "pre-existing neurologic disease" Petitioner suffers from.[9] Moreover, Wilking studied the exacerbation of pre-existing neurological disease in 365 *pediatric* patients in the context of the flu *infection*, not the vaccine, and concluded only that patients with a confirmed *infection* were more likely to experience CNS disease manifestations (with 3.1% of patients experiencing sensorineural hearing loss). Wilking at 1.

Otherwise, Dr. Axelrod posited that the timing of Petitioner's injury supported his contention that his SNHL was indeed vaccine-caused. As he described it, Petitioner received the flu vaccine and within 24 hours experienced an innate response via the upregulation of cytokines, resulting in damage to his inner ear tissue. First Axelrod Rep. at 4-5; Christian at 1, 5. All subsequent damage to the ear could occur via a primary or secondary adaptive immune response to the inner ear thereafter through a molecular mimicry/epitope spreading mechanism (possibly abetted by flu vaccines Petitioner received *years* prior to injury onset). First Axelrod Rep. at 5. His report did not specifically address how long it would take for an overall process like the above to occur, but the literature filed suggests an adaptive response to a vaccine requires anywhere from seven to thirty-five days to occur. *See, e.g.*, Nachamkin at 229; *see also* T. Lawley, et al., *A Prospective Clinical and Immunologic Analysis of Patients with Serum Sickness*, 311 New. Eng. J. Med. 1407 (1984), filed as Ex. 9-T (ECF No. 19-18) ("Lawley") (finding eleven out of twelve pediatric patients treated with horse antithymocyte globulin developed symptoms of serum sickness between eight and thirteen days following administration).

Dr. Axelrod's second report primarily attempted to rebut Respondent's alternative cause theory, which attributed Petitioner's SNHL to the Azithromycin medication he had taken for his

[9] In reference to the Wilking paper discussed above, Petitioner's request for a ruling on the record seemingly clarifies that his "prior hearing loss" made him more susceptible to a flu vaccine reaction. Mot. at 7.

bronchitis diagnosis (roughly two weeks prior to vaccine administration). Based on his review of the relevant scientific literature on the topic, which categorized possible SNHL explanations, Dr. Axelrod's deemed the flu vaccine a superior explanation. Second Axelrod Rep. at 2.[10] Moreover, Dr. Axelrod countered that epidemiologic evidence does not suggest any association between hearing loss and the use of Azithromycin. *Id.* He acknowledged that there are case reports in existence associating Azithromycin with the onset of hearing loss, but asserted that the same can be said for the flu vaccine. *Id.* Dr. Axelrod filed no literature directly discussing Azithromycin or its associated hearing-loss symptoms, however.

B. *Respondent's Expert—Dr. Douglas Bigelow*

Respondent's expert filed a single written report in this case. *See* Expert Report, dated November 27, 2017, filed as Ex. B-9 (ECF No. 36-1) ("Bigelow Rep."). According to Dr. Bigelow, Petitioner's hearing loss symptoms were not caused by his receipt of the flu vaccine.

Dr. Bigelow received his medical degree from the University of Minnesota School of Medicine. He thereafter completed a general surgery internship at Hennepin County Medical Center in Minneapolis, followed by an otolaryngology-head and neck surgery fellowship at Washington University in St. Louis. Bigelow CV, filed as Ex. C (ECF No. 36-2) ("Bigelow CV") at 1. Dr. Bigelow is currently an associate professor in the Department of Otorhinolaryngology at the University of Pennsylvania School of Medicine ("Penn"). *Id.* at 2. At Penn, his duties also include serving as the Acting-Director of the Speech and Hearing Center and Co-Director of the Center for Cranial Base Surgery. Dr. Bigelow is board certified in otolaryngology and neck surgery, with a subspecialty in neurotology. Bigelow Rep. at 11 He holds medical licenses in both Missouri and Pennsylvania. Bigelow CV at 2. Dr. Bigelow has over twenty-six years of experience as an attending physician managing patients with otology problems, hearing loss, dizziness, and acoustic neuromas in a tertiary care setting. Bigelow Rep. at 11.

Consistent with Dr. Axelrod's opinion, Dr. Bigelow characterized Petitioner's hearing loss as idiopathic SNHL. Bigelow Rep. at 7. But he attributed Petitioner's condition to the Azithromycin medication he had taken (two weeks) prior to symptom onset rather than the subsequent flu vaccine. *Id.* at 7-8.[11] Dr. Bigelow cited to various pieces of scientific literature associating Azithromycin with the onset of hearing loss. *Id.* at 8; *see, e.g.*, A. Tseng, et al., *Azithromycin-Related Toxicity in Patients Infected with Human Immunodeficiency*, 24 CID 76 (1997), filed as Ex. G (ECF No. 36-6) (seventeen percent of 46-patient study experienced ototoxicity including hearing loss and tinnitus following use of Azithromycin, and 5/8 experienced bilateral symptoms) ("Tseng"); M. Wallace, et

[10] Dr. Axelrod's second report cites to an SNHL review article attempting to identify the cause of the condition. Axelrod Second Rep. at 2; *see* J. Chau, et al., *A Systemic Review of Pediatric Sensorineural Hearing Loss in Congenital Syphilis*, 73 Int. J. Pediatric Otorhinoaryngol. 787 (2009). This article was not filed.

[11] Dr. Bigelow's report also cited to Petitioner's pre-existing bronchitis as a possible alternative cause for his SNHL symptoms. Bigelow Rep. at 11. He cited no literature supporting the association of such an infection with hearing loss, however, and it does not appear to be further developed elsewhere in his report.

al., *Ototoxicity With Azithromycin*, 343 Lancet 241 (1994), filed as Ex. H (ECF No. 36-7) (fourteen percent of 21-patient study experienced bilateral hearing loss audiometrically, with 2/3 in moderately severe category, following Azithromycin use) ("Wallace"). Hearing loss is even listed on the package insert as an anticipated potential side effect. Bigelow Rep. at 8.

Dr. Bigelow's report also cited to case report studies of documented SNHL following Azithromycin use. *See, e.g.*, B. Ress, et al., *Irreversible Sensorineural Hearing Loss as a Result of Azithromycin Ototoxicity: A Case Report*, 109 Ann. Otol. Rhinol. Laryngol 435 (2000), filed as Ex. E (ECF No. 36-4) (reporting onset of irreversible sudden onset bilateral tinnitus and hearing loss associated with low dose Azithromycin); P. Mick et al., *Sensorineural Hearing Loss as a Probable Serious Adverse Drug Reaction Associated with Low-Dose Oral Azithromycin*, 36 J. Otolarygol. 257 (2007), filed as Ex. F (ECF No. 36-5) (case study reporting one case of irreversible onset of SNHL with use of low dose Azithromycin).

Besides proposing a more likely cause for Mr. Inamdar's hearing loss, Dr. Bigelow took issue with Dr. Axelrod's suggested biologic mechanism offered in his causation theory. Bigelow Rep. at 9. In his view, Dr. Axelrod "combined portions of various papers" unrelated to SNHL in attempts to reach the "fabricated" conclusion that Petitioner's condition was caused by his receipt of the flu vaccine. *Id.* at 10. Kuemmerle-Deschner, for example, was offered by Dr. Axelrod to support the assertion that IL-6 and TNF-alpha cytokine levels are elevated in SNHL patients. *Id.* at 9. But all it shows is that cytokine levels are increased in patients with MWS (a condition unrelated to the hearing loss Petitioner experienced). *Id.* Christian similarly reported on cytokine production post-flu vaccination in pregnant versus non-pregnant women (and moreover concluded there was no *significant* increase in cytokine levels following vaccination – explicitly undercutting the conclusion that wild upregulation of cytokines inherently follows vaccination). *Id.* In addition, Dr. Axelrod offered Pathak to show that IL-6 cytokine levels are increased in patients with AIED. *Id.* But, as noted by Dr. Bigelow, the Pathak researchers reported an increase in IL-6 only *after* exposure to a different, unrelated trigger – mold – that is not comparable to vaccination. *Id.* Based on the above, Dr. Bigelow argued that the papers offered by Dr. Axelrod did not persuasively show that cytokine levels are elevated in patients diagnosed with SNHL. *Id.* at 9.

Dr. Bigelow also observed that the scientific literature filed to support Dr. Axelrod's alternative causation mechanism (molecular mimicry due to homology between flu vaccine components and neuronal ear structures) involved a distinctly different injury than the one Petitioner experienced. Bigelow Rep. at 9-10; *see, e.g.*, Nachamkin at 226 (flu vaccine causing Guillain-Barré syndrome ("GBS")); Weise at 1267 (same); Markovic-Plese (discussing multiple sclerosis). These papers made no mention of any association between the flu vaccine and SNHL, and thus were inapplicable to Petitioner's case. Bigelow Rep. at 10.

In addition, Dr. Bigelow contested the medical appropriateness of the timing of Petitioner's symptom onset (which he described as occurring less than 24 hours following vaccination), in light of the scientific literature filed in support as well as Petitioner's medical records. Bigelow Rep. at

10. A period of a single day (or slightly less) was in his view far too short for development of an autoimmune inner ear condition secondary to vaccination (whether cytokine-mediated or cell-mediated due to autoimmune antibody attacks). *Id.* At best, the literature filed by Petitioner supported an onset of autoimmune clinical manifestations between 10-25 days after exposure to a foreign antigen (far longer than the onset alleged herein). *Id.* (citing Lawley at 1408, 1410). The timing of Petitioner's symptoms, by contrast, evidenced nothing but a temporal association (especially in light of the other deficiencies identified with the proffered medical theory and supporting literature). *Id.* at 11.

Apart from the above, Dr. Bigelow briefly referenced his own clinical experience treating patients diagnosed with SNHL (whether deemed idiopathic or thought to be triggered by a respiratory or viral illness). Bigelow Rep. at 11. Upon review of Petitioner's records, Dr. Bigelow identified Petitioner's pre-existing bronchitis illness prior to onset as possible trigger for Petitioner's SNHL, as well as his Azithromycin use. *Id.* In his over twenty-six years of practice, Dr. Bigelow posited that he has "never seen any cases of sudden hearing loss that were associated with vaccination." *Id.* Given his own treatment experience, Dr. Bigelow could not conclude that the vaccine was the more likely cause (especially in light of these pre-existing circumstances). *Id.* He otherwise saw no evidence in Petitioner's records suggesting he was experiencing any acute inflammation or autoimmune abnormalities (which would evidence a more severe inflammatory response attributable to SNHL). *Id.* at 10.

III. Procedural History

Petitioner initiated this case on October 9, 2015. Pet. at 1. Petitioner thereafter endeavored to obtain and file the relevant medical records, filing the Statement of Completion on March 29, 2016. ECF No. 13. Respondent filed his Rule 4(c) Report on May 31, 2016. ECF No. 14. In it, Respondent raised an argument concerning a possible alternative cause for Petitioner's symptoms: a prior use of Azithromycin (as, in his view, the medication had been shown to be associated with hearing loss). *Id.* Petitioner continued with the case by filing an initial expert report from Dr. Axelrod on November 17, 2016, as well as pharmacy records in attempts to rebut Respondent's assertions. ECF No. 19, 20-1, 23-1.

Upon review of the records (and in light of Respondent's continued defense of the alternative cause theory), I set the matter for a factual hearing on March 20, 2017. ECF No. 27. Thereafter, based upon fact testimony offered by Petitioner, his wife, and his daughter, I issued a fact ruling on April 28, 2017, determining that Petitioner more likely than not filled and took the Azithromycin medication prescribed. ECF No. 31. Petitioner thereafter timely sought review of my determination by filing a Motion for Reconsideration, dated May 17, 2017. ECF No. 32. I subsequently held a status conference at which time I informed Petitioner that I was disinclined to grant the motion, given that it cited no new evidence supporting reconsideration, but that I would defer ruling at that time to allow Petitioner the opportunity to locate such evidence in the future. *See* Order, dated May 31, 2017 (ECF No. 33).

The case thereafter proceeded in a timely fashion. In light of my fact determination, Petitioner submitted a supplemental expert from his retained immunologist, Dr. Axelrod, on August 18, 2017. ECF No. 34. Respondent thereafter submitted an expert report from Dr. Bigelow on November 27, 2017. ECF No. 36. At a status conference conducted in December of that same year, I directed Petitioner to file a supplemental expert report (preferably from an ENT specialist with knowledge of SNHL). *See* Order, dated Dec. 6, 2017 (docket entry). Petitioner subsequently informed me that he had been unable to secure an additional expert to support his claim. Thereafter, and at my urging, Petitioner filed a Motion for Ruling on the Record on August 5, 2018. ECF No. 41. Respondent filed a response on September 7, 2018 (ECF No. 42), followed by Petitioner's reply on September 14, 2018 (ECF No. 43). The matter is now ripe for adjudication.

IV. Parties' Respective Arguments

A. Motion for Ruling on Record

Petitioner relies on the immunological conclusion of Dr. Axelrod that 1) proinflammatory cytokines can increase within 24 hours following receipt of the flu vaccine; 2) proinflammatory cytokines are elevated in patients with SNHL; 3) certain cytokines (IL-6 and TNF-alpha) are pathologically associated with the onset of SNHL and can indeed trigger such a disease; and 4) further (or additional) inner ear damage could also result via molecular mimicry/epitope spreading induced by certain flu vaccine components (exacerbated somewhat by receipt of *prior* flu vaccines). Motion for Ruling on Record, dated Aug. 5, 2018 (ECF No. 41) ("Mot.") at 5-8. Petitioner maintains that his causation contentions are well-supported by the filed medical literature, and thus support Petitioner's argument that his receipt of the September 2013 flu vaccine caused damage resulting in SNHL. *Id.* at 11.

In addition, Petitioner argues that Respondent's expert has not offered a persuasive rebuttal in response to the theory proffered by Dr. Axelrod. Mot. at 8. Petitioner directly disputes Respondent's contention that Azithromycin use (or an earlier-in-time bronchitis illness) could constitute an alternative cause for Petitioner's SNHL. *Id.* at 8-11. At best, Petitioner contends that Dr. Bigelow offered case reports in support of hearing loss induced by Azithromycin use. *Id.* at 8. He otherwise asserts that the earlier-in-time bronchitis illness was not related and evidenced only a temporal association. *Id.* at 10.

In response, Respondent argues that Petitioner has failed to establish that the flu vaccine was responsible for Petitioner's onset of SNHL. Response, dated Sept. 7, 2018 (ECF No. 42) ("Opp.") at 4. Respondent dismissed Dr. Axelrod's theory, arguing that it was not adequately supported by reliable medical literature. *Id.* at 4-6. Rather, Respondent posited that the medical articles relied on by Petitioner showed associations between increased cytokine levels and onset of hearing loss in

patients with distinguishable medical conditions, or alternative triggers not comparable to a flu vaccine. *Id.* at 4-5. Moreover, Respondent asserted that Petitioner's secondary theory (relating to molecular mimicry/epitope spreading due to prior vaccination) was vaguely described and also poorly supported by the scientific articles filed on the topic. *Id.* at 6-7.

Respondent also maintains that the medical record is devoid of any evidence (i.e. acute inflammation) suggesting Petitioner experienced any inflammatory response to the flu vaccine. Opp. at 8. Rather, Respondent attributes Petitioner's SNHL solely to the Azithromycin medication used close-in-time to onset, and argues that it is the more likely cause of Petitioner's symptoms. *Id.* at 9-11. In addition, Respondent argues that an onset of hearing loss occurring less than 24 hours post vaccination is too short to be medically acceptable. *Id.* at 8. According to Respondent, Petitioner filed no literature supporting this point. *Id.* Respondent also questioned Dr. Axelrod's qualifications to opine on SNHL, and argued that his retained expert, Dr. Bigelow, was more qualified to offer an opinion on hearing loss-related conditions. *Id.* at 6.

Petitioner's reply restated the medical theory of causation set forth in the motion for a ruling, but added that the present case "appears to be one of the first petitions in the Vaccine [P]rogram to allege bilateral SNHL without accompanying [ADEM]" or other neurological disease (presumably to excuse the lack of more direct evidence linking the flu vaccine to hearing loss). *See* Reply, dated Sept. 14, 2018 (ECF No. 43) at 2. The reply attempted to further address the dispute regarding the more likely cause of Petitioner's SNHL (whether vaccination or use of Azithromycin), albeit mainly by restating the arguments proffered in the original motion. *Id.* at 2-4. Petitioner also accused Respondent of "denigrat[ing] Dr. Axelrod's qualifications as an opining expert, and emphasized that the opinions given in this mater are both reliable and sound. *Id.* at 3.

B. Motion for Reconsideration Regarding Findings of Fact

As noted above, Petitioner has also requested reconsideration of my April 28, 2017 fact ruling determination pursuant to Vaccine Rule 10(e)(3). Mot. at 10-11. Petitioner's Motion for Reconsideration, dated May 17, 2017, sets forth his arguments relating to the above. ("Second Mot.") ECF No. 32.

Petitioner argues that the direct testimony of witnesses at hearing demonstrate that Petitioner never filled or used the prescribed Azithromycin medication for his bronchitis illness prior to receipt of the flu vaccine. Second Mot. at 2. In support, Petitioner references the relevant pharmacy records from the time period in question, which he asserts showed he did not obtain the medication (citing Ex. 5, 10). *Id.* He also contends that testimony from both his wife and daughter suggests they also did not fill the prescription. *Id.* at 2, 6; *see* Tr. at 7. Petitioner otherwise states that he personally does not recall taking the medication himself. Second Mot. at 2-3 (citing Tr. at 27-28).

Petitioner next asserts that I over-relied on certain references in the medical record in ruling

without giving the appropriate weight to testimony offered by Petitioner's caretakers. Petitioner acknowledges that a September 16, 2013 medical record from MEEI indicates that Petitioner was currently taking the Azithromycin medication prescribed for his bronchitis. Second Mot. at 3-4. He asserts, however, that the September 16th notation relating to Azithromycin must have been a resuscitation or interpretation of his earlier-in-time medical records indicating a prescription was written (*not* filled and taken). *Id.* at 3. In support, Petitioner contends that he (and his caretakers) both denied affirmatively telling Petitioner's treaters that he was using (or had used) Azithromycin to treat his bronchitis symptoms. *Id.* at 3-5 (citing Tr. at 70, 96, 100-101).[12]

Petitioner's request otherwise contends that the timeline of events surrounding his medical history in the weeks prior to vaccination make it unlikely that he would have taken Azithromycin. Second Mot. at 5-6. Although Petitioner's September 16, 2013 MEEI record references current use of Azithromycin, Petitioner argues that other medical visit notes around that same time do not reference its use. *Id.* at 5. Petitioner cites to a PCP visit note, dated September 12, 2013 (the day he received the flu vaccine), which notes "no active complaints" at that time. *Id.* at 5-6. The lack of documentation suggesting Azithromycin use on the day of vaccination, he argues, further supports his contention that the treater statements in the record (noting Petitioner's use of Azithromycin) were evidence of the existence of a prescription, not Petitioner's direct use. *Id.* at 5-6. In addition, Petitioner argues that his recommended prescription for Azithromycin included only a 4-day course of the medication. *Id.* at 5 (citing Ex. 4 at 41). Since Petitioner was vaccinated over one week following the bronchitis diagnosis, he found it reasonable to conclude that Petitioner was also not "currently" using the medication as noted in the September 16th record. *Id.* at 6. He otherwise offered no new evidence (or filings) in support of the request.

V. Relevant Legal Standards

A. *Claimant's Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).

[12] Petitioner's request for reconsideration does acknowledge that witness statements at hearing indicated it was *possible* that caretakers could have informed Petitioner's treaters that he used the medication. Counsel, however, categorizes these statements as answers in response to hypothetical questions. Second Mot. at 4-5.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.*

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, the petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id*. at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases may be enough to satisfy Althen prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d

1363 (Fed. Cir. 2017); *see also Andreu*, 569 F.3d at 1375. But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not per se bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v.*

Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs*., 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant

symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

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

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

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

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs*., 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the weighing of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the ipse dixit of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

D. *Consideration of Medical Literature*

Both parties filed some medical and scientific literature in this case, including articles offered in support of their causation theories (as well as articles that do not factor into the outcome of this decision). I have reviewed all of the medical literature submitted in this case, but I only discuss those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.,* 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted)); *see also Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Resolution of Case Via Ruling on Record*

Following my April 2017 fact ruling, and based on my review of the record as a whole, I proposed determining entitlement based on written submissions and evidentiary filings, including both side's expert reports, rather than by holding a hearing, and the parties acceded to my proposal. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

After careful review of the expert reports, medical records, and the arguments of both sides, I conclude that Petitioner has not established preponderant evidence in favor of his claim.

I. Petitioner Has Not Demonstrated that the Flu Vaccine Can Cause SNHL

Numerous reasoned Program decisions have determined that a variety of vaccines (including the flu vaccine) are *not* associated with hearing loss comparable to that alleged in this case. *See, e.g.*, *Trainer v. Sec'y of Health & Human Servs.,* No. 10-865V, 2013 WL 4505803 (Fed. Cl. Spec. Mstr.

July 24, 2013) (Hep A vaccine not causative of hearing loss); *Doe/16 v. Sec'y of Health & Human Servs.*, No. 06-670V, 2008 WL 2390064 (Fed. Cl. Spec. Mstr. June 2, 2008) (special master rejected petitioner's claim that flu vaccine caused hearing loss); *Hopkins v. Sec'y of Health & Human Servs.*, No. 00-746V, 2007 WL 5403504 (Fed. Cl. Spec. Mstr. Dec. 14, 2007) (hearing loss was not shown to be caused by DPT, Hib, and OPV vaccines), *aff'd*, 84 Fed. Cl. 517 (2008); *Malloy v. Sec'y of Health & Human Servs.*, No. 99-193V, 2003 WL 22424968 (Fed Cl. Spec. Mstr. May 1, 2003) (same); *Lunn v. Sec'y of Health & Human Servs.*, No. 97-436V, 2000 WL 246237 (Fed. Cl. Spec. Mstr. Feb. 17, 2000) (DTP vaccine not causative of hearing loss); *Hines v. Sec'y of Health & Human Servs.*, No. 89-90V, 1990 WL 608692 (Fed. Cl. Spec. Mstr. June 22, 1990) (bilateral sensorineural hearing loss found not to have been caused by the MMR vaccine), *aff'd*, 21 Cl Ct. 634 (1990), *aff'd*, 940 F.2d 1518 (Fed. Cir. 1991). While such decisions are not binding herein, they underscore the evidentiary problems posed by Petitioner's claim.

Petitioner's causation theory specifically proposes that the flu vaccine can induce the production of proinflammatory cytokines, thereby causing inflammation sufficient to create a favorable environment for hearing loss. But I have noted in other cases (including ones where Dr. Axelrod advanced a similar opinion) that this theory has several deficiencies. *See, e.g., Dean v. Sec'y of Health & Human Servs.*, No. 13-808V, 2017 WL 2926605 (Fed. Cl. Spec. Mstr. Jun. 9, 2017) (ruling on the record that the "cytokine storm" theory was not a persuasive causation theory explaining Petitioner's neurological deficits following the DTaP and Hib vaccines) *mot. for rev. den'd,* slip op. (Fed. Cl. Sept. 26, 2017); *Wolf v. Sec'y of Health & Human Servs.*, No. 14-342V, 2016 WL 6518581, at *13 (Fed. Cl. Spec. Mstr. Sept. 15, 2016) (dismissing claim on the record after determining that the proinflammatory cytokine expression theory was insufficiently reliable to explain how vaccination caused Petitioner's developmental impairments); *Godfrey v. Sec'y of Health & Human Servs.*, No. 10-565V, 2015 WL 10710961, at *10-14 (Fed. Cl. Spec. Mstr. Oct. 27, 2015) (insufficient reliable scientific evidence supported proposition that cytokine upregulation induced by HPV vaccine was pathogenic enough to cause juvenile ankylosing spondylitis), *mot. for review den'd*, slip op. (Fed. Cl. Apr. 29, 2016).

First, the argument that cytokine upregulation can be a pathogenic mechanism unsuccessfully attempts to leverage what is known about how vaccines generally affect the immune system into proof that these anticipated processes can also be pathogenic. To be sure, components of this theory are based on reliable science. Petitioner has referenced reliable literature establishing that certain proinflammatory cytokines (including IL-6 and TNF-alpha) have been shown to be elevated following vaccine administration (s*ee, e.g.*, Christian at 1, 5), or that these same cytokines may play a role in the process of hearing loss (Kuemmerle-Deschner, Pathak). But the theory lacks similar support for its connecting proposition – that the cytokine upregulation *leads* to or causes hearing loss – as well as the concept that vaccination can instigate the entire disease process. It is not enough to note that increased numbers of inflammatory-associated cytokines have been measured in the context of certain injuries or illnesses (or are involved in the body's reaction to those illnesses). Dr. Axelrod does not personally have demonstrated expertise studying these unsupported elements of the theory,

and no persuasive or reliable literature was offered on such points.

In addition, even the reliable items of literature offered by Petitioner do not merit the evidentiary weight urged because they are distinguishable from present circumstances. As pointed out by Respondent's expert, Dr. Bigelow, for example, Kuemmerle-Deschner revealed the presence of elevated levels of IL-6 and TNF-alpha cytokines in patients diagnosed with MWS – a disease characterized by a genetic mutation wholly separate from SNHL. Kuemmerle-Deschner at 5; *see also* Christian at 1, 5 (discussing elevated cytokine levels associated with flu vaccine administration during pregnancy). In addition, triggering events discussed in the supporting literature revealed instances of cytokine upregulation following *infection* with the wild flu virus, or mold exposure, and thus involved circumstances distinct from the impact of the killed-virus form of the flu vaccine that Petitioner received. *See, e.g.*, Pathak at 1-2 (finding elevated levels of IL-6 and IL-beta cytokines in AIED patients following mold exposure); Levine at 41 (implicating the influenza A wild virus as damaging to myelin cells following direct trauma or infection). While petitioners of course are not required to provide direct proof of causation to prevail (and indeed, it is more often than not impossible for them to do so, since science cannot fully explain why a rare vaccine injury may have occurred), such deficiencies in the offered medical literature diminish the strength of Mr. Inamdar's showing.

Petitioner also did not adequately substantiate the *how* (i.e. the mechanistic process) portion of his theory – the manner in which the rapid upregulation of cytokines would cause tissue damage in the ear resulting in hearing loss. At best, Dr. Axelrod's report cites to Levine in support of this part of his theory, but that article involved direct stimulation of myelin cells with the flu *virus*, not the vaccine. Levine at 41. Levine also suggests that studies exist discussing the production of proinflammatory cytokines following trauma or infection with the flu virus, but Dr. Axelrod did not offer a persuasive explanation for how cytokines produced in response to the flu *vaccine* could result in damage to inner ear myelin.

Petitioner's alternative theory, that certain components of the flu vaccine could cross-react with structures in the inner ear (thereby resulting in persistent tissue damage encouraged by the secondary mechanism of epitope spreading), was similarly unsupported by the filed literature. Nachamkin, for example, discussed the cross-reactivity potential between components of the flu vaccine and the anti-GM_1 antibody only in the context of GBS – a peripheral nervous system illness that is distinguishable from SNHL. Nachamkin at 226. The remaining literature similarly focuses on diseases distinct from the hearing loss Petitioner experienced. *See, e.g.*, Csurhes at 409 (discussing GBS); Markovic-Plese (discussing multiple sclerosis). Vojdani implicates the concept of epitope spreading in the context of an *infectious* agent (Theiler's murine encephalitis virus, specifically), not vaccination. Vojdani at 1, 6. Petitioner offered no literature addressing the ability of the flu vaccine (whether alone or in the context of *prior* flu vaccines), or any other vaccine, to cross-react with self-structures in the inner ear.

At bottom, Petitioner's theory places great emphasis on the fact of his injury's close temporal association to vaccination. But he has not fleshed the theory out with reliable and persuasive literature suggesting that the flu vaccine could produce hearing loss of the sort experienced. And Dr. Axelrod's expertise, while sufficient to explain the theory, was not enough (based on his actual practice and inexperience with hearing disorders) to fill in the theory's many gaps. Petitioner has not met the Program's preponderant evidentiary standard with respect to the first *Althen* prong.

II. Petitioner Cannot Satisfy the Remaining Althen Prongs

Petitioner's obligation under the second *Althen* prong is to demonstrate a logical sequence of cause and effect connecting the particular facts of his case to his medical theory, while the third requires him to show that onset of his injury occurred in a medically appropriate timeframe consistent with his theory. *Sturdivant v. Sec'y of Health & Human Servs.*, No. 07-788V, 2016 WL 552529, at *18 (Fed. Cl. Spec. Mstr. Jan. 21, 2016) (discussing *Althen* prong two); *de Bazan*, 539 F.3d at 1352 (discussing standards for prong three). Here, Petitioner has failed to establish either prong, for several reasons.

With respect to the "did cause" prong, the overall record does not support the conclusion that the flu vaccine was likely causal of Petitioner's post-vaccination condition. Dr. Bigelow's reading of the relevant medical records and filed scientific literature was particularly persuasive on this point. The medical record simply does not offer substantiation (in the form of lab testing or some other exam result) for the proposition that Mr. Inamdar was experiencing some kind of cytokine-derived reaction when his hearing loss occurred. Also, as noted by Dr. Bigelow, the record does not establish that Petitioner experienced some other immediate reaction to the vaccine (i.e. swelling or pain at the injection site) or an underlying systemic reaction (i.e. evidenced by indicia of acute inflammation). At best, a single treater at one point proposed *some* possible relationship between Petitioner's vaccination and his development of SNHL. *See* Ex. 5 at 9. But that speculation was never later confirmed by any subsequent treater more qualified than Dr. de Venecia (an ENT specialist) to so opine.

At the same time, Respondent has offered reliable and persuasive evidence suggesting an alternative explanation for Petitioner's symptoms. As noted above, the record establishes that Petitioner was prescribed Azithromycin roughly two weeks prior to vaccine administration for treatment of bronchitis (and my fact ruling determined that he most likely took this medication). Ex. 4 at 39-42; Fact Ruling at 10-12. Petitioner thereafter presented to treaters (subsequent to his onset of SNHL) who referenced his use of Azithromycin for the recent illness. Ex. 4 at 26-27; Ex. 5 at 30. Respondent offered various pieces of medical literature suggesting that Azithromycin is associated with bilateral SNHL. *See, e.g.*, Tseng at 76; Wallace at 241. Case reports confirmed this assertion. *See, e.g.*, Ress at 435; Mick at 257. Although case reports are not especially strong proof of causation, they have some evidentiary value and cannot therefore be completely disregarded. *See*,

e.g., *Campbell v. Sec'y of Health & Human Servs.*, 97 Fed. Cl. 650, 668 (2011) ("[c]ase reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value . . . [but] the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight").

Petitioner reasonably responded that the above evidence did not establish a definitive causal link between SNHL and Azithromycin. Second Axelrod Rep. at 2. Notably, however, Petitioner's expert filed no literature attempting to rebut Respondent's assertion that the two have been reliably associated, or that the association with the flu vaccine is stronger. Because the above evidence undermines his argument, it needed to be effectively rebutted as part of Petitioner's case in chief. *See, e.g.*, *Dingle v. Sec'y of Health & Human Servs.*, No. 08-579V, 2013 WL 4083220, at *22 (Fed. Cl. Spec. Mstr. July 23, 2013 (citing *de Bazan*, 539 F.3d at 1353).[13] The fact that he could not do so is another basis for finding that he failed to establish that the flu vaccine "did cause" his SNHL – since he received a particular medication right before the vaccination that has been *more* reliably established as associated with his injury.

Regarding the third *Althen* prong, Petitioner hangs his hat on circular reasoning, concluding that the close timing of his injury (within 24 hours) to receipt of the flu vaccine establishes a reasonable timeframe for a vaccine-induced injury. Admittedly, Petitioner does cite to literature support (albeit weak) for the contention that cytokines can be shown to be elevated within 24 hours following receipt of the flu vaccine (in certain patient cohorts). *See, e.g.*, Christian at 5. He also references literature suggesting that myelin cells injected directly with the flu *virus* (as opposed to vaccine) can cause damage within 24 hours following direct infection. Levine at 41. But this evidence does not go far enough to suggest that the timeframe from vaccination to hearing loss would reasonably occur in a single 24-hour day.

In fact, the opposite is true – as the literature offered by Respondent (and discussed by Dr. Bigelow) established, it would likely take *days* to generate an adaptive immune response to be pathologic in the manner proposed by Petitioner's theory (i.e via molecular mimicry/epitope spreading. *See, e.g.*, Nachamkin at 229 (at least seven days); Lawley at 1407 (eight to thirteen days). Petitioner otherwise offered no literature discussing a medically appropriate timeframe for a mimicry/epitope reaction (based upon Petitioner's flu vaccinations in *years* prior, under some kind of "challenge/rechallenge" mechanism).[14] This, plus the broader deficiencies with Petitioner's

[13] Indeed, the burden of proof does not shift to Respondent to prove an alternative cause *until* a petitioner carries his initial burden of proof. *See, e.g.*, *Rus v. Sec'y of Health & Human Servs.*, 129 Fed. Cl. 672, 680 (2016).

[14] Challenge-rechallenge is "a paradigm for exploring whether one substance caused an adverse reaction. Under this model, an individual who has had an adverse reaction to the initial vaccine dose (the challenge event) suffers a worsening of symptoms after a second or third injection (the rechallenge event.)" *Viscontini v. Sec'y of Health & Human Servs.*, No. 98–619V, 2011 WL 5842577, at *22 (Fed. Cl. Spec. Mstr. Oct. 21, 2011) (quoting *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 603 (2010) (quotations omitted)), *mot. for review den'd*, 103 Fed. Cl. 600 (2012).

theory (which did not otherwise establish that the flu vaccine could directly cause SNHL), renders me unable to find that the timing at issue in this case of the alleged vaccine-induced hearing loss has been shown to be medically acceptable.

III. Petitioner's Request for Reconsideration

As noted above, Petitioner's request for a ruling on the record is combined with his 2017 request for reconsideration of my earlier-in-time fact ruling regarding Petitioner's use of Azithromycin. Although I informed the parties in 2017 that I did not find the request to be well-taken, I hereby rule formally upon it.

Petitioner requests reconsideration pursuant to Vaccine Rule 10(e)(3),[15] which governs motions for reconsideration of a special master's decision. It provides that "[e]ither party may file a motion for reconsideration of the special master's decision within 21 days after the issuance of the decision . . . ." Vaccine Rule 10(e)(1). Special masters have the discretion to grant a motion for reconsideration if to do so would be in the "interest of justice." Vaccine Rule 10(e)(3).

As noted by another special master, "there is a dearth of law interpreting Vaccine Rule 10(e)(3)," beyond the conclusion that (as the rule itself makes clear) it is within the special master's discretion to decide what the "interest of justice" is in a given case. *R.K. v. Sec'y of Health & Human Servs.*, No. 03-632V, 2010 WL 5572074, at *3 (Fed. Cl. Spec. Mstr. Jan. 10, 2011) (granting reconsideration of decision dismissing case for failure to prosecute). Many decisions analogize the standard for reconsideration to the "manifest injustice" standard utilized under Rule 59(a) of the Rules of the Court of Federal Claims, which has been defined to be unfairness that is "clearly apparent or obvious." *Amnex, Inc. v. United States*, 52 Fed. Cl. 555, 557 (2002); *see also R.K.*, 2010 WL 5572074, at *3-5 (citations omitted). Overall, however, the "interest of justice" standard is somewhat more lenient, emphasizing whether reconsideration would provide a Vaccine Act petitioner a full opportunity to prove her case. *Id.* at 5. The standard is nonetheless demanding, requiring that the movant to show (a) an intervening change in the controlling law; (b) the availability of evidence that was not previously available; or (c) a manifest injustice that would be prevented by reconsideration. *Hall v. Sec'y of Health & Human Servs.*, 93 Fed. Cl. 239, 251 (2010), *aff'd*, 640 F.3d 1351 (Fed. Cir. 2011). Reconsideration is not available simply to "give an unhappy litigant an additional chance to sway the court." *Id.*

[15] There appears to be some dispute in the Program regarding the application of Vaccine Rule 10(e) to a special master's ruling that has not been addressed by a higher court. *See, e.g., Coran v. Sec'y of Health & Human Servs.*, No. 15-777V, 2017 WL 4349189 (Fed. Cl. Spec. Mstr. Sept. 7, 2017) (Vaccine Rule 10(e) applies only to a special master's final decision concerning entitlement not an onset ruling), *aff'd*, 136 Fed. Cl. 360 (2018); *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2006 WL 3734216 (Fed. Cl. Spec. Mstr. Nov. 29, 2006) (stating the same); *but see Gerard v. Sec'y of Health & Human Servs.*, No. 08-786V, 2014 WL 4293342 (Fed. Cl. Spec. Mstr. Aug. 8, 2014) (granting reconsideration of a fact ruling under Rule 10(e)). Even so, I will consider Petitioner's request as framed.

Despite having had since May 2017, Petitioner has not identified *any* additional evidence not considered at the fact hearing that would warrant a granting of reconsideration. Instead, he attempts to argue against my weighing of the evidence presented at hearing. Thus, although it was unrebutted that Petitioner was indeed *prescribed* Azithromycin to treat his bronchitis, Petitioner continues to assert that the testimony offered by the fact witnesses best supports the conclusion that Petitioner did not *fill* the prescription (and thus did not take it) before receiving the flu vaccine. Second Mot. at 2-3. He otherwise asserts that the relevant pharmacy records affirm this point. *Id.* at 2. But both issues were brought up at the fact hearing and considered in my subsequent ruling – which noted that the fact witness testimony contained unexplained ambiguities that (when coupled with the medical record) tended to support the conclusion that the Azithromycin was likely filled. These arguments therefore would not change the outcome of my determination (which turned on my assessment of statements made by Petitioner's daughter that suggested her admission of awareness that he had in fact taken the medication).

Petitioner next asserts that documented treater statements in the record (suggesting the medication *was taken*) were simply interpretations of prior-in-time records noting a prescription had been written, rather than proof of direct use. Second Mot. at 3-5. As my fact ruling noted, however, the records in question unequivocally state that Petitioner was "currently" taking Azithromycin at the time of the appointment (September 13, 2013). *See* Ex. 5 at 30. Moreover, Petitioner does not indicate *which* prior record (in the alternative) Petitioner's treater would have been repeating in making erroneous statements about his medical history. *See* Second Mot. at 3. In his brief, Petitioner references portions of records from Harvard Vanguard and compares those to the MEEI record. *See id.* But, the sections included do not involve discussion of Azithromycin use. Thus no evidence not considered at hearing has been offered to suggest such record statements are wrong.

Overall, Petitioner's discontent with the weight afforded to the contemporaneous medical record does not meet the standards for reconsideration set forth in Rule 10(e)(3). Moreover, even if it did – and Petitioner *had* offered new evidence that was strong enough for me to reverse my prior determination, and find that he never took the Azithromycin – my ruling in the case would be the same, based upon his inability to establish either (a) that the flu vaccine "can cause" SNHL, or (b) that it did so in this case, and in a medically reasonable timeframe. The finding that the association between Azithromycin and hearing loss was no longer relevant to the case would only aid Petitioner on *Althen* prong two, leaving my finding that his theory associating the flu vaccine to hearing loss is implausible. And as discussed above, there is an overall lack of record support (beyond the temporal association between vaccination and injury) establishing that Petitioner's theory of causation occurred "in real time" in this case as alleged. It is therefore not manifestly unjust to deny the reconsideration motion independently of the persuasiveness of its evidentiary re-weighing arguments.

CONCLUSION

The record does not support Petitioner's contention that the flu vaccine caused him to develop SNHL, and the expert support offered for his causation theory was deficient. Petitioner has therefore not established entitlement to a compensation award, and I must DISMISS his claim. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[16]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[16] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.