In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-1332V

(to be published)

ANDREW FANTINI,	*	Chief Special Master Corcoran
Petitioner,	*	Dated: May 2, 2022
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Adriana Ruth Teitel, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On November 5, 2015, Andrew Fantini filed a petition for compensation under the National Vaccine and Injury Compensation Program (the "Vaccine Program").[2] (ECF No. 1) ("Petition"). Mr. Fantini alleges that he experienced a small fiber neuropathy ("SFN") and tinnitus due to receipt of an influenza ("flu") vaccine administered on October 11, 2012, and/or meningitis, polio, and rabies vaccine administered to him on November 7, 2012. Petition (ECF No. 1) ("Pet.") at 1.

[1] This Decision shall be posted on the Court of Federal Claims' 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 at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to Section 300aa of the Act (but will omit the statutory prefix).

The parties have agreed that the matter could reasonably be resolved via ruling on the record and filed briefs in support of their respective positions. *See* Petitioner's Motion, dated June 15, 2021 (ECF No. 83) ("Mot."); Respondent's Opposition, dated September 28, 2021 (ECF No. 88) ("Opp."); Petitioner's Reply, dated December 10, 2021 (ECF No. 93) ("Reply"). Having reviewed the above plus the filed medical records, expert reports, and associated literature, I hereby deny an entitlement award. As discussed in greater detail below, Petitioner has not preponderantly established a medical theory that any of the vaccines he received could cause SFN, or that they did so in a medically-acceptable timeframe. In addition, the record does not corroborate the alleged SFN injury in the first place.

I. Factual Background

Pre-Vaccination History

Mr. Fantini's medical history before the vaccination at issue includes one notable finding: a history of sharp pain above his right eyebrow that lasted for approximately three weeks, and which was documented during a consultation on May 29, 2007 (thus five years pre-vaccination). Ex. 12 at 2. He was examined by neurologist Grace Forde, M.D., who concluded that Mr. Fantini "had point tenderness midway between the hairline and the eyebrow on the right in the mid line of the pupil. He had mechanical allodynia but not static allodynia. No sensory abnormalities were noted. He ha[d] mild weakness in the muscle. . . ." *Id.* at 3.

Dr. Forde ordered a brain magnetic resonance imaging ("MRI") scan, and noted her impression was that "[t]he etiology of the patient's symptoms [wa]s unclear at this time but there appear[ed] to be a neuropathic component to the pain." Ex. 12 at 3. During a follow up visit on June 26, 2007, Petitioner continued to complain of severe pain above his right eyebrow. *Id.* at 5. Dr. Forde now stated that Petitioner's brain MRI images revealed no abnormalities, leading her to propose a differential diagnosis of "trigeminal neuralgia versus atypical facial pain." *Id*.; Ex. 4 at 8. Although Petitioner was instructed to follow up in a month, he did not appear at the next appointment. Ex. 12 at 7.

Vaccinations and Symptom Onset

On October 11, 2012, Mr. Fantini (who was then 44 years old) received the flu vaccine from a CVS pharmacy in Syosset, New York. Ex. 8 at 2. Twenty-seven days later, on November 7, 2012, Petitioner received three different vaccines—meningitis, polio, and rabies vaccinations—from Passport Health in Roslyn Heights, NY. Ex. 1 at 1. There is no evidence in the record of any reported reaction to any of these vaccines.

The following month, on November 13, 2012, Petitioner was seen by primary care physician ("PCP") Rupert Exconde, M.D., at the Noran Neurological Clinic ("Noran") in

Minneapolis, Minnesota. Ex. 4 at 12. Petitioner informed Dr. Exconde that on November 8, 2012 (the day after his receipt of the second set of vaccines at issue), he had experienced "paraesthesias involving one foot, which then spread[] to the other side. This ha[d] continually spread in a patchy distribution in the upper limbs and at the back of the head, and the left lower lip." *Id.* Except for subjective complaints of paraesthesias between the first and second toes bilaterally and a weak ankle reflex, however, the neurological examination yielded normal results, demonstrating normal muscle bulk, tone, and power/dexterity, plus no stance or gait abnormalities. *Id.* at 12–13. Dr. Exconde's impression was "[a]scending patchy numbness after a recent vaccination . . . [o]n the top of the differential diagnosis would be very early demyelinating polyradicular neuropathy."[3] *Id.* at 13.

That same day, Petitioner underwent a nerve conduction study ("NCS")[4] and electromyogram ("EMG")[5] at Noran that also yielded normal results, with "no electrophysiologic evidence of a generalized neuropathy or myopathy. . . ." Ex. 4 at 6–7. It was specifically noted at this time that there was no evidence Petitioner was experiencing Guillain-Barré syndrome ("GBS"), cervical or lumbosacral radiculopathy, ulnar or peroneal neuropathy, or carpal tunnel syndrome. *Id.*

Examinations and Testing to Confirm Diagnosis/Etiology

A week later, on November 20, 2012, Petitioner presented to Neurological Specialties of Long Island, and was seen by neurologist Itzak Haimovic, M.D. Ex. 7 at 11–12. At this initial visit, Petitioner reported that one day after his rabies, meningitis, and polio vaccines he developed tingling and numbness in his toes that ascended to both thighs and caused muscle soreness. *Id.* at 11. He subsequently developed the same tingling and numbness sensations on the left side of his mouth and chin. *Id.* The neurological examination conducted by Dr. Haimovic, however, showed normal results, including a sensory examination revealing normal sensation to pinprick, light touch, and proprioception. *Id.* at 12. Reflexes were decreased at 1+ throughout. *Id.* Dr. Haimovic

[3] Although this impression did not specify which vaccination Dr. Exconde was referring to, it was probably the November 7, 2012 vaccinations. He only briefly mentioned that Petitioner received the flu shot a month prior to this visit, but Petitioner never became ill. Ex. 4 at 12.

[4] A nerve conduction study measures the amount and speed of conduction of an electrical impulse through a nerve to determine nerve damage and destruction. *Nerve Conduction Studies*, Health Library, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/emg_lab/nerve_conduction_study html (last visited Apr. 20, 2020).

[5] Electromyography is the process by which "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." *Dorland's Illustrated Medical Dictionary* 595 (33rd ed. 2020) ("*Dorland's*").

raised the "possibility of post vaccination neuropathy," and indicated that GBS or a central nervous system demyelinating disorder should be considered." *Id.*

At a follow-up neurology visit with Dr. Exconde on November 26, 2012, Petitioner reported more numbness, plus night sweats and fatigue. Ex. 4 at 11. Upon examination, however, he had "intact reflexes and actually brisk except for diminished ankle reflexes bilaterally." *Id.* Petitioner also reported having "subjective tinnitus and numbness around [his] lip." *Id.* Dr. Exconde's impression (considering objective examination findings along with Petitioner's more subjective reporting of symptoms) was "ascending patchy numbness with so far [an] unrevealing workup." *Id.* The workup also included consideration of normal cerebrospinal fluid ("CSF") findings from a November 23, 2012 lumbar puncture, in addition to the NCS/EMG conducted on November 13, 2012. *Id.* at 5, 11, 40–47. At this visit, Dr. Exconde ordered several lab tests and a brain MRI, which all came back as normal. *Id.* at 4, 14–39.

Petitioner underwent a second NCS/EMG on December 3, 2012, which "included testing in all four extremities." *Id.* at 1. The results (again) came back normal, "with no findings to suggest a generalized neuropathic process." *Id.*

On December 12, 2012, Petitioner returned to Dr. Haimovic with continued complaints of "severe burning, numbness, and pins and needles sensation of the arms and legs." Ex. 7 at 8. Dr. Haimovic noted that the brain MRI and EMG had been unremarkable. *Id.* The neurological examination was positive for trace ankle jerk. *Id.* His impression was "[p]ossible post-infectious neuropathy" and he ruled out transverse myelitis. *Id.* He prescribed Prednisone and ordered an MRI of the cervical and thoracic spine. *Id.*

On December 17, 2012, Petitioner was seen by yet another neurologist—Syed Shahkhan, M.D. Ex. 4 at 9–10. Petitioner again reported that the day after his polio, meningitis, and rabies vaccinations he began to experience numbness in his toes, cold sensations in his legs, and swelling in his jaw, which he described as lymphadenopathy. *Id.* at 9. Petitioner also reported that in addition to those symptoms, "for the last three-and-a-half weeks, he ha[d] constant ringing in his ears," but indicated his hearing was intact and he had no dizziness. *Id.* Petitioner noted that his "sensory symptoms ha[d] plateaued but the abnormal sensations continu[ed]. He ha[d] numbness in the thumb and the index finger and big and little toe on both sides. He report[ed] muscle aches in his thighs and in his forearms." *Id.* Dr. Shahkhan also noted that Petitioner "had CSF done to check for inflammatory or infectious causes and this was also normal." *Id.*

Upon examination, Dr. Shahkhan observed "[n]o tremor. Motor tone [and] bulk strength [were] normal throughout the upper and lower extremities." Ex. 4 at 9. Petitioner's deep tendon reflexes were noted to be "symmetric in the arms and legs." *Id.* There was "no focal sensory loss to modalities of temperature and vibration." *Id.* Based upon all the foregoing, Dr. Shahkhan's

assessment was "paresthesias, which are migratory, but no clinical deficits on examination." *Id.* He noted that Petitioner described "symptoms of small-fiber neuropathy and autonomic neuropathy," and suggested it was "possible that [Petitioner] had an autoimmune phenomenon, which caused the small-fiber neuropathy." *Id.* at 9–10. Dr. Shahkhan ordered blood tests to look for generalized evidence of inflammation or infection but did not recommend autonomic nerve testing or skin biopsy due to improved symptoms." *Id.* Petitioner was referred to an ear, nose, and throat specialist ("ENT") for further evaluation of his reported ear ringing sensation. *Id.*

The next day, on December 18, 2012, Petitioner presented to North Shore Open MRI, where radiologist Richard Silvergleid, M.D., performed a cervical and thoracic spine MRI. Ex. 7 at 9–10. There was no significant stenosis observed in his thoracic spine. *Id.* at 10. However, the MRI report revealed mild abnormalities such as minor disc herniation early degenerative disc disease. *Id.* at 9. It otherwise did not reveal abnormalities that seemed severe enough to have possibly caused Petitioner's symptoms. *Id.* Petitioner also went to ENT specialist Dr. Emil Ganjian that same December, for evaluation of his tinnitus. Ex. 5 at 1. The otologic examination was normal, but the audiography revealed very mild bilateral sensorimotor hearing loss. *Id.* at 1, 3. Dr. Ganjian's impression was tinnitus that was "likely immune mediated and related to vaccination." *Id.* at 2.

Treatment from 2013 to the Present

The medical records from subsequent periods reveal sporadic efforts by Petitioner to treat his alleged neuropathy. Thus, Petitioner had a consultation with cardiologist Andressa Borges, M.D., at Long Island Heart Associates on January 9, 2013. Ex. 13 at 8. He complained of palpitations, described as "a sensation of skipped beats" for the past two weeks. *Id.* Under past medical history, it was noted that Petitioner was previously told he had experienced an autoimmune response to the meningitis, polio, and rabies vaccine, and "developed upper extremity numbness and dizziness."[6] *Id.* Dr. Borges's examination revealed Petitioner's symptoms were "significant for tinnitus, lower extremity muscle aches, numbness and [he had] symptoms suggestive o[f] gastroesophageal reflux disease." *Id.* But the focus of this consultation was more on cardiac issues and treatment than neurologic matters. *Id.* at 9.

Later that month (January 16, 2013), Petitioner was seen at North Shore Allergy & Asthma Institute. Ex. 6 at 2. The handwritten notes of the physician he saw are difficult to read but seem to memorialize Petitioner's recent medical history. Ex. 6 at 2–6. Mr. Fantini was now diagnosed

[6] Although the consultation included a statement that Petitioner had received an extensive workup at the Mayo Clinic, the Mayo Clinic Health Information Management Services confirmed (in connection with discovery conducted in this case) that their files do confirm that Petitioner was ever a Mayo Clinic patient at any time over the past ten years. Ex. 13 at 8; Ex. 31 at 1.

with GBS (although it was unclear as to the basis of this conclusion, due to the illegibility of the note) and was also advised to follow-up with a rheumatologist. *Id.* at 6.

There is a subsequent two-year medical records gap, revealing no additional treatment for Petitioner's neuropathic symptoms. The next record is from January 8, 2015, when Mr. Fantini returned to Dr. Haimovic without new complaints. Ex. 7 at 2. At this time, Petitioner denied "new headaches, weakness, numbness, pins and needles sensation, or neurological disturbances," but reported "severe, persistent pain in his back and legs Pain in the thighs is noted as well." *Id.* The neurological examination (consistent with many prior exams), however, provided normal results, including muscular strength and reflexes, as well as no sensory deficits. *Id.* at 2–3. Dr. Haimovic's assessment was "intractable symptoms of weakness, pain and heaviness in the legs [and] intractable tingling and numb sensation of the toes." *Id.* But he also raised the "possibility of new disc herniation and progression of lumbar stenosis," and recommended a repeat MRI of lumbar spine, as well as another NCS/EMG of Petitioner's lower extremities. *Id.*

Petitioner delayed additional treatment for yet another year,[7] returning to ENT specialist Dr. Ganjian on January 11, 2016, for additional treatment of his tinnitus, which he reported had been constant since 2012, increasing in severity in proportion to his episodes of numbness. Ex. 10 at 1. The physical exam, however yielded normal results. *Id.* at 1–2. Dr. Ganjian's impression was that Petitioner's hearing had been stable for four years, with no change in the audiogram or tinnitus, and proposed a diagnosis of bilateral sensorineural hearing loss. *Id.* at 2. Under the impression and plan, Dr. Ganjian noted Petitioner reported that his tinnitus had "[s]tarted shortly after vaccination. Immunologic? Vaccine related?" *Id.*

The following day (January 12, 2016), Petitioner had a new patient examination by internal medicine physician Sybil Resnick, M.D. at Long Island Heart Associates. Ex. 11 at 18. Under past medical history, Dr. Resnick appears to have recorded "? Guillain Barre Syndrome with persistent paresthesia distal LE and right hand." *Id*. But the neurological examination was described as "grossly non focal." *Id.* Petitioner was to send Dr. Resnick his records from Dr. Haimovic. *Id.*

On March 7, 2016, Petitioner returned to Dr. Shahkhan for a follow up "after three years" for his paresthesia and numbness. Ex. 9 at 1. The record noted that at his prior visits, Dr. Shahkhan had recommended a skin biopsy for nerve fiber testing, but Petitioner had declined to undergo the test. *Id.* Petitioner conveyed that "his symptoms plateaued and did not worsen," adding that he had numbness in his big toes and right thumb plus thigh pain that could last several hours when it manifested. *Id.* Dr. Shahkhan noted that Petitioner had experienced "paresthesias" after receiving vaccinations for "flu, polio, meningitis, and…rabies." *Id.* Upon examination, however, Petitioner displayed normal motor tone, bulk, and strength in all four extremities, and symmetric deep tendon reflexes. *Id.* There was "no focal sensory loss to modalities of temperature and vibration." *Id.*

[7] No records have been filed for the period between January 8, 2015, and January 11, 2016.

Under assessment, Dr. Shahkhan wrote:

> The patient has *subjective* paresthesias and these have not worsened in the last three years. We have done investigations (MRI of brain, EMG and CSF tests) to find the cause of his paresthesias but they came back as normal. On clinical exam, I do not see neurological deficit. I do not think that any further investigation is needed at this time.

Ex. 9 at 1–2 (emphasis added). In an addendum, Dr. Shahkhan noted that in addition to the EMG, CSF, and MRI, his "blood tests for infectious and inflammatory and metabolic causes of neuropathy came back as normal." *Id.* at 2.

Later that month, on March 30, 2016, Petitioner returned to Long Island Heart Associates for a cardiovascular evaluation with cardiologist Michael Friedman, M.D. Ex. 13 at 1. Petitioner complained of "4 months of progressively worsening intermittent exertional [shortness of breath], dizziness, palpitations and [bilateral] leg pain when flying/traveling for business trips." *Id.* Dr. Friedman's assessment included dyspnea, peripheral vascular disease, fatigue, and dizziness. *Id.* at 2.

Twenty-two months later (and two years after the claim's filing), Petitioner had a telehealth consultation with neurologist Svetlana Blitshteyn, M.D., on January 31, 2018. Ex. 37 at 2–3. Petitioner at this time again reported the symptoms he claimed to have experienced not long after the second series of vaccines he received in early November 2012. *Id.* at 2. He also described the associated pain, contending that his symptoms had remained unabated over several years. *Id.* Based solely on the symptoms described and a review of Dr. Kinsbourne's expert report, Dr. Blitshteyn proposed that Petitioner likely had SFN with secondary neuropathic pain and tinnitus with onset after vaccination. *Id.* at 3. Dr. Blitshteyn further recommended additional diagnostic tests - including a skin biopsy and MR angiography ("MRA") of the head and neck to rule out vascular malformations or an aneurysm as the causes of his tinnitus. *Id.* No evidence of any such testing results have been filed, and no records after May 2019 have been provided.[8]

II. Expert Reports

A. Petitioner's Experts

1. *Marcel Kinsbourne, M.D.* – Dr. Kinsbourne, a pediatric neurologist, submitted an expert report for the Petitioner in support of the argument that SFN can reasonably

[8] At that time, Petitioner appears again to have followed up with Dr. Ganjian for treatment of his tinnitus. Ex. 38 at 1–4.

be thought to be the product of an autoimmune process, that the flu vaccine did cause Mr. Fantini's neuropathy, and that the timeframe of 28 days from vaccination to onset was medically acceptable. Report, dated July 27, 2017, filed as Ex. 14 (ECF No. 38-1) ("Kinsbourne Rep.").

Dr. Kinsbourne received his medical degree in the United Kingdom and has been licensed to practice medicine in North Carolina since 1967. *Curriculum Vitae*, filed as Ex. 15 on July 27, 2017 (ECF No. 38-2) ("Kinsbourne CV") at 1. From 1967 to 2015, Dr. Kinsbourne served as an associate professor in pediatrics and neurology and a senior research associate at Duke University Medical Center before holding a series of academic positions, including professorships in pediatrics, neurology, and psychology. *Id.* at 2–3. His clinical experience includes serving as a senior staff physician in Ontario from 1974-1980, and a clinical associate in neurology at Massachusetts General Hospital ("MGH") from 1981-1991, although (as noted in other cases) many years have passed since he regularly saw patients. *Id.*; *see e.g., Strong v. Sec'y of Health & Hum. Servs.*, No. 15-1108V, 2018 WL 1125666, at *6 (Fed. Cl. Spec. Mstr. Jan. 12, 2018); *Pope v. Sec'y of Health & Human Servs.,* No. 14–078V, 2017 WL 2460503, at *8 (Fed. Cl. Spec. Mstr. May 1, 2017). Dr. Kinsbourne has also published over 430 articles and books pediatrics, neurology, and psychology. Kinsbourne CV at 7–39.

Dr. Kinsbourne's report began with a summary of Mr. Fantini's medical history. Kinsbourne Rep. at 1–2. Dr. Kinsbourne opined that Mr. Fantini had SFN and tinnitus. He defined SFN as a neurologic disorder that often affects both the small, mostly unmyelinated somatic and the autonomic nerve fibers. *Id.* at 3; J. Tavee & L. Zhou, *Small Fiber Neuropathy: A Burning Problem*, Cleveland Clinic J. Med. 297–305, 297–98 (2009), filed as Ex. 14 on July 27, 2017 (ECF No. 38-1) ("Tavee"). The autonomic fibers are associated with the autonomic arm of the nervous system, responsible for mediating pain, heat, and autonomic functions. Tavee at 297–98. The small somatic fibers include some myelinated A-delta fibers (which sense cold) and nonmyelinated C fibers (which sense warmth and pain). *Id.* Patients with SFN develop sensations of burning feet and numb toes, which gradually spread through the patient's limbs, and then (uncommonly) to the trunk and face. Kinsbourne Rep. at 3; Tavee at 298. Mr. Fantini never experienced any of those associated conditions—although they are only observed in half of all SFN cases. Kinsbourne Rep. at 3; Tavee at 303.

SFN can be difficult to diagnose. Individuals suffering from SFN typically present normal results during neurological examinations, NCS, and EMGs – just like Petitioner. Kinsbourne Rep. at 3; Tavee at 301. Consequently, a skin biopsy, which evaluates intraepidermal nerve fiber density, or quantitative sudomotor axon reflex testing ("QSTART"), which assesses sudomotor autonomic functions, are considered the best means of confirming a suspected case of SFN. Kinsbourne Rep. at 4. Neither such test was ever performed with respect to Petitioner. Arguably, however, Mr. Fantini's complaints did not point to a problem with his autonomic nervous system or concurrent autonomic disorders (other than occasional night sweats), so Dr. Kinsbourne did not

deem QSART testing to have value herein. *Id.* at 5.[9] And he also proposed that the diagnostic usefulness of a skin biopsy in this case, five or more years after onset, was questionable. *Id.*[10]

Dr. Kinsbourne also discussed the possibility that Mr. Fantini had dorsal root ganglionopathy, given that some symptoms (patchy numbness on the trunk and face) were not consistent with SFN. Kinsbourne Rep. at 3. He defined this as an SFN variant, citing some literature that makes vague or indirect reference to it. *See,* e.g., F. Gemignani et al., *Non-Length Dependent Small Fiber Neuropathy. A Prospective Case Series,* J. Peripheral Nervous Sys. 57–62, 58 (2010), filed as Ex. 17 on July 27, 2017 (ECF No. 38-4) (reporting a series of patients with non-length dependent small fiber neuropathy, some involving legs, hands, trunk and face); J.G. Hoeijmakers et al., *Small-Fiber Neuropathies—Advances in Diagnosis, Pathophysiology and Management*, Nature Rev.'s: Neurology 369-379, 370 (2012), filed as Ex. 18 on July 27, 2017 (ECF No. 38-5) (". . . a non-length dependent pattern of symptoms has been reported [in patients with SFN], showing a patchy distribution of neuropathy in the face, scalp, tongue or trunk"). In summation, he favored an SFN diagnosis. Kinsbourne Rep. at 3.

Tinnitus, manifesting as a result of Mr. Fantini's neuropathy, was also a proper diagnosis in Dr. Kinsbourne's estimation. Kinsbourne Rep. at 5. This diagnosis was supported both by treaters like Dr. Ganjian (an ENT specialist who in fact characterized the tinnitus as "likely immune mediated and related to vaccination,") and by evidence that irritation to Petitioner's trigeminal nerve was causing the pain and numbness in his lower face he was experiencing. Ex. 5 at 2; Kinsbourne Rep. at 5. (Notably, however, the only mention of any trigeminal nerve issue was in connection with Petitioner's 2007 *pre-vaccination* neurologic issues. *See generally* Ex. 12 at 5; Ex. 4 at 8. And there was never any follow-up on this matter in the five years thereafter, up to the vaccinations in question).

Trigeminal neuralgia, Dr. Kinsbourne maintained, is associated with small nerve fiber dysfunction. Kinsbourne Rep. at 5; G. Cruccu et al., *Small-Fiber Dysfunction in Trigeminal Neuralgia: Carbamazepine Effect on Laser-Evoked Potentials,* Neurology 1722–726, 1725 (2001), filed as Ex. 16 on July 27, 2017 (ECF No. 38-3). Another piece of literature was offered to establish that cochlear damage (in the inner ear) was known to induce tinnitus, as it increased the "spontaneous firing rates in neurons in both the dorsal and ventral cochlear nucleus." S.E. Shore, *Plasticity of Somatosensory Inputs to the Cochlear Nucleus – Implications for Tinnitus,* Hearing Res. 38–46, 40 (2011), filed as Ex. 26 on July 27, 2017 (ECF No. 38-13) ("Shore"). This association was important because research discussed in the article (though not separately cited) demonstrated an auditory connection between the "dorsal column and trigeminal systems at the

[9] Dr. Kinsbourne in fact has directly acknowledged that Mr. Fantini's symptoms reflected no autonomic dysfunction whatsoever. Kinsbourne Rep. at 3

[10] Dr. Kinsbourne's report was submitted in 2017—five years after onset—and is now itself nearly five years old.

very lowest levels of each sensory system, where cells in the dorsal root- and trigeminal ganglia send axons to terminate in the cochlear nuclear." Shore at 1723. And Dr. Kinsbourne offered a third piece of literature to establish that temporomandibular joint disorders and neck injuries could be associated with tinnitus, and that "[t]he underlying mechanism is probably the effect of afferent somatosensory input from the trigeminal nerve and C2 fibres on central auditory pathway activity via interaction at the dorsal cochlear nucleus at brainstem level." B. Langguth et al., *Tinnitus: Causes and Clinical Management,* Lancet Neurology 920–930, 921 (2013), filed as Ex. 22 on July 27, 2017 (ECF No. 38-9) ("Langguth"). Langguth also noted that ". . . abnormal somatosensory afferent input from the neck and face region can affect activity in central auditory pathways and might also contribute to the generation of tinnitus." *Id.* Thus, it was reasonable in Dr. Kinsbourne's view to associate the tinnitus as a secondary result of Petitioner's primary neuropathic injuries - although none of these items of literature associate SFN with tinnitus.

Dr. Kinsbourne next proposed how a vaccine could cause SFN, focusing on the flu vaccine Petitioner received on October 11, 2012, rather than the second round of vaccinations from November 7, 2012. Kinsbourne Rep. at 5–6. First, he emphasized that the flu vaccine is a "well known" cause of neuropathies like GBS or chronic inflammatory demyelinating polyneuropathy ("CIDP"). *Id.* at 3. Mr. Fantini's electrodiagnosis did not reveal the expected findings for these disorders, which primarily implicate large nerve fibers, but Dr. Kinsbourne maintained that dysfunction in small nerve fibers (many of them unmyelinated C fibers) cannot be measured by routine electrodiagnosis (though there was no cited literature to support this point). *Id.* Thus, Dr. Kinsbourne opined that the very fact that this category of nerve conduction testing yielded negative results actually *confirmed* that the disorder of peripheral sensation Mr. Fantini experienced was likely reflective of SFN. *Id.*

Second, Dr. Kinsbourne proposed a causation mechanism relating to the flu vaccine's propensity to encourage the release of proinflammatory cytokines as part of the immune system's innate response to the vaccine. Kinsbourne Rep. at 5. Although Dr. Kinsbourne acknowledged that this cascade of events is typically harmless (and in fact is integral to a vaccine's immunogenicity and function), on occasion a host will aberrantly overproduce cytokines in reaction to a vaccine, resulting in a bystander activation of an inflammatory response within the substance of the small nerve fibers. *Id.* at 5–6.

Several items of literature, Dr. Kinsbourne maintained, showed how such a cytokine-driven aberrant immune response could result in SFN. Kinsbourne Rep. at 4; D. Lacomis, *Small-Fiber Neuropathy,* Muscle & Nerve 173–188, 182 (2002), filed as Ex. 20 on July 27, 2017 (ECF No. 38-7) ("Lacomis") ("[i]n some patients with idiopathic small fiber neuropathy, an *inflammatory autoimmune* basis has been hypothesized and circumstantial evidence is available") (emphasis in original); N. Uceyler et al., *Elevated Proinflammatory Cytokine Expression in Affected Skin in Small Fiber Neuropathy*, Neurology 1806–813, 1808, 1810 (2010), filed as Ex. 29 on July 27,

2017 (ECF No. 38-16) (suggesting that pro-inflammatory cytokines such as tumor necrosis factor alpha are strongly involved in the generation and maintenance of neuropathic pain, and reporting elevated levels of cytokines in affected skin in SFN). But no article or evidence was offered to establish that any vaccine could sufficiently upregulate cytokines to cause SNF—let alone what that level would be.

Dr. Kinsbourne also noted that SFN itself can present secondarily to GBS or comparable autoimmune-mediated injuries.[11] V. Martinez et al., *Small-Fibre Impairment Predicts Neuropathic Pain in Guillain-Barré Syndrome*, Pain 1–4, 2 (2010), filed as Ex. 21 on July 27, 2017 (ECF No. 38-8)[12] (citing to an abstract of a study that acknowledges that a subset of GBS patients also experience neuropathic pain associated with small nerve fibers); E. Hoitsma et al., *Small Fiber Neuropathy: A Common and Important Clinical Disorder,* J. Neurological Sci.'s 119–30, 124 (2004), filed as Ex. 19 on July 27, 2017 (ECF No. 38-6) (commenting that "it is remarkable that SFN seems to be frequent in immune mediated diseases such as sarcoidosis Sjogren's disease and [systemic lupus erythematosus] leading to the hypothesis that there might be a common pathway in immune mediated diseases resulting in SFN"); U. Seneviratne & S. Gunasekera, *Acute Small Fiber Sensory Neuropathy: Another Variant of Guillain-Barré Syndrome?*, J. Neurology, Neurosurgery Psychiatry 540–54, 542 (2002), filed as Ex. 25 on July 27, 2017 (ECF No. 38-12) ("[t]his study hints that in Guillain-Barré syndrome small sensory fibres are a possible target for selective damage by antibodies") ("Seneviratne"). If SNF is a comorbid condition associated with GBS, then arguably what is known about GBS's pathogenesis (and more specifically the role the flu vaccine can play in causing it) has relevance herein—even though this record in no way establishes that Mr. Fantini ever had GBS.

Alternatively, Dr. Kinsbourne proposed molecular mimicry as another causal mechanism. Kinsbourne Rep. at 6. But he offered little to substantiate this aspect of his opinion, citing only to one piece of literature discussing a GBS variant—acute motor axonal neuropathy—in which antiganglioside autoantibodies (presumably generated in response to an infectious antigen) are known to drive the disease via a cross-attack on nerve structures. Y. Sekiguchi et al., *Antiganglioside Antibodies are Associated with Axonal Guillain-Barré Syndrome: A Japanese-Italian Collaborative Study,* J. Neurology, Neurosurgery and Psychiatry 23–28, 25–27 (2012), filed as Ex. 24 on July 27, 2017 (ECF No. 38-11) ("Sekiguchi"). Those autoantibodies are believed to be produced as a result of mimicry between presenting antigens (whether in a virus/bacterium or vaccine) and self structures on the nerve myelin surface. Sekiguchi at 1. But Dr. Kinsbourne

[11] Dr. Kinsbourne noted that some illnesses, such as Sjogren's syndrome and sarcoidosis, respond to IVIG infusion, like GBS – thus underscoring their likely autoimmune nature (since IVIG is usually reserved for such conditions). Kinsbourne Rep. at 4. But this does not mean that *all* illnesses deemed to be autoimmune are more comparable than not, and Dr. Kinsbourne offered no literature to support this supposition. *Id.*

[12] Petitioner only filed the abstract of this article, so the findings it purports could not be confirmed.

admitted that the exact homology between the vaccine's surface antigens and constituents of small nerve fibers were still unknown, and thus his opinion sheds little specific light on how the flu vaccine would trigger SFN in this way, beyond assuming that what is possible for one kind of peripheral neuropathy is possible for another. Kinsbourne Rep. at 6; Sekiguchi at 25–27.

Finally, Dr. Kinsbourne addressed the other two causal elements that Program petitioners must satisfy. He argued that the vaccine and Mr. Fantini's subsequent injuries were logically related, noting no alternative explanations, such as a pre-onset identified infection. Kinsbourne Rep. at 3. And treaters like Dr. Shahkhan had proposed that Mr. Fantini's SFN was attributable to "an autoimmune phenomenon." *Id.*; Ex. 4 at 9–10. Thus, it was likely the vaccines petitioner received had caused his SFN.

Dr. Kinsbourne also deemed the onset for Petitioner's symptoms to be medically acceptable. Kinsbourne Rep. at 6. In his view, onset most likely occurred around 28 days after receipt of the flu vaccine (even though he did not cite to a specific event in which he was basing this timeframe). *Id.* This was consistent with relevant literature about how long the autoimmune process would take to produce symptoms after triggering. *See,* e.g.*,* C. Poser, *Neurological Complications of Swine Influenza Vaccination*, 66 Acta Neurology Scandinavia 413–31, 416–21 (1982), filed as Ex. 23 on July 27, 2017 (ECF No. 38-10) ("Poser") (1982 case study found that the onset of neurological complications after a swine flu vaccine occurred between 1 and 63 days); K. Stratton et al., *Adverse Events Associated with Childhood Vaccines Other Than Pertussis and Rubella: Summary of a Report From the Institute of Medicine*, 271 JAMA 1602–604, 1604 (1994), filed as Ex. 27 on July 27, 2017 (ECF No. 38-14) ("Stratton") (indicating an incidence for *Haemophilus influenza* type b ("Hib") disease within seven days of Hib vaccination, but adding that the authors could "not estimate the risk of the other adverse reactions because of a lack of controlled data"). Dr. Kinsbourne did not say anything else regarding the temporal interval.

2. *Anne L. Oaklander, M.D., PhD.* – Dr. Oaklander, a neurologist specializing in SFNs, prepared one written report. Report, dated June 5, 2020, filed as Ex. 32 (ECF No. 64-1) ("Oaklander Rep."). Dr. Oaklander opined that Mr. Fantini had SFN. Oaklander Rep. at 1–3.

Dr. Oaklander received her Master of Science, medical degree, and doctorate from the Albert Einstein College of Medicine. *Curriculum Vitae*, filed as Ex. 33 on June 5, 2020 (ECF No. 64-2) ("Oaklander CV") at 1. She is currently working as an Associate Professor of Neurology at Harvard Medical School and Assistant in Pathology (Neuropathology) at the Massachusetts General Hospital ("MGH"). *Id.* at 2; Oaklander Rep. at 1. At MGH, she provides two types of clinical care, which include working directly with patients and interpreting skin biopsies. Oaklander Rep. at 1. She is also the Director of the Nerve Unit at MGH. *Id.* She has authored over 130 publications on the topic of small fiber pathology. *Biography*, filed as Ex. 34 on June 5, 2020 (ECF No. 64-3). Dr. Oaklander is also board certified in neurology. Oaklander CV at 41.

Dr. Oaklander focused her report on diagnosis. Oaklander Rep. at 1–3. She began by differentiating between small and large nerve fibers, describing the former as thinner in diameter than five micrometers. *Id.* at 2. She noted that this difference was attributable to the fact that the axons in large fibers have a myelin sheath, which helps send electrical signals rapidly and carry messages to the muscles to control body movements. *Id.* Large fibers also receive and carry sensations like touch, vibration, and balance to the spinal cord and brain. *Id.* Small fibers, on the other hand, do not tend to be myelinated, and send messages about illness and injury, and in some cases autonomic small fibers also carry messages that control the internal organs. *Id.* Thus, the structure and function of the different nerve fibers are distinguishable.

Dr. Oaklander discussed her working diagnosis for Petitioner. She argued that given Mr. Fantini's symptoms of tingling, numbness, and pins and needles sensations, coupled with the lack of large fiber dysfunctions reported by his NCS/EMG studies, he most likely had SFN. *Id.* at 1. She noted that SFNs in healthy people with no known risks may become autoimmune and later produce similar symptoms to GBS and CIDP. *Id.* at 1–2; A. Oaklander, *Chapter 10 Dysimmune Small Fiber Neuropathies*, Dysimmune Neuropathies 1–35, 15–16 (2020), filed as Ex. 35 on June 5, 2020 (ECF No. 64-4). She did not discuss in further detail why she believed her diagnosis was accurate, however, noting that she still needed to review Mr. Fantini's medical records in their entirety, but had not done so as of the date of her report. However, Dr. Oaklander never submitted a supplemental report.

Dr. Oaklander's report included the specific request that Mr. Fantini undergo neurodiagnostic skin biopsies and focused the remainder of her report to discussing what occurs during a skin biopsy, the types of results she expected to see in SFN patients, and her lab's role in performing such testing. Oaklander Rep. at 2; A. Oaklander & M. Nolano, *Scientific Advances in and Clinical Approaches to Small-Fiber Polyneuropathy*, JAMA Neurology E1–E12, E6 (2019), filed as Ex. 36 on June 5, 2020 (ECF No. 64-5) ("Oaklander Article"). Biopsies providing positive results are objective proof that an individual had an SFN (although she would not in this case abandon the SFN diagnosis even if the test produced a negative result). Oaklander Rep. at 3.

The only mention of the causation prongs in Dr. Oaklander's report was her supposition that she "believe[d] that vaccines are a very credible medical cause of acute dysimmune small fiber neuropathy as they are of large-fiber neuropathy," although she did not substantiate this contention. *Id.* at 2–3. However, she noted that she could speak more to vaccine causation after Mr. Fantini obtained a skin biopsy. *Id.* No additional report was filed, and it has not been established in this case that Petitioner ever underwent the skin biopsy.

B. Respondent's Expert – Peter D. Donofrio, M.D.

Dr. Donofrio, a neurologist with extensive experience in the diagnosis and treatment of patients with neuropathies, prepared a single written report for Respondent. Report, dated

December 15, 2017, filed as Ex. A (ECF No. 47-1) ("Donofrio Rep."). Dr. Donofrio did not accept a diagnosis of GBS or SFN for Petitioner (although he expressed no opinion as to an alternative). *Id.* at 7.

Dr. Donofrio received his degree from the Ohio State University School of Medicine and completed residencies in internal medicine and neurology at Good Samaritan Hospital in Cincinnati, Ohio, and the University of Michigan Medical Center, respectively. *Curriculum Vitae*, filed as Ex. B on December 15, 2017 (ECF No. 47-2) ("Donofrio CV") at 1. He also completed a neuromuscular fellowship at the University of Michigan. *Id*. Currently, he is a Professor of Neurology at Vanderbilt University Medical Center. *Id.* at 2; Donofrio Rep. at 1. He is also board certified in neurology, internal medicine, neuromuscular disorders, and electrodiagnostic medicine. Donofrio CV at 2; Donofrio Rep. at 1. Dr. Donofrio has also published papers in the field of GBS, CIDP, and other neuropathies. Donofrio Rep. at 1.

Dr. Donofrio examined the three potential injuries alleged by Petitioner and his experts—GBS, SFN, and tinnitus. Donofrio Rep. at 5–7. He defined GBS as "a monophasic illness that typically begins with paresthesias in the toes and feet and ascends the legs to affect the upper extremities over several days." *Id.* at 5. About 30 percent of GBS patients develop facial weaknesses, and the majority of individuals reach symptoms nadir three to four weeks after onset, before they see a plateau and their symptoms begin to improve. *Id.* About 65 percent of patients have a full recovery while 15 percent are left with permanent neurologic symptoms. *Id.* One article identified the criteria for diagnosing GBS as "flaccid weakness in the arms and legs and either absent or diffusely reduced reflexes in 4 limbs." *Id.*; A. Asbury & D. Cornblath, *Assessment of Current Diagnostic Criteria for Guillain-Barré Syndrome*, Annals Neurology S21–S24, S21 (1990), filed as Ex. A, Tab 1 on April 24, 2020 (ECF No. 61-1) ("Asbury & Cornblath"). Another article had criteria set at different levels depending on the certainty of a GBS diagnosis, noting level 1 as the strongest support for a GBS diagnosis.[13] J. Sejvar et al., *Guillain-Barré Syndrome and Fisher Syndrome. Case Definitions and Guidelines for Collection, Analysis, and Presentation*

[13] Level 1 of diagnostic certainty includes bilaterally and flaccid weakness of the limbs; decreased or absent deep tendon reflexes in weak limbs; monophasic illness pattern and interval between onset and nadir of weakness between 12 hours and 28 days and subsequent clinical plateau; electrophysiologic findings consistent with GBS; cytoalbuminologic dissociation (i.e., elevation of CSF protein level above laboratory normal value and CSF total white cell count <50 cells/ µl; and absence of an identified alternative diagnosis for weakness. J. Sejvar et al., *Guillain-Barré Syndrome and Fisher Syndrome. Case Definitions and Guidelines for Collection, Analysis, and Presentation of Immunization Safety Data,* Vaccine 599–612, 604 (2011), filed as Ex. A, Tab 2 on April 24, 2020 (ECF No. 61-2) ("Sejvar"). Level 2 of diagnostic certainty includes decreased or absent deep tendon reflexes in weak limbs; monophasic illness pattern and interval between onset and nadir of weakness between 12 hours and 28 days and subsequent clinical plateau; CSF total white cell count <50 cells/ µl (with or without CSF protein elevation above laboratory normal value), or if CSF not collected or results not available, electrophysiologic studies consistent with GBS; and absence of identified alternative diagnosis for weakness. *Id.* Level 3 of diagnostic certainty includes bilateral and flaccid weakness of the limbs; decreased or absent deep tendon reflexes in weak limbs; monophasic illness pattern and interval between onset and nadir of weakness between 12 hours and 28 days and subsequent clinical plateau; and absence of identified alternative diagnosis for weakness. *Id.*

of Immunization Safety Data, Vaccine 599–612, 604 (2011), filed as Ex. A, Tab 2 on April 24, 2020 (ECF No. 61-2) ("Sejvar").

Relying on the above, Dr. Donofrio maintained that the record did not support the conclusion that Petitioner's presentation met either the Asbury & Cornblath or Sejvar criteria for a GBS diagnosis. Donofrio Rep. at 5. In his view, Petitioner could not even achieve level three of the Sejvar criteria (the easiest to satisfy) because he never displayed bilateral flaccid paralysis or decreased or absent deep tendon reflexes in all limbs. *Id.*; Sejvar at 604. Additionally, Petitioner's NCS tests ruled out any large fiber neuropathy—the predominant finding in most GBS patients. Donofrio Rep. at 5.

Next, Dr. Donofrio described the characteristics of SFN, comparing them to what the record revealed. Patients with SFN typically lose sensations of cold and pain perception in their toes, feet, and hands, with such symptoms in most cases ascending to their legs and forearms. Donofrio Rep. at 5–6; Tavee at 297; Lacomis at 174; C. Gibbons, *Small Fiber Neuropathies*, Continuum 1398–412, 1399 (2014), filed as Ex. A, Tab 5 on April 24, 2020 (ECF No. 61-5) ("Gibbons). But in this case, none of Mr. Fantini's treaters observed evidence of sensory loss to cold and pain. Donofrio Rep. at 6. Importantly, Petitioner had never undergone one of the primary diagnostic tests used to confirm SFN, like a skin biopsy, autonomic testing, or QSART testing—as Petitioner's experts acknowledged. *Id.*; Oaklander Rep. at 2. And Petitioner had complained of certain symptoms—night sweats, fatigue, and an enlarged lymph node (Ex. 4 at 10–11)—that in Dr. Donofrio's view were more reflective of distinguishable systemic problems (though he did not specify what those could be) that could have produced Petitioner's numbness and paresthesia. Donofrio Rep. at 6.

Other evidence offered by Petitioner in support of the proposed SFN diagnosis was unpersuasive to Dr. Donofrio. Thus, although one treater, Dr. Shahkhan, had speculated that SFN was a possible diagnosis, Dr. Donofrio argued that this was merely a hypothesis which was not later confirmed or embraced, due to the lack of support from other testing. Donofrio Rep. at 6; Ex. 4 at 10. He also took issue with Dr. Kinsbourne's view that the failure to diagnostically confirm *other* forms of neuropathy through testing (NCS or EMG, for example) made SFN more likely, given Petitioner's symptoms. Donofrio Rep. at 6; Kinsbourne Rep. at 3. Dr. Donofrio argued that this was not an accepted practice amongst neurologists for reaching a diagnosis. Rather, testing specific to confirming one kind of condition only ruled out *that* condition if negative, but was not positive evidence of something else—and in this case, the testing most specific to SFN was never performed. Donofrio Rep. at 6.

Dr. Donofrio's report also included a brief discussion of tinnitus, which he admitted was not a condition commonly evaluated by neurologists. Donofrio Rep. at 6. He did not believe that Petitioner's symptoms were consistent with trigeminal neuralgia, although he did not comment on whether tinnitus could be connected to a nerve problem. *Id.* He deferred his opinion on a tinnitus

diagnosis and the possibility of a causal role of vaccinations on this injury to an otolaryngologist or an audiologist. *Id.*

III. Procedural History

Mr. Fantini filed his Petition on November 5, 2015. Pet. at 1. A year later, Respondent filed a Rule 4(c) Report on December 2, 2016, contesting Petitioner's right to compensation. ECF No. 29. Expert reports were filed through the summer of 2020. Beginning in June 2020, the special master gave Petitioner time to obtain a skin biopsy, but Petitioner ultimately declined to this form of testing even knowing that every expert recommended a skin biopsy for diagnostic purposes of the claim. *Scheduling Order*, dated June 8, 2020. After the matter was transferred to me on January 27, 2021, I held a status conference with the parties and subsequently set a schedule for a ruling on the record. The parties had fully briefed the matter by December 2021, and it is now ripe for resolution.

IV. Parties' Arguments

Petitioner argues that he was correctly diagnosed with SFN based on several treater encounters—in particular, a December 17, 2012 visit to Dr. Shahkhan, and the January 31, 2018 telehealth consult with Dr. Blitshteyn—plus the testimony of his two experts. Mot. at 6–8; Reply at 2–6. Even though Petitioner has never undergone a skin biopsy, Petitioner's experts still deem SFN as the likely diagnosis—and in any event the biopsy test is not critical to the diagnosis. Reply at 4–6; *Lapierre Sec'y of Health & Hum. Servs*., No. 17-227V, 2019 WL 6490730, at *18 (Fed. Cl. Spec. Mstr. Oct. 18, 2019) ("cases alleging a small fiber sensory neuropathy injury have succeeded even where the skin biopsy was inconclusive, *as long as* reliable treater support for the diagnosis was evident") (emphasis in original); *Shaw v. Sec'y of Health & Hum. Servs*., No. 01-707V, 2013 WL 2897425, at *15 (Fed. Cl. Spec. Mstr. May 24, 2013) (noting the skin biopsy yielded inconclusive results, but the special master still concluded that the evidence pointed to a diagnosis of SFN). He also argues that he was correctly diagnosed with tinnitus based on Dr. Shahkhan's review on December 17, 2012, Dr. Ganjian's December 21, 2012 notes, and Dr. Kinsbourne's expert report. Mot. at 8; Reply at 5–6.

Moving on, Petitioner maintains that he has met his causation-in-fact burden based on the factors established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274 (Fed. Cir. 2005); Mot. at 9–17; Reply at 7–15. Statements from Petitioner's experts, he purports, support his contention that the flu vaccine (the only vaccine of those he received discussed by his causation experts) can cause SFN on "an inflammatory autoimmune basis," through the overproduction of cytokines, or alternatively via molecular mimicry. Mot. at 9–10; Reply at 9–10. He also links the evidence regarding SFNs to the connection between GBS and strands of the flu vaccine to support his argument. Mot. at 11–13; Reply at 10–11.

Mr. Fantini next claims that he has demonstrated a logical sequence of cause and effect that the flu vaccine "did cause" his injuries. Two treating neurologists[14] not only diagnosed Petitioner with SFN but proposed a causal link to vaccination. (However, it is worth noting that the two neurologists Petitioner refers to are Dr. Shahkhan—who referred to the polio, meningitis and rabies vaccines *not* proposed as causal under Petitioner's theory—and Dr. Blitshteyn, whose input was based only on telecommunication contact, and whose involvement occurred well after the case's initiation). Mot. at 14–15; Reply at 13–14. Finally, the timing of his onset—approximately 28 days after receiving his flu vaccine—constitutes in Petitioner's view a medically-acceptable timeframe, given filed literature on demyelinating disorders and the defined 3–42-day period for onset of a GBS Table claim in the Program (even though GBS was not the alleged injury). Mot. 16–17; Reply at 14–15.

In opposing entitlement, Respondent questions the factual basis for the alleged injury, maintaining that Mr. Fantini suffers from various neurological symptoms of an unknown overall etiology—meaning that he has not identified an "injury" outright, as required by the Program. Opp. at 23–28. Moreover, Respondent argues that even if it is assumed SFN best characterizes Petitioner's injury, the *Althen* prongs have not been satisfied. *Id.* at 29–35. Thus, Petitioner has not preponderantly established a reliable medical theory causally connecting his vaccinations to SFN on an "an inflammatory autoimmune basis," in which cytokine expression explains the pathogenesis of his disease course. *Id.* at 29–30. Additionally, the alternative theory of molecular mimicry was not developed sufficiently by Dr. Kinsbourne to show how it applies to causation this case, but instead was employed solely to bolster the link between SFNs and GBS, and thus does not support the conclusion that the flu vaccine could cause SFN itself due to a mimic (even if GBS—which is not established to have occurred in this case—*could* have molecular mimicry as its mechanism). *Id.* at 30–32.

Under *Althen* prong two, Respondent argues, Petitioner and his experts partially rely on *post-hoc, ergo propter hoc* reasoning, which is not considered sufficient to establish causation in the Program. Opp. at 33. Although Respondent acknowledges that certain treaters speculated that vaccination could possibly explain Petitioner's injury, such treater evidence is not sacrosanct—and is rebutted under the facts of this case, since Petitioner's lab work results did not confirm the existence of an autoimmune response. *Id.* at 33–34. And Petitioner's showing under *Althen* prong three also fails, because it relies on evidence linking GBS and the flu vaccine—but does not posit what would be a medically acceptable timeframe specific to SFN. *Id.* at 34–35.

In addition, Respondent also argues that the claim that Petitioner's tinnitus was vaccine-caused fails under the *Althen* prongs. *Id.* at 35. Though Dr. Kinsbourne references involvement of the trigeminal nerve and cochlear damage as possible mediating factors that (if first injured due to

[14] Petitioner does not mention another treater, Dr. Ganjian, during this argument, but I note that he also discussed a potential causal effect due to vaccination—albeit in the context of Petitioner's tinnitus only.

vaccination) could theoretically produce tinnitus, Petitioner has not provided preponderant evidence demonstrating that *either* injury occurred and/or could explain his tinnitus. *Id.* And although Dr. Ganjian speculated at an initial visit that Petitioner's tinnitus might be immune-mediated/vaccine-related, he later expressed less certainty, and never proposed formally an explanation for how this would have occurred. *Id.* at 35–36. Respondent did not discuss *Althen* prong three in addressing the tinnitus injury. *Id.*

V. Applicable Law

A. *Standards for Vaccine Claims*

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 & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[15] In this case, Petitioner cannot assert a Table claim based on CIDP.

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 & Hum. 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 & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. 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

[15] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Circuit in *Althen*, 418 F.3d at 1278: "(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 proximate temporal relationship between vaccination and injury."

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, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. 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 & Hum. 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*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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 & Hum. 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 & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, 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 & Hum. 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 be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. 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); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 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." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align 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 & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

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 & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that 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 determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. 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 & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to 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 & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often 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 & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *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, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly 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 & Hum. 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*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. 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 & Hum. 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 of Health & Hum. 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 or other evidence, such as testimony at hearing, 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 & Hum. 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 & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> 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).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. 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 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 & Hum. 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 & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I discuss only 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 & Hum. 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 & Hum. Servs.,* 527 F. Appx. 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. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Mot. at 1; Opp. at 1. 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. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. 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 case 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 & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Overview of Relevant Medical Terms and Prior Decisions

A. *Small Fiber Neuropathy*

As noted above, SFNs have been defined as a disorder affecting the small somatic and autonomic fibers, which are largely unmyelinated. Tavee at 297–98. It results in the loss of cold and pain perception, along with developing sensations of burning and numbness in the feet and toes, which gradually spreads through the patient's limbs and atypically to the trunk and face. *Id.* SFN patients present normal results during most neurological examinations, so confirmation of the diagnosis via a skin biopsy or QSTART test is necessary. *Id.* at 303.

SFN is readily distinguishable from GBS, the diagnosis of which requires proof of the existence of several criteria, under different diagnostic schema. Asbury & Cornblath, for example, requires evidence of "flaccid weakness in the arms and legs and either absent or diffusely reduced reflexes in 4 limbs." Asbury & Cornblath at S21. Sejvar requires at the very least bilateral *and* flaccid weakness of the limbs; decreased or absent deep tendon reflexes in weak limbs;

monophasic illness pattern and interval between onset and nadir of weakness between 12 hours and 28 days and subsequent clinical plateau; and absence of identified alternative diagnosis for weakness. Sejvar at 604. SFN has also been deemed a secondary result of GBS. Seneviratne at 542.

SFN has been alleged as a vaccine injury in prior cases, and petitioners have succeeded in these claims, although the analysis for how or why this may have occurred is limited.[16] *See, e.g., Swaiss v. Sec'y of Health & Hum. Servs.*, No. 15-286V, 2019 WL 6520791, at *17, 27 (Fed. Cl. Spec. Mstr. Nov. 4, 2019) (granting entitlement but noting that "the limited case reports proposing a GBS small fiber variant invoke molecular mimicry and call for further research on the specific cross-reactivity involved"); *Doe v. Sec'y of Dep't of Health & Hum. Servs.*, 2007 WL 3120297, at *7 (Fed. Cl. Spec. Mstr. Oct. 18, 2007) (finding that the flu vaccine caused petitioner's serum sickness and SFN).

However, more often than not, such petitioners' claims have been unsuccessful. *See e.g., Todd v. Sec'y of Health & Hum. Servs*., No. 15-860V, 2020 WL 727973 at *21 (Fed. Cl. Spec. Mstr. Jan. 8, 2020) (denying entitlement for SFN allegedly caused by flu vaccination because petitioner failed to establish the existence of systemic inflammation that would be associated with a chronic autoimmune neuropathy; *Lapierre*, 2019 WL 6490730, at *20; *Jones v. Sec'y of Health & Hum. Servs.*, No. 15-1239V, 2018 WL 7139212, at *17 (Fed. Cl. Spec. Mstr. Dec. 21, 2018) (finding that Petitioner's non-specific symptoms were not a basis for entitlement); *Shaw*, 2013 WL 2897425, at *16 (". . .the medical literature does not specifically link the hepatitis B vaccination or any vaccination to the injury of small fiber neuropathy"). I have myself acknowledged in a prior decision that it is unclear even whether an SFN is an autoimmune-driven condition. *E.S v. Sec'y of Health & Hum. Servs.*, No. 17-480V, 2020 WL 9076620, at *45 (Fed. Cl. Spec. Mstr. Nov. 13, 2020), *mot. for review den'd,* 154 Fed. Cl. 149 (2021) (". . . it is far from certain that small fiber neuropathy *is* an autoimmune-driven condition . . .").

B. *Tinnitus*

Tinnitus is also alleged herein as a vaccine injury. Though tinnitus was not defined, it is understood as a ringing or buzzing in a person's ears. *Dorland's* at 1900. Dr. Kinsbourne offered literature that argued for a possible connection between the trigeminal nerve and cochlear damage as capable of inducing tinnitus. Shore at 40; Langguth at 921. In the Program, however, claimants

[16] Prior decisions from different cases do not control the outcome herein. *Boatmon*, 941 F.3d at 1358–59; *Hanlon v. Sec'y of Health & Hum. Servs*., 40 Fed. Cl. 625, 630 (1998). But special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs*., 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim") (emphasis added). They would therefore be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

typically allege sensorineural hearing loss,[17] with associated symptoms of tinnitus. However, petitioners are often unsuccessful in attributing such hearing loss to vaccination. *See, e.g., Kelly v. Sec'y of Health & Hum. Servs.*, No. 16-878V, 2021 WL 5276373, at *1 (Fed. Cl. Spec. Mstr. Oct. 18, 2021) (finding that Petitioner was not able to establish that the flu vaccine could cause sensorineural hearing loss); *Inamdar v. Sec'y of Health & Hum. Servs.*, No. 15-1173V, 2019 WL1160341, at *16 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (referencing multiple prior negative decisions involving sensorineural hearing loss).

II. Petitioner Has Not Preponderantly Established SFN as His Likely Injury

It is often appropriate for a special master to first determine whether an alleged injury has evidentiary support before applying the *Althen* test—particularly when the injury is disputed, so that "the special master [can] subsequently determine causation relative to the injury." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). In some cases, determining the injury obviates entirely the need for an *Althen* analysis, since the petitioner's claim, and causation theory, is dependent on a finding of a specific injury. *Id.*

In this case, the parties dispute the proper diagnosis—and indeed it is the case that Petitioner's claim relies on a determination that he likely suffered from SFN. Although I cannot ascertain on this record the most likely nature of (and hence proper descriptor for) Petitioner's symptoms, I find he has not preponderantly established SFN as the likely injury, for several reasons.

There is *some* record evidence that favors Petitioner's diagnostic contention. In particular, Petitioner can point to instances of treater support from the record—a strong kind of evidence as a general matter, although it is not considered sacrosanct and does not necessarily bind me. Here, I do not find that these treater views ultimately warrant much weight.

The first treater diagnosis is the more trustworthy of the two. Dr. Shahkhan (a neurologist) on December 17, 2012 (two months after vaccination) observed that Petitioner had symptoms of an SFN that he felt could be autoimmune in origin—but he did not fully embrace the diagnosis, instead opting to order testing. Then, at a follow-up appointment over three years later (March 7, 2016), Dr. Shahkhan no longer seemed to opine that Petitioner could have suffered from an SFN, but instead (based on additional testing) found Petitioner suffered from *subjective* paresthesias for the past three years, observing no other neurologic deficits that would corroborate the diagnosis. Thus, his nascent views about the potential applicability of SFN were not ultimately borne out by the totality of Petitioner's medical history.

The second treater diagnosis, from Dr. Blitshteyn, is more definitive—but far less reliable. Her diagnosis not only was offered *after* this case was initiated but was not based on a first-hand

[17] Defined as "hearing loss due to a lesion in either the cochlea (sensory mechanism of the ear), the vestibulocochlear nerve, the central neural pathways, or a combination of these structures." *Dorland's* at 816.

encounter with Petitioner or a history of treating him (a history that is punctuated by several large gaps). Rather, it was the product of a brief telephonic consultation, and was somewhat reliant upon Petitioner's subjective reporting of his history. Ex. 37 at 2. Dr. Blitshteyn's diagnosis finds little record corroboration from other treaters who actually cared for Petitioner when he initially presented with symptoms and reads more like an after-the-fact expert interpretation (and I have in prior cases criticized this kind of treater input—in particular from Dr. Blitshteyn herself). *See, e.g., America v. Sec'y of Health & Hum. Servs.*, No. 17-542V, 2022 WL 278151, at *29 (Fed. Cl. Spec. Mstr. Jan. 4, 2022) (stating that Dr. Blitshteyn's non-contemporaneous, post-litigation initiation telehealth consults warranted less weight than expert reports).

The SFN diagnosis was, further, unsupported by many other aspects of the record. For example, at his November 20, 2012 visit to Dr. Haimovic, Petitioner underwent a neurological examination that yielded normal results, including a sensory examination revealing normal sensation to pinprick, light touch, and proprioception—all especially significant in establishing the presence of SFN. Ex. 7 at 12. At his December 17, 2012 visit, Dr. Shahkhan specifically noted there was "no focal sensory loss to modalities of temperature and vibration" upon examination, and under assessment he wrote "paresthesias, which are migratory, but no clinical deficits on examination." Ex. 4 at 9–10. Even years later, a January 8, 2015 neurological examination revealed normal results, including muscular strength and reflexes, as well as no sensory deficits. Ex. 7 at 2–3. Dr. Haimovic's assessment during this visit was "intractable symptoms of weakness, pain and heaviness in the legs [and] intractable tingling and numb sensation of the toes." *Id.*

Dr. Kinsbourne also acknowledged some discrepancies between SFN's typical presentation and Mr. Fantini's symptoms, noting that SFN affects both autonomic fibers and small somatic fibers, but that Mr. Fantini's autonomic fibers were not affected. Additionally, Mr. Fantini had symptoms in his neck and face, which usually are not associated with SFN. Otherwise, Dr. Kinsbourne's contention that testing did not corroborate the existence of other neuropathic injuries, like GBS, made SFN more likely illogical. If anything, since there is reliable scientific support for the conclusion that SFN can be secondary to GBS, the lack of testing results consistent with GBS (an incontrovertible fact, as evidenced by the medical records in this case) only *further* reduced the likelihood that Petitioner was experiencing SFN.

Dr. Oaklander for her part was very competent to opine on the nature of Petitioner's injury, but her embrace of the diagnosis was incomplete. She appears, for example, to have relied more on discussions with counsel and Dr. Kinsbourne in embracing the diagnosis than on a full review of the medical record. Oaklander Rep. at 1. And although she affirmatively stated that a negative biopsy result did not preclude the SFN diagnosis, she hesitated to embrace a theory of vaccine causation without such testing. *Id*. at 3 ("[b]efore discussing my thoughts on vaccine causation, and before reviewing his entire medical record, I would first like to review the results of Mr. Fantini's biopsy"). In fact, the biopsy appears to be critical if the diagnosis is to be reliable. One of her own articles noted that "when symptoms are nonspecific and examination findings are muted or subjective, *objective confirmation [of SFN] is a critical step* . . . ." Oaklander Article at

E6 (emphasis added). Thus, I cannot give Dr. Oaklander's opinion the full weight it might in other contexts merit.

This highlights a foundational deficiency with the proposed SFN diagnosis: it was never corroborated by a skin biopsy. This is something *all* experts in this case accepted as important to confirming the proposed diagnosis. Kinsbourne Rep. at 5; Oaklander Rep. at 2–3; Donofrio Rep. at 6; *see also* Tavee at 301 (noting that a skin biopsy is one of the best methods for a SFN diagnosis). Indeed, the medical record itself contains numerous instances in which Petitioner was recommended to obtain a skin biopsy (a recommendation that the procedural history for this case reflects was at one point taken up by the special master who previously presided over the matter), but Petitioner eventually decided against it (with only his counsel truly knowing the reason behind this decision). *Scheduling Order*, dated June 8, 2020; *Scheduling Order*, dated July 9, 2020; *Scheduling Order*, dated Sept. 14, 2020; *Scheduling Order*, dated Oct. 20, 2020; *Scheduling Order*, dated Oct. 30, 2020. Though Petitioner correctly notes that the absence of skin biopsy confirmation does not completely negate the diagnosis, the failure to corroborate it in this manner despite due opportunity makes it difficult to accept the diagnosis, given the absence of other preponderant evidence in its support. *See Shaw*, 2013 WL 2897425, at *15 (even though the skin biopsy yielded inconclusive results, the special master still concluded that the evidence supported SFN diagnosis).

Overall, the record does not by itself support the conclusion that Petitioner more likely than not experienced SFN—and that conclusion is not sufficiently supported by treaters' views or expert opinions.

III. Petitioner Has Not Established his Alleged SFN was Vaccine-Caused

A. *Althen Prong One*

Even if SFN *had* been proven as the proper diagnosis, Petitioner has not preponderantly established a causal relationship between the flu vaccine (the one his primary causation expert almost exclusively focuses on) and SFN. The fact that reliable science establishes an association between GBS and the flu vaccine (a topic Dr. Kinsbourne devoted some time to addressing) does *not* inerrantly lead to the conclusion that SFNs can also be deemed to be similarly-associated, given the facial differences in the nature of these conditions (and indeed the obvious distinctions between the kinds of nerves involved—with SFN affecting *unmyelinated* thin nerves that perform a wholly different function from the peripheral nerves involved in GBS). Asbury & Cornblath at S22; Gibbons at 1; Sejvar at 600; Tavee at 298.

Petitioner thus needed to offer scientific or medical evidence showing how a flu vaccine could harm the relevant nerves in SFN or initiate the condition generally (as opposed to it

developing secondarily to GBS).[18] But he did not do so. Little reliable evidence was offered showing cytokine overproduction could be instigated by the vaccine—let alone that this in turn could cause a harmful result. Petitioner did not even discuss the innate immune system, which is arguably the aspect of the immune response associated with an overproduction of cytokines.

Petitioner's alternative theory of molecular mimicry was no better supported. In a prior case, I rejected the theory when offered in a different context (to substantiate how the HPV and Hepatitis A vaccines—arguably different vaccines than those alleged here—could instigate an autoimmune process leading to autonomic dysfunction), where the expert witness "struggled… to specify *where* in the body this autoimmune cross-reaction was purportedly occurring." *See McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 4072113, at *21 (Fed. Cl. Spec. Mstr. July 15, 2019) (emphasis in original). In more similarly situated cases I have emphasized that ". . . merely chanting the magic words 'molecular mimicry' in a Vaccine Act case does not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or vaccine in question." *See,* e.g., *Mason v. Sec'y of Health & Hum. Servs.*, No. 17-1383V, 2022 WL 600415, at *27 (Fed. Cl. Spec Mstr. Feb. 4, 2022) (alleging unsuccessfully that the flu vaccine caused petitioner's CIDP, with experts opining on other possible diagnoses, which included GBS and SFN), citing *McKown*, 2019 WL 4072113, at *21, *50. Petitioner's contention herein was similarly conclusory and vague (and otherwise was far more relevant to the mechanism thought to cause *GBS*, with no comparable showing that it can also cause SFN).

B. *Althen Prong Two*

Petitioner also was unsuccessful in establishing that the flu vaccine likely "did cause" Mr. Fantini to experience SFN. Admittedly, Petitioner herein was able to locate some treater support for causation, as noted above.[19] However, I am not bound to accept a treater's opinion. *Snyder*, 88 Fed. Cl. at 746 n.67. And here, there is a secondary problem with this speculation. Dr. Shahkhan's analysis appears to rely on the polio, meningitis and rabies vaccination causing an SFN, based on Petitioner's reporting at the time that his symptoms were temporally associated with this second vaccine event - whereas *in this case* it is alleged that the flu vaccine was causal.

By contrast, many other aspects of the record are unsupportive of the conclusion that the flu vaccine triggered SNL in Petitioner. There is, for example, no evidence of any reaction to that vaccine in the almost four-week period between the relevant vaccinations. Moreover, none of

[18] Not only does the record not support the conclusion that Petitioner ever experienced GBS in this case after receipt of the flu vaccine, but Petitioner himself does not so argue.

[19] In particular, on December 17, 2012, Dr. Shahkhan's commented that Petitioner had symptoms of an SFN possibly due to an "autoimmune phenomenon." Ex. 5 at 2. On December 21, 2012, Dr. Ganjian proposed that Petitioner's tinnitus was "likely immune mediated and related to vaccination." Ex. 5 at 2.

Petitioner's lab work results confirmed the existence of an autoimmune/inflammatory response. Ex. 4 at 12–13; Ex. 9 at 1–2. Petitioner thus mostly relies on a temporal association—the kind of *post-hoc, ergo propter hoc* reasoning that has consistently in the Program been deemed insufficient to establish causality. *See Galindo v. HHS*, No. 16-203V, 2019 WL 2419552, at *20 (Fed. Cl. Spec. Mstr. May 14, 2019) (citing *U.S. Steel Group v. United States*, 96 F. 3d 1352, 1358 (Fed Cir. 1996) ("But to claim that the temporal link between these events proves that they are casually related is simply to repeat the ancient fallacy: *post hoc ergo propter hoc*").[20]

C. *Althen Prong Three*

The medical acceptability of onset was left largely unaddressed by Petitioner. Dr. Kinsbourne favored an onset date of 28 days post-vaccination, measured from the date of the flu vaccine's administration (though he nor Petitioner cited to any medical records to support this assertion). Dr. Donofrio did not offer a timeframe for SFN but disputed that the 28-day period was not medically acceptable.

Petitioner's literature regarding the expected post-vaccination onset focused on comparing SFNs to distinguishable demyelinating conditions like GBS. Poser at 416–21 (comparing swine flu and GBS); Stratton at 1604 (Hib and GBS). He correctly notes the timeframe (3-42 days (or up to six weeks)) for a Table GBS claim—but Program claimants cannot "piggyback" on the Table requirements when attempting to prove a non-Table claim. *See Greene v. Sec'y of Health & Hum. Servs.*, No. 11-631V, 2018 WL 3238611, at *9 (Fed. Cl. Spec. Mstr. May 7, 2018) (noting that an expert's opinion on the timing issue of a brachial neuritis claim relied on conclusory determinations that the "Table time periods were not that far off the time period in question (something Program law says is not permitted)").[21]

[20] Petitioner's experts also did not attempt to differentiate symptoms that might have predated vaccination from those Petitioner experienced thereafter. Thus, the record reveals that in 2007 Petitioner had severe pain in his face, particularly above his right eyebrow, with an MRI revealing a potential neuropathic component to his pain. Ex. 12 at 3. When the symptoms ceased was unclear, as Petitioner stopped appearing for follow-up appointments after June 2007. Then, beginning in November 2012, Mr. Fantini began to experience parasthesias to the back of his head and lower lip, with other complaints that month that these sensations were also on the left side of his mouth and chin. Ex. 4 at 12–13; Ex. 7 at 11–12. Although I do not deem these symptoms as having been preponderantly established to be likely related to Petitioner's post-vaccination illness, such neuropathic symptoms raise questions that were not fully addressed in this case.

[21] At best, the fact that Table claims reflect the Government's reasoned interpretation of persuasive medical science thinking on a causation theory means they might have some supportive evidentiary value. *See generally Marino v. Sec'y of Health & Hum. Servs.*, No. 16-0622V, 2017 WL 6206383, at *2, n.6 (Fed. Cl. Spec. Mstr. Apr. 18, 2017) (even though petitioner's claim was filed before the injury of "Shoulder Injury Related to Vaccine Administration" was added to the Table, the special master properly relied on the Table elements in analyzing the claimant's causation-in-fact claim).

More importantly, *this is not a GBS case*. There are clear distinctions between GBS and SFNs (even more so than GBS and CIDP), with etiology, symptoms, and timeframe of symptoms progression. Tavee at 297; Lacomis at 174; Asbury & Cornblath S21; Sejvar at 604. Filed literature establishes that SFNs feature a "slowly progressive course," with little discussion of a specific timeframe. Tavee at 304. GBS, by contrast, is shown to have an acute onset that can occur in six weeks or less. Sejvar at 601. Thus, what is known about GBS's onset timeframe cannot simply be borrowed as a template to understand a likely onset timeframe for SFNs. Dr. Kinsbourne's opinion on onset timeframe was too reliant on GBS to provide fully reliable evidence on what would be expected for SFNs.

Petitioner has not offered sufficient evidence to suggest what the expected timeframe for vaccine-caused SFN would be.[22] As a result, I cannot find herein that the proposed timeframe for onset is medically acceptable, nor that Petitioner's injuries more likely than not occurred within that timeframe.

IV. Petitioner has not Established his Tinnitus was Vaccine-Caused

Mr. Fantini's alleged tinnitus injury is better established than his alleged SFN injury. Petitioner had reported shortly after his vaccination that he had constant ringing in his ears (a common characteristic of tinnitus). Ex. 4 at 9–10. And though Dr. Blitshteyn's telehealth consultation lacks reliability (as already established above), Dr. Ganjian's contemporaneous impression as an ENT specialist is more trustworthy. Ex. 10 at 1–2.

But even if the tinnitus diagnosis was itself preponderantly established, Petitioner has not also shown that it is likely a secondary symptom of SFN (and could not—since I do not find on this record that the proposed SFN diagnosis was established), or that it could independently be attributed to the flu vaccine. Petitioner's expert on causation also offered no opinion on the timeframe for onset of tinnitus due to neuropathy of any kind.

IV. This Case Was Appropriately Decided on the Papers

In ruling on the record, I am choosing not to hold a hearing. Determining how best to resolve a case is a matter that lies generally within my discretion, and although the parties have not objected to my choice of this method of adjudication, I shall explain why a hearing was not required.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each

[22] Dr. Kinsbourne did not offer an opinion that the rabies/polio/meningitis vaccine was causal, so there is no need to consider whether an onset the day after this vaccination could be medically acceptable.

party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes without a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

The present claim could be, and was, resolved fairly, without the need for live testimony from the experts. The parties did not agree on Mr. Fantini's diagnosis, but the record alone allows me to conclude that Petitioner's contentions about its character lack substance. The question of causation itself was also something that could be resolved through reading the expert reports and associated literature, especially because that question raised issues (the propensity of the flu vaccine to cause neuropathic injuries) with which I have extensive familiarity. And evidence that a vaccine "did cause" the alleged injury, or did not, could be adduced from the record, without the need for witness assertions.

Overall, careful review of briefs, expert reports, articles/literature, and the record were sufficient to reach a just and defensible conclusion. This case is nearly seven years old, and thus there was value to selecting the most expeditious form of resolution for such a claim.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such as showing. It cannot be assumed that because GBS is closely associated with the flu vaccine, that *any* related neuropathy is likely similarly attributable. Rather, claimants must do the "heavy lifting" imposed upon them in causation-in-fact cases and show how the vaccine in question could cause a different condition. *Lampe*, 219 F.3d at 1360. What is known about the related condition and vaccine may well supply a useful "roadmap," but in the end the claimant's showing must reliably establish causation. This has not been accomplished in this case, so Petitioner is not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[23]

IT IS SO ORDERED.

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

[23] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.