

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 17-1691V

ANGELA KAY STACY,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Chief Special Master Corcoran

Filed: August 8, 2024

Isaiah Kalinowski, Bosson Legal Group, Fairfax, VA, for Petitioner.

Felicia Langel, U.S. Dep’t of Justice, Washington, DC, Respondent.

ENTITLEMENT DECISION¹

On November 3, 2017, Angela Kay Stacy filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the “Vaccine Program”).² Petitioner alleges that she suffered a movement disorder as a result of receiving an influenza (“flu”) vaccine on November 7, 2014. Petition (ECF No. 1) at 1.

A two-day hearing was held in Washington, D.C. on January 8–9, 2024. Now, based on the evidence adduced at hearing, plus the medical records and other briefs filed, I hereby deny entitlement. Petitioner has not preponderantly demonstrated that her condition, however defined, could be caused by the flu vaccine.

¹ Under Vaccine Rule 18(b), each party has fourteen (14) 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 in its present form. *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) (“Vaccine Act” or “the Act”). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

Vaccination and Subsequent Initial Symptoms

Ms. Stacy received the flu vaccine in her left deltoid on November 7, 2014. Ex. 2 at 1; Ex. 6 at 43. She had a prior medical history of urinary tract infection, sinusitis, pneumonia, strep pharyngitis, oral candidiasis, vitamin B12 deficiency, abdominal pain, gastroesophageal reflux, low back pain, and hemorrhoids. *See generally* Ex. 3, 5, 39. There is no record evidence of any initial vaccine reaction.

On November 20, 2014 (thirteen days post-vaccination), Petitioner visited an urgent care provider reporting sinusitis and low back pain. Ex. 4 at 28. Upon examination, she displayed nasal discharge and an erythematous (*i.e.*, red) throat, and tested positive for strep pharyngitis. *Id.* at 29. Petitioner was given an antibiotic and pain medication. *Id.* at 30.

Three weeks later, on December 11, 2014, Petitioner went to the emergency department at Whitesburg ARH Hospital, reporting muscle twitching that she reported had begun in her left leg about four weeks prior (which would be close in time to vaccination), spread to her back two weeks later, and then intensified over the previous two days. Ex. 7 at 123–24. Petitioner also stated that the “jerking” sensation had started after she received her flu vaccine the prior month (although no earlier records set this forth). *Id.* at 124. Upon examination, Petitioner exhibited spastic twitching of her body and legs, although the twitching decreased when she was laying down with her eyes closed. *Id.* at 124–25. Petitioner was transferred to Pikesville Medical Center in Pikesville, Kentucky (“Pikesville”) for a neurological work-up. *Id.* at 127.

Petitioner was admitted to Pikesville on December 12, 2014, at which time she reported that several days after she had been treated for strep pharyngitis the prior month, she had developed intermittent left leg spasms that later spread to her back and torso. Ex. 7 at 70. She reiterated that she received the flu vaccine four weeks prior, and that over the last three days her muscle spasms had been constant. *Id.* These records further indicate that Petitioner did not report experiencing any muscle spasms while she was asleep. *Id.* at 70. Petitioner underwent thoracic and lumbar MRIs which showed a meningioma at T9/10 but were otherwise normal. *Id.* at 86–88. An electroencephalogram (“EEG”)³ was also performed and returned normal results, leading hospitalist John Watson, M.D., to speculate whether Petitioner’s muscle spasms were “psychogenic” due to their absence whenever she was asleep. *Id.* at 92.

³ EEG is defined as “a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. The normal dominant frequency of these potentials is about 8 to 10 cycles per second and the amplitude about 10 to 100 microvolts. Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria.” *Electroencephalogram*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=15813&searchterm=electroencephalogram> (last visited Aug. 8, 2024).

The next day, neurologist Naveed Ahmed, M.D., evaluated Petitioner and documented “intermittent generalized jerking, involuntary, which were able to be suppressed with distraction.” Ex. 7 at 74. Dr. Ahmed noted that “clinically and historically, there is no suggestion that [Ppetitioner] has acute inflammatory demyelinating polyneuropathy.” *Id.* Dr. Ahmed prescribed clonazepam, ordered a bone scan for the meningioma seen on MRI, and planned to order a brain MRI if Petitioner’s condition remained unchanged. *Id.*

Petitioner was discharged from Pikesville on December 14, 2014, with prescriptions for clonazepam and Baclofen and with a diagnosis of “muscle fasciculations thought to be secondary to polyneuropathy versus mild radiculopathy, now resolving.” Ex. 7 at 65. Two days later, she saw primary care provider Kassi Marshall, M.D., informing Dr. Marshall that she had been experiencing “severe jerking” in both legs for three weeks. Ex. 6 at 3. An exam revealed “myoclonus of [Petitioner’s] full body that [was] toward [the] left side,” but a brain MRI for “left vision loss and myoclonus” was ultimately unremarkable. *Id.* at 6, 29.

On December 24, 2014, Dr. Marshall prepared a physician statement for Petitioner’s short-term disability application. Ex. 6 at 37. The statement indicated that Petitioner’s symptoms first appeared in November 2014, and that she had ceased working on December 12, 2014. *Id.* Dr. Marshall noted that Petitioner had “uncontrollable myoclonus and [was] at high risk for falls,” was ataxic and “only ambulatory with assistance,” and that “stressful situations [were] likely to exacerbate [her] myoclonus and weakness.” *Id.* at 37–38, 41. Dr. Marshall further stated, however, that because Petitioner’s “official diagnosis [was] still pending,” she was reluctant to opine on subsequent treatment or expected outcomes. *Id.* at 40–41.

Efforts to Diagnose Condition in 2015

Ms. Stacy followed up with Dr. Marshall on January 5, 2015. Ex. 6 at 32. Petitioner now reported that her left side jerking was getting worse, and that she had fallen to her knees once since her last visit. *Id.* Petitioner further stated that “[c]ertain positions . . . initiate the jerking type movements or exacerbate them.” *Id.* A week later, on January 12, 2014, Petitioner saw neurologist Toufic Fakhoury, M.D., following a referral from Dr. Ahmed for evaluation of a possible seizure disorder. Ex. 37 at 2. Upon examination, Petitioner exhibited no focal abnormalities, and it was noted that there was no report of altered awareness associated with Petitioner’s body jerks. *Id.* at 8.

Petitioner underwent an in-patient video EEG on January 12–14, 2015, which showed seven stereotypical spells during the two days of monitoring “consisting predominantly of head jerks to the left.” Ex. 37 at 5. But “no epileptiform abnormality” was observed, and Dr. Fakhoury diagnosed Petitioner with “[n]onepileptic spells,” recommending an “outpatient consultation with a therapist.” Ex. 42 at 2, 19–21. The next month, Petitioner followed-up with Dr. Ahmed, reporting whole-body jerks that were relieved with medication, numbness in her left leg, tingling in both

legs, low back pain, and incontinence. Ex. 6 at 51. Dr. Ahmed referred Petitioner to the movement disorder clinic at the University of Kentucky Neuroscience Institute (the “UK Institute”). *Id.* at 54.

Petitioner subsequently saw neurologist, John Slevin, M.D.—a movement disorder specialist at the UK Institute⁴—on April 13, 2015. Ex. 11 at 2. At that time, she reported blurry vision in her left eye and pain in her back, left foot, leg, and arm “since flu shot on Nov[ember] 21[, 2014].” *Id.* at 7–9. She also stated that her muscle spasms were diminishing, and that she had “good days and bad days.” *Id.* at 2.

Upon examination, Petitioner displayed “periodic abnormal movements generally to the left[—]uninvolved muscles of the trunk and proximal left arm” which “[t]he velocity was more characteristic of a dystonia than myoclonus.” Ex. 11 at 3. Dr. Slevin also noted Petitioner’s post-vaccination URI and strep infection. *Id.* at 7–9. He similarly documented Petitioner’s family history of autoimmune disease, and noted that her previous autoimmune workup “raise[d] questions about a role of her individual immune responsivity.” *Id.* at 3.

Overall, Dr. Slevin characterized Petitioner’s neurologic exam results as normal. Ex. 11 at 3. He deemed it “difficult, if not impossible, to determine what role was played” by various independent factors in causing her symptoms (such as her earlier infections, or receipt of the flu vaccine). *Id.* Dr. Slevin also did not embrace any specific diagnosis, although he did list in his “active problems” section of the record “myoclonic jerking.” *Id.* at 4. He further noted that although Ms. Stacy had not displayed opsoclonus,⁵ some scientific literature suggested that plasmapheresis was an effective treatment for opsoclonus-myoclonus. *Id.*, citing A. Piquet et al., *Opsoclonus-Myoclonus Syndrome Post-Vaccination and Viral Illness*, 3 Int’l J. Clinical Med. 304 (2012), filed as Ex. 20 (ECF No. 37-9) (“Piquet”). Otherwise, Dr. Slevin recommended waiting for “presumed continued improvement,” and he saw no need to schedule a follow-up visit. Ex. 11 at 3, 4.

Treatment from Subsequent Periods of Time

Petitioner’s treatment history after her visit to Dr. Slevin sheds little light on the causation issues in contention in this case. On July 17, 2015, Petitioner had a second follow-up appointment with Dr. Marshall. Ex. 6 at 94–96. She now reported a burning pain in both feet for the last two weeks, but was experiencing fewer muscle spasms despite not using her medication regularly. *Id.* Petitioner was referred back to Dr. Ahmed for an electromyography⁶ (“EMG”)/nerve conduction

⁴ See About, UK HealthCare, <https://ukhealthcare.uky.edu/doctors/john-slevin> (last visited Aug. 8, 2024).

⁵ “Opsoclonus” is defined as “a condition characterized by nonrhythmic horizontal and vertical oscillations of the eyes, observed in various disorders of the brainstem or cerebellum.” *Opsoclonus*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=35338&searchterm=opsoclonus> (last visited Aug. 8, 2024).

⁶ “Electromyography” is defined as “an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical

study.⁷ *Id.* at 97. That study of her upper and lower extremities was performed on November 16, 2015, and yielded normal results. Ex. 7 at 34–44.

Petitioner followed-up with Dr. Marshall monthly from 2015–18 to request medication refills for muscle spasms that would wax and wane, among other things. *See generally* Ex. 6. She also saw other medical providers during this time for a variety of other complaints. *See also* Ex. 43, 48.

On April 28, 2019, Petitioner went to neurologist Chandrashekar Krishnaswamy, M.D., reporting that her “intermittent jerky movements . . . [were] getting worse lately.” Ex. 43 at 32. Dr. Krishnaswamy referred Petitioner back to the UK Institute. *Id.* at 33. But it is not evident from the filed medical records that this ever occurred. Several months later, on August 7, 2019, Petitioner saw Dr. Marshall and reported an increase in her muscle spasms, and that she had stopped taking her medication. Ex. 40 at 56. Upon examination, Dr. Marshall documented spasms, and also referred Petitioner back to the UK Institute (although no record of this recommended visit has been filed either). *Id.* at 57–58. Petitioner again saw Dr. Marshall on November 5, 2019, reporting that the UK Institute had recommended cognitive behavioral therapy to better address her muscle spasms. *Id.* at 46.

Petitioner also continued to follow-up with Dr. Marshall every four months between 2019 and 2020. *See generally* Ex. 40.

II. Hearing Testimony

A. *Angela Stacy*

Petitioner was the only fact witness to testify at hearing. *See generally* Tr. at 9–68. Prior to vaccination, she stated, she was in good health generally, and had never experienced any neurological conditions or symptoms of twitching or jerking. Tr. at 20. She received the flu vaccine as a general preventive measure. *Id.* at 19. She testified that she previously had received the vaccine approximately two or three times prior, and had experienced the flu earlier that year. *Id.* at 20.

The day of her vaccine, Petitioner felt slightly flushed, but that the sensation did not last long. Tr. at 20. But three days later, she began to experience other symptoms such as numbness in her toes and on her left side. *Id.* at 21. She further explained that at the time the numbness sensation

stimulation; performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals.” *Electromyography*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography> (last visited Aug. 8, 2024).

⁷ “Nerve Conduction Study” is “an essential tool in the evaluation of the peripheral nervous system [where] [t]he sensory nerve action potential (SNAP) provides information on the sensory nerve axon and its pathway from the distal receptors in the skin to the dorsal root ganglia, while the compound muscle action potential (CMAP) is an assessment of the motor nerve fibers from their origins in the anterior horn cell to their termination along muscle fibers.” *Nerve Conduction Studies: Basic Concepts*, <https://pubmed.ncbi.nlm.nih.gov/31277849/> (last visited Aug. 8, 2024).

was not debilitating, but simply more irritating to deal with. *Id.* Six days post-vaccination, Petitioner recalled, she began experiencing a jerking sensation in her left leg, progressing as time passed. *Id.* She described the jerking as involuntary, painless, but quite noticeable. *Id.* at 22–23.

On the morning of December 11, 2014, Petitioner woke up to a stark change in her jerking sensation, and she testified that “[her] whole body would jerk, . . . and it was nothing [she] could control in any manner.” Tr. at 26. She explained that she proceeded with her work commitments (*i.e.*, a live bluegrass concert hosted by the radio show she volunteered with), but that by the end of the event, the jerking continued to worsen, leading her to seek medical assistance. *Id.* at 27–28. Petitioner went to the emergency room at Whitesburg ARH where she was later transferred to Pikeville. *Id.* at 30–31. The Pikeville staff described her symptoms as myoclonic jerks, and she was prescribed Klonopin and advised to follow up with Dr. Ahmed in a couple of months. *Id.* at 33.

Following her hospital discharge, Petitioner testified, her symptoms only progressed and eventually caused her to experience multiple falls and a loss of balance between December 2014 and September 2015. *Id.* at 34. In addition to the persistent jerking, Petitioner soon developed back pain and fatigue and exhaustion as a result of all the jerking. Tr. at 35. Petitioner recalled seeing several different physicians shortly after being discharged from the hospital—including neurologist, Dr. Fakhoury, who performed observational testing over a two-day period to monitor her jerks. *Id.* at 39. Petitioner testified that she did not recall Dr. Fakhoury ever diagnosing her with epilepsy or a seizure disorder, and that she had never been diagnosed with any mental health conditions, despite Dr. Fakhoury opining that Petitioner’s condition could be psychogenic or psycho somatic. *Id.* at 39–40.

Petitioner recalled that the jerking sensations continued daily, despite less frequently, after her initial visit with Dr. Slevin in April 2015. *Id.* at 43. However, she also testified that the pain only intensified as a result of the “wear and tear from all the jerk[ing].” *Id.* at 44. As a result of the constant jerking, pain, and fatigue, Petitioner eventually was let go from her employer and she never returned to the radio station to work as a volunteer. *Id.* at 46–47. Petitioner recalled hiring a former high school friend for several months (early 2015 to October 2015) to assist her with getting to and from appointments because she was advised not to drive, and her family was either unable to help or lived too far away. Tr. at 52–53. She proceeded to explain how the constant jerking affected her daily living, including her ability to work, drive, care for family members, or partake in various hobbies. *Id.* at 58–62.

B. *Lawrence Steinman, M.D., Ph.D.*

Dr. Steinman, a neurologist, prepared three written reports and testified on behalf of Petitioner. Report, dated Jan. 12, 2020, filed as Ex. 10 (ECF No. 25-1) (“Steinman First Rep.”); Report, dated May 26, 2021, filed as Ex. 34 (ECF No. 39-1) (“Steinman Second Rep.”); Report, dated Dec. 7, 2021, filed as Ex. 36 (ECF No. 46-1). He proposed that the flu vaccine Petitioner

received more likely than not had triggered an immune response which ultimately led to her development of a movement disorder. Tr. at 191.

As shown in his CV, Dr. Steinman received his undergraduate degree from Dartmouth College, and his medical degree from Harvard Medical School. *Curriculum Vitae*, filed as Ex. 14 (ECF No. 37-3) (“Steinman CV”) at 1. He then completed residencies in neurology and pediatrics at Stanford University. *Id.* He has worked as a professor of neurology and pediatrics at Stanford for the past 40 years. *Id.*; Steinman First Rep. at 1. He is board certified in neurology from the American Board of Psychiatry and Neurology. Steinman CV at 2. Dr. Steinman has also published hundreds of peer-reviewed publications on neurology and autoimmune diseases. *Id.* at 6–49. He holds several patents related to the diagnosis and treatment of autoimmune and demyelinating diseases. *Id.* at 2–3. He presently serves as the George A. Zimmerman Professor of Neurological Sciences, Neurology, Genetics and Pediatrics at Stanford University. *Id.* at 1.

Dr. Steinman began his testimony by first briefly describing the difference between myoclonus and dystonia. Tr. at 86. As he explained, “myoclonus is best described as a rapid jerking movement” whereas “[d]ystonia is more of a slow and steady abnormal movement”—and he deemed Petitioner’s presentation most consistent with myoclonus. However, Dr. Steinman also acknowledged that none of Petitioner’s treating physicians had ever settled on a firm diagnosis or etiological explanation for her injury. *Id.* Despite this lack of treater confirmation, Dr. Steinman maintained that “[b]eginning after the influenza vaccine, [Petitioner] developed a movement disorder [—] a disorder that is manifest[ed] by jerking of [the] extremities.” *Id.* at 88. His diagnostic characterization relied on evidence of the jerking of Petitioner’s extremities and her body in a certain direction—noting further that her “chief complaint” was the movement disorder. By contrast, Dr. Steinman did not seem to consider Petitioner’s initial complaint of “an odd sensation in her three toes” as part of her myoclonus-like presentation. *Id.* at 89–90.

Myoclonus, Dr. Steinman opined, “can be caused by an immune-mediated cross reaction against neurological components produced as [Petitioner’s] symptoms.” Tr. at 88. In turn, he opined, such an immune-mediated cross-reaction could be instigated by the flu vaccine. *Id.* at 94. In so maintaining, Dr. Steinman invoked the theory of molecular mimicry, in which “[t]here’s something on a foreign material, like a vaccine designed from a virus, to prevent viral diseases, and something that’s on [one’s] own self-molecules, [] the immune system mistakenly recognizes ... the self-molecule, [which] [] can lead to trouble.” *Id.* at 96. Exact similarity or homology between the amino acid sequences in a foreign antigen and self-antigen, however, is not required for molecular mimicry to take place. *Id.*; A. Gautam et al., *A Polyalanine Peptide with only Five Native Myelin Basic Protein Residues Induces Autoimmune Encephalomyelitis*, 176 *J. Exp. Med.* 605, 608 (1992), filed as Ex. 29 (ECF No. 37-18) (“Gautam”) (stating that “[s]ince only four or

five native residues in a peptide were able to induce EAE, it is conceivable that a pathogen with limited homology to self and few amino acid residues may trigger autoimmune disease.”).⁸

Dr. Steinman also attempted to rebut the contention (largely advanced by Respondent’s experts) that the frequency of molecular mimicry in nature reduces its probative value as a causal mechanism for autoimmune conditions. Tr. at 111. He accepted that “there are factors that mitigate the occurrence from becoming a real autoimmune disease,” such as immune cells generated by the human body that can suppress the immune response. *Id.* Thus, in many cases aberrant antibodies might be generated due to molecular mimicry, but might not actually result in the development of a clinical disease, if immunologic “checks and balances” prevent this from occurring. *Id.* But genetic variation or mutation can impact the human body’s ability to regulate the immune response—as evidenced by an article Dr. Steinman co-authored, which concluded that “[c]ertain genes conferring susceptibility to disease and certain factors in the environment are both critical for the development of autoimmunity.” L. Steinman & M. Oldstone, *More Mayhem from Molecular Mimics*, 3 *Nature Med.* 1321 (1997), filed as Ex. 24 (ECF No. 37-13). Thus, Dr. Steinman maintained, even if “more often than not” molecular mimicry alone “is not sufficient to actually trigger the disease, . . . sometimes it is.” Tr. at 115.

Here, Dr. Steinman opined, homology could be demonstrated between neuraminidase found in a component of the flu vaccine and a self-structure: the “PNKD” protein. Tr. at 130; Steinman First Rep. at 12–13. PNKD, Dr. Steinman explained, stands for “paroxysmal, nonkinesigenic, dyskinesia”—a nervous system disorder occurring “like a bolt” and “not associated with a participatory antecedent movement.” *Id.* at 132. Of course, *none of Petitioner’s treating physicians had diagnosed her with PNKD*, but Dr. Steinman maintained that she had displayed manifestations of it, and otherwise likely possessed that particular protein as well, making it a reasonable comparison. *Id.*; M. Bruno et al., *Genotype-phenotype Correlation of Paroxysmal Nonkinesigenic Dyskinesia*, 68 *Neurology* 1782 (2007), filed as Ex. 31 (ECF No. 37-20) (discussing PNKD and its clinical manifestations which are due to mutations in the MR-1 protein). In addition, Dr. Steinman argued, the PNKD protein is significant in ensuring the proper functioning of the neurologic system, and thus is not simply relevant to PNKD disease. Tr. at 138; D. Kanduc, *Describing the Hexapeptide Identity Platform between the Influenza A H5N1 and Homo Sapiens Proteomes*, 4 *Biologics: Targets & Therapy* 245, 256 (2010), filed as Ex. 30 (ECF No. 37-19) (finding that a “high number of influenza A H5N1 hexapeptides are seen in numerous human proteins that play a crucial role in neural networks and functions”).

In addition, Dr. Steinman referenced other evidence that he argued independently associated the flu vaccine with other movement disorders. Tr. at 168; J. Prasuhn et al., *Transient*

⁸ Dr. Steinman emphasized his view that Gautam clearly established that a homologous sequence of just four or five amino acids would be enough for a mimicking cross-reaction to occur. Tr. at 100. And he took considerable time attacking the arguments of Respondent’s experts to the contrary. *Id.* at 105. However, this case does not turn on the success of this aspect of Dr. Steinman’s causation opinion, and I therefore do not include extensive discussion of it.

Generalized Chorea in Influenza A Encephalopathy, 591 Tremor Other Hyperkinet Mov 1, 2 (2018), filed as Ex. 18 (ECF No. 37-7) (“Prasuhn”) (determining that “[t]he influenza A infection was considered to be the underlying cause for the presented symptoms, although irrevocably proving a causal relationship is not possible”). Prasuhn focuses on chorea,⁹ not dystonia or myoclonus, but Dr. Steinman deemed chorea to be a reasonably-comparable movement disorder (“more fluent” than a myoclonic jerk, but “less fixed” than dystonia). Tr. at 170. He also offered literature specific to opsoclonus-myoclonus, another arguably-comparable condition (albeit something else Petitioner was never diagnosed with), including the Piquet article that the movement disorder specialist Petitioner saw, Dr. Slevin, had referenced when discussing potential treatments. A. Morita et al., *Opsoclonus-Myoclonus Syndrome Following Influenza A Infection*, 51 Intern med 2429 (2012), filed as Ex. 19 (ECF No. 37-8) (finding an adult case of opsoclonus-myoclonus syndrome following influenza A virus infection); Piquet at 305 (concluding that “[t]he vaccination in combination with the viral illness potentiated the immune mechanism thought to be noted in [opsoclonus-myoclonus syndrome]”).

Dr. Steinman next proposed what would constitute a medically-acceptable timeframe for an antibody attack against the PNKD protein to manifest clinically significant symptoms. Tr. at 175. He emphasized that his opinion on this matter was dependent on whether Petitioner had ever received the vaccine before—and Petitioner had testified that she had received it at least two or three times in her life. As a result, and due in part to immune memory, Dr. Steinman opined that “it certainly could come up within a couple of weeks, that abnormal feel in [Ppetitioner’s] three toes” as a recall response “if that had anything to do with a subsequent movement disorder.” *Id.* at 175–76. (As noted above, however, Dr. Steinman had also disclaimed the toe-related sensations as related to Petitioner’s movement disorder). Ultimately, in Dr. Steinman’s view a time interval between six and fifteen days post-vaccination would be a medically acceptable period in which initial, clinically significant symptoms (*i.e.*, twitching) might manifest, with a longer timeframe of three to five weeks for clinically acute symptoms to appear (*i.e.*, twitching and jerking of her whole body). *Id.* at 176–77.

Dr. Steinman also addressed the possibility of alternative causes for a movement disorder suggested by aspects of Petitioner’s pre-vaccination medical history. Tr. at 177. Respondent had proposed that some of Petitioner’s comorbidities (*i.e.*, obesity, interstitial cystitis, B-12 deficiency, fatty liver disease, etc.) were potential explanations, but Dr. Steinman maintained that these were not only distinguishable from Petitioner’s movement disorder but were common to middle-aged individuals like Petitioner. *Id.* at 178. Otherwise, Petitioner’s medical records did not suggest that she had diabetes, diabetic neuropathy or any other neurological problem and/or condition prior to the receipt of the flu vaccine. *Id.*

⁹ “Chorea” is defined as “the occurrence of a variety of continual, rapid, highly complex, jerky, dyskinetic movements that look well-coordinated but are actually involuntary.” *Chorea*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=9555&searchterm=chorea> (last visited Aug. 8, 2024).

At most, Petitioner had been diagnosed with shingles in July/August 2014, but this infectious event was in Dr. Steinman's view too temporally remote from her movement symptoms onset in November. Tr. at 183–84. However, Dr. Steinman also addressed the apparent streptococcus infection Petitioner had experienced in the same month as her vaccination. *Id.* He acknowledged that “strep infections have been associated with movement disorders, and the etiology has been that ...there are sugars that mimic sugars in the nervous system.” *Id.* But Dr. Steinman did not believe this intercurrent infection could have been the sole cause of Petitioner's injury (although it could have been a co-factor). *Id.*

Dr. Steinman also attempted to address an error in his analysis pointed out by Respondent's immunology expert, Dr. Ross Kedl. Dr. Kedl had observed that Dr. Steinman's initial homology showing was based on the erroneous assumption that a particular influenza strain was included in the vaccine Petitioner received. *See generally* Tr. at 141–60; Steinman First Rep. at 12–13; Steinman Second Supp. Rep. at 2–5. Dr. Steinman admitted the error, but argued that he could still demonstrate homology based on the correct vaccine components. Steinman Second Supp. Rep. at 5–6. In so maintaining, he reiterated arguments about the degree of homology necessary for a cross-reaction (although they do not impact my determination). Tr. at 161.

C. *Ross Kedl, Ph.D.*

Dr. Kedl prepared three written reports and testified on behalf of Respondent. Report, dated Aug. 15, 2020, filed as Ex. A (ECF No. 35-1) (“Kedl First Rep.”); Report, dated Oct. 1, 2021, filed as Ex. E (ECF No. 41-1); Report, dated Feb. 5, 2022, filed as Ex. G (ECF No. 48-1).

Dr. Kedl is a Professor of Immunology in the Department of Immunology and Microbiology at the University of Colorado Denver. Kedl First Rep. at 1. He received his Ph.D. in Pathobiology from the University of Minnesota. *Curriculum Vitae*, filed as Ex. H (ECF No. 61-3) (“Kedl CV”). Thereafter, he completed a postdoctoral fellowship at the National Jewish Medical and Research Center in Denver, Colorado, then spent three years as a senior immunologist at 3M Pharmaceuticals in their Immune Response Modifier Program. Kedl First Rep. at 1. Since joining the University of Colorado in 2004, Dr. Kedl has maintained a National Institutes of Health (“NIH”) funded research program “centered on the biology of vaccine adjuvants and their capacity to induce robust and enduring cellular immunity.” *Id.* Dr. Kedl has authored or co-authored numerous publications in areas “focused on vaccine adjuvants and the mechanisms by which they induce adaptive (T and B cell) immunity.” *Id.* at 1–2; Kedl CV at 14–26.

Dr. Kedl's testimony focused heavily on his criticisms of molecular mimicry as explaining the pathophysiology of how a vaccine might cause some form of autoimmune injury. Tr. at 211. He characterized molecular mimicry as the idea that “an immune response is generated against either an infection or a vaccine antigen, and there's a certain amount of significant biologically relevant and pathological cross-reactivity that is generated against a self-tissue that has enough similarity to that vaccine or infectious antigen to cause pathological cross-reactivity in the disease.” *Id.* However, Dr. Kedl deemed the theory to be in need of updating, in particular because

of advances in the scientific community's search capacity for sequencing of the amino acids contained in proteins. *Id.* at 212.

Dr. Kedl particularly questioned the concept that short sequences of amino acid chains were sufficient to induce autoimmunity, simply due to similarity with self-structures also featuring those chains, explaining that “if we allow the idea that ... a single peptide with a five amino acid similarity between one self-antigen and one vaccine antigen actually is sufficient to launch autoimmune pathology, ... then it would stand to reason that if [we] found more similarities to something else, then all the more likely autoimmune manifestations should occur in that case.” Tr. at 213; Kedl First Rep. at 5–6. But if that were so, no genetic variability could ever explain why some individuals would or would not incur an autoimmune disease. Tr. at 213. In addition, Dr. Kedl noted that antecedent infectious agents are well understood to play a role in causing some autoimmune diseases, yet “one cannot decide that [the] infection drove the autoimmune manifestations [as a result] of molecular mimicry.” Tr. at 215 (“the mechanism by which they do that is still mildly under debate”); *Adverse Effects of Vaccines: Evidence and Causality* 70–73 (Stratton et al., eds. 2012), filed as Ex. A Tab 13 (ECF No. 61-2).

Dr. Kedl spent some time addressing the bases offered by Dr. Steinman to support molecular mimicry occurring due to short, homologous chains of amino acids in antigenic proteins. Tr. at 218. He maintained, for example, that Dr. Steinman over-relied on animal tests that reached experimental conclusions (often based on inclusion of chemical elements intended to provoke a measurable response) incomparable to how the body would react to vaccination. *Id.* at 220–21. He also questioned whether short sequences of amino acids were sufficient for molecular mimicry to even occur. Tr. at 241 (referencing Gautam) (finding “the standards for autoimmune pathology induction as put forward by [the] Gautam [papers], as exceptionally low, and this doesn't even meet that”). And he challenged Dr. Steinman's database search-oriented methodology for identifying mimics between vaccine components and self-structures, contending that this approach was highly unreliable from a scientific standpoint. *Id.* at 230–31; A. Silvanovich et al., *The Value of Short Amino Acid Sequence Matches for Prediction of Protein Allergenicity*, 90 *Toxicological Sciences* 252, 252–58 (2006), filed as Ex. A Tab 3 (ECF No. 35-4) (finding that “searches for short amino acid sequence matches of eight amino acids or fewer to identify proteins as potential cross-reactive allergens is a product of chance and adds little value to allergy assessments for newly expressed proteins”). Dr. Kedl denied that Dr. Steinman had even identified an actual molecular mimic in the present case. Tr. at 238.

Although Dr. Kedl did not purport to offer an opinion as to Petitioner's actual injury, he maintained that there was “absolutely no evidence biologically or literature-wise that an immune response generated” the symptoms experienced by Petitioner. *Id.* at 216–17. He also argued that the record in this case did not support the conclusion that a “combination of events”—a molecular mimic associated with infection, plus a molecular mimic associated with vaccination—could have together prompted Petitioner's injury. *Id.* at 216.

D. *Peter Donofrio, M.D.*

Dr. Donofrio, a neurologist, prepared two written reports and testified on behalf of Respondent. Report, dated Nov. 13, 2020, filed as Ex. C (ECF No. 36-1) (“Donofrio First Rep.”); Report, dated Oct. 4, 2021, filed as Ex. F (ECF No. 42-1).

Dr. Donofrio is board certified in neurology, internal medicine, electrodiagnostic medicine, and neuromuscular medicine. *Curriculum Vitae*, filed as Ex. I (ECF No. 61-4) (“Donofrio CV”). After receiving his M.D. from Ohio State University School of Medicine, he completed residencies in internal medicine and neurology and a neuromuscular fellowship. *Id.* at 1–2. Throughout his career, Dr. Donofrio held various academic appointments at Vanderbilt University School of Medicine, Wake Forest University School of Medicine, and University of Michigan Medical Center. *Id.* at 2–3. He retired from the practice of neurology in July 2021. *Id.* at 2. He “has experience [] evaluating a spectrum of neuropathies such as [GBS] ... and the related condition of [MFS],” and he has also published on these areas. Donofrio First Rep. at 1. Dr. Donofrio also has experience reviewing “literature and data on vaccine-related GBS, transverse myelitis, MS, brachial neuritis[,] and other neurologic conditions.” *Id.*

Dr. Donofrio briefly discussed the difference between *hyperkinetic* and *hypokinetic* movement disorders, defining the former as “one that is rapid in frequency, large in amplitude, whereas a hypokinetic would be a minor movement of low amplitude and low frequency.” Tr. at 287. In his understanding, the majority of movement disorders were classified as hyperkinetic—such as “the resting tremor of Parkinsonism” or myoclonus—while dystonia and chorea are examples of hypokinetic movement disorders. *Id.* He further defined dystonia as an “abnormal posturing, usually of a limb, a hand, or a foot.” *Id.* at 288.

Dr. Donofrio agreed that Petitioner had experienced *some* type of movement disorder following her vaccination in November 2014, but emphasized that a formal diagnosis was never clearly embraced or proposed by any of Petitioner’s treating providers Tr. at 285, 290. He also did not himself fully accept myoclonus as the proper diagnosis. Donofrio First Rep. at 7–9. And it was unclear, he opined, from the medical records whether Petitioner’s development of a movement disorder occurred organically or non-organically (meaning attributable to a psychiatric or psychological problem). *Id.* at 286, 294. Dr. Donofrio noted that it was “quite unusual” for there to be so few treater notes in November 2014 mentioning even the possibility of a movement disorder, given Petitioner’s description of her symptoms at this time. *Id.* at 295.

Petitioner also was never formally diagnosed with dystonia, despite a brief treater note from Dr. Slevin during the course of his evaluation of Petitioner on April 13, 2015. Tr. at 286; Ex. 11 at 3 (documenting Dr. Slevin’s comments regarding the “velocity” of Petitioner’s abnormal movements and noting it was more characteristic of a dystonia than myoclonus). But Dr. Donofrio interpreted Dr. Slevin’s comments in the record to suggest that Dr. Slevin deemed Petitioner’s presentation as *closer* to dystonia rather than myoclonus—although he admitted that Dr. Slevin

had not gone into greater detail as to which part of Petitioner’s body was dystonic, or even openly commented upon the possibility of dystonia in his overall impression. Tr. at 289.

Further evidence that Petitioner had not experienced myoclonus, Dr. Donofrio maintained, was found in Petitioner’s EEG and MRI findings. Tr. at 290–91. In Dr. Donofrio’s experience, an MRI of the brain will produce normal findings in many movement disorders, such as in Parkinsonism, essential tremors, and dystonias. *Id.* But EEG results for an individual suffering from a movement disorder will usually be associated with brain discharge—and here, there was no corresponding brain discharge following the seven episodes of jerking. *Id.* at 291. Moreover, one of Petitioner’s treating physicians, Dr. Ahmed, observed Petitioner’s jerking sensations to disappear when distracted, which he opined should not occur in myoclonus. *Id.* at 293. And Dr. Dr. Slevin’s “watch and wait” treatment plan for Petitioner was not consistent with a myoclonus diagnosis; Dr. Donofrio would have expected the initiation of a more specific and targeted treatment if Petitioner had been deemed to be likely experiencing a movement disorder. *Id.* at 294.

On cross-examination, Dr. Donofrio briefly discussed his opinions regarding the International Classification of Diseases, which sets forth clinical medication codes for common movement disorders. Tr. at 300. Petitioner argued that it is quite possible that the lack of a documented diagnosis by Petitioner’s treating physicians is likely due to a lack of understanding for proper coding protocol. *Id.* at 304. Dr. Donofrio, however, explained that he did not necessarily look at Petitioner’s records from the standpoint of event coding, but instead analyzed them based on the details of the treating physicians’ notes and their documented impressions. *Id.* at 305. Despite Petitioner’s reliance on several treating physicians documenting the appropriate code for myoclonus or dystonia, Dr. Donofrio argued that “[t]he purpose of accurate coding is to accurately described the diagnosis and to get maximum reimbursement for [one’s] office visit.” *Id.* at 339. Moreover, Dr. Donofrio suggested that what mattered herein was the terminology used by Petitioner’s treating physicians when describing the symptoms of her movement disorder. *Id.* at 340.

II. Procedural History

This matter was originally assigned to a different special master. Respondent filed his Rule 4(c) Report contesting Petitioner’s right to compensation on September 17, 2018. *See* Report, dated Sept. 17, 2018 (ECF No. 17). Thereafter, the process of obtaining expert reports began, with the final report from Dr. Kedl filed in February 2022. The parties submitted pre-hearing submissions and a two-day Entitlement Hearing took place on January 8–9, 2024, in Washington, D.C. The matter is now ripe for resolution.

III. Applicable Legal Standards

A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); see also *Moberly v. Sec’y of Health & 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).¹⁰ There is no Table claim for a movement disorder, let alone myoclonus, caused by the flu vaccine.

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 Circuit in *Althen v. Sec’y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.”

¹⁰ 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. App’x. 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).

Each *Althen* prong 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 (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit¹¹ has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory’s scientific or medical *plausibility*. See *Kalajdzic v. Sec’y of Health & Hum. Servs.*, No. 17-792V, 2022 WL 2678877 (Fed. Cl. Spec. Mstr. June 17, 2022), *mot. for review den’d*, Dkt. No. 79 (Fed. Cl. Oct. 27, 2022), *aff’d* No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments “for a less than preponderance standard” deemed “plainly inconsistent with our precedent” (citing *Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also *Howard v. Sec’y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *aff’d*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). 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*,

¹¹ While I am aware of a very-recent Court determination suggesting a plausibility standard applies to the first prong, that determination does not govern this matter. And *far more* Court decisions are consistent with preponderance as the proper standard, and the Federal Circuit has also recently suggested preponderance applies over plausibility. See, e.g., *Kalajdzic v. Sec’y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024).

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 den’d*, 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. den’d 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 rev. den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & 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 or written testimony (provided in the form of an affidavit or declaration) 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:

(1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

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 den'd*, 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 medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, 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.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 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. App’x 875, 884 (Fed. Cir. 2013) (“[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered”).

ANALYSIS

Although the parties reasonably dispute the precise nature of Petitioner’s injury, evidence preponderantly supports the conclusion that she experienced *some* form of movement disorder with “myoclonus-like” features. Several treaters maintained a myoclonus diagnosis after examining Ms. Stacy, and many of her symptoms were consistent with it as well. At the same time, Respondent’s diagnostic expert, Dr. Donofrio, observed a number of factors not fully consistent with a myoclonus diagnosis, especially when the totality of test results are taken into account, as well as Petitioner’s history. Most importantly, the treater most qualified to opine on the subject, Dr. Slevin, was equivocal in embracing myoclonus—suggesting that myoclonus *per se* cannot be fully applied to Petitioner’s condition.

This case does not turn on diagnosis, however. Ultimately, entitlement has not been demonstrated—primarily due to Petitioner’s inability to show that the flu vaccine can likely cause a myoclonus-like movement disorder. The matter is thus properly dismissed for failure to satisfy the first *Althen* prong (since all three prongs must be met if a petitioner is to receive damages). *Dobrydnev v. Sec’y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014).

Dr. Steinman’s opinion was simply unreliable and unpersuasive overall. Here, he has done as he so often does in too many Program cases, and raised the molecular mimicry “flag,” attaching arguments about it to his own database findings purporting to identify sufficient homology between vaccine components and some putative target for an autoimmune attack. But putting aside his initial error in making the homology comparison, his argument over-relies on the template established for showing how the flu vaccine (and a few others) *might* cause a variety of peripheral and central nervous system inflammatory neuropathies—but without enough of a specific showing relevant to the present injury. I have often noted that simple invocation of molecular mimicry is not enough to prove causation, when a proposed association to injury is not also bulwarked by additional evidence, circumstantial or otherwise, suggesting the vaccine can actually result in something akin to the injury at issue. *McKown v. Sec’y of Health & Hum. Servs.*, No. 15-1451V,

2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (“merely chanting the magic words ‘molecular mimicry’ in a Vaccine Act case does not render a causation theory scientifically reliable, absent *additional* evidence specifically trying the mechanism to the injury and/or vaccine in question”) (emphasis in original).

That supporting evidence is lacking here. Foundationally, Dr. Steinman’s causal theory relies on a showing of homology with the PNKD protein—a protein related to a condition Petitioner has *not* been diagnosed with—but without demonstrating that myoclonus would likely involve that protein, let alone be instigated by an attack on it. It is insufficient for him simply to posit that the identified antigenic target might have some general relevance to a large number of conditions involving movement disorder-like symptoms.

In addition, Dr. Kedl established a number of reasons to doubt the reliability of molecular mimicry as a general explanatory mechanism in this case. Admittedly, not all of his arguments—the trustworthiness of results from certain animal testing when applied to human disease processes,¹² or whether Dr. Steinman had demonstrated enough of a homologous sequence of amino acids for a putative mimic-derived autoimmune cross-reaction to occur—were by themselves fatal to Dr. Steinman’s theory. But Dr. Kedl did observe Dr. Steinman’s initial error in even identifying specific homology, by incorrect comparison of antigenic components *not found* in the vaccine to the proposed self-structures—and that error (although admitted by Dr. Steinman) underscored the rote aspect of Petitioner’s theory (reflecting his haste to identify *some* association between the vaccine and the injury, rather than a measured evaluation relying on applicable evidence). Kedl First Rep. at 4.

In addition, Respondent overall (via Dr. Kedl in part) also established persuasively the limits of reliance on molecular mimicry to *this* specific vaccine injury claim. Mimicry is common from a physiologic standpoint—yet does not always, or even most of the time, cause injury, underscoring the need for some evidence *more* than the kind of homologous “matching” Dr. Steinman’s reports performed. Yet here, the best Petitioner could do was identify a self-structure specific to a condition Petitioner admittedly *does not have*, PKND, and then compare a vaccine-containing amino acid sequence to it. This facially-weak comparison was not sufficient to stand as

¹² Thus, Dr. Kedl was correct that Experimental Autoimmune Encephalomyelitis (“EAE”)—an animal model that can simulate certain kinds of autoimmune central nervous system conditions—cannot simply be applied to the injury at issue, and that it is a better model for evaluating how medical science can *limit* the pathogenic causes of mimicry-triggered injury than a measure of likely cross-reactions (since it relies on an exaggerated, experimentally-oriented inflammatory milieu encouraged by a specific kind of adjuvant never included in vaccines, rather than reflects the likely degree of inflammation a vaccine would induce in nature). *Nieves v. Sec’y of Health & Hum. Servs.*, No. 18-1602 V, 2023 WL 3580148 (Fed. Cl. Spec. Mstr. May 22, 2023), n.32, *mot. for review den’d*, 167 Fed. Cl. 422 (2023). However, experiments and studies utilizing reasonable models should not be cast aside evidentiarily simply because they are in part artificial, in comparison to an apples-to-apples test on the human body. *See, e.g., Koehn v. Sec’y of Health & Human Servs.*, 773 F.3d 1239, 1244, n.1 (Fed. Cir. 2014) (noting that certain blood testing experiment could only provide useful data based on in vitro efforts).

preponderant proof of causation, especially given the many other reasons Dr. Kedl provided for questioning Dr. Steinman's showing.

Nothing else offered by Dr. Steinman was enough to account for these deficiencies in his causation theory. Little evidence was offered suggesting *any* vaccine is associated with myoclonus, in the absence of other symptoms or proof of nerve demyelination. And to the extent Petitioner relied on case reports, they are generally recognized in the Program to be entitled to limited probative weight. *Campbell v. Sec'y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011) (“[c]ase reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value,” even if they should receive some weight). Worse, the reports offered herein pertained to *other* movement disorders, like chorea, or to conditions not pertaining to Petitioner, such as opsoclonus-myoclonus. *See generally* Piquet at 305; Prasuhn at 591. And no other items filed in this case suggested even a wild viral infection association with myoclonus. Studies like Piquet and Prasuhn finding a possible viral association to *other* conditions involving movement disorders only provide Petitioner faint support.

In the end, Petitioner's “can cause” showing did not cross the preponderant line. And this case is a good example of why preponderance is *properly applied as the evidentiary standard bearing on a claimant's prong one showing*. Petitioner is seeking to establish that a loose constellation of symptoms she experienced within a month or so of vaccination was attributable to that vaccination. To do so, she cannot simply rest on the implicit assumption that it is “plausible” the vaccine caused it merely on account of the temporal association, since the Program has long noted temporal relationships do not establish causation. *Moberly*, 592 F.3d at 1323 (“a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury.”) (quoting *Grant*, 956 F.2d at 1148). Nor is it enough to offer an opinion from a generally-qualified expert, like Dr. Steinman,¹³ and then assume causation has been established. I am not compelled to accept his opinion merely upon its utterance. *Bean-Sasser v. Sec'y of Health & Hum. Servs.*, 127 Fed. Cl. 161, 165 (2016) (holding that the special master “is not required to accept an expert's opinion simply because the expert is found qualified to opine in a medical or scientific discipline”).

The Program demands more in the causation context, even if it does not require certainty. To argue otherwise—to claim that a showing of plausibility ends the prong one analysis—is to call for a legal standard in which *every single non-Table vaccine injury claim* would be compensated, simply based on a science-rich showing involving speculation about the mysteries of the immune

¹³ Despite his background as a highly-credentialed neurologist, Dr. Steinman has no specific demonstrated expertise in the treatment or study of movement disorders (unlike Petitioner's actual treater, Dr. Slevin—who tellingly did not embrace fully a myoclonus diagnosis, and otherwise never proposed the flu vaccine was causal). Nor did he establish that he possesses experience studying their immunologic etiologies. He simply hoped to leverage his overall biochemistry competence and general expertise as a neurologist, along with the style of report he routinely offers in Program cases (and I say this based on my review of *50 or more of his reports in various matters*), into what might amount to a persuasive opinion. One size does not fit all.

system—and the fact that injury followed vaccination. This is unquestionably not what the Act establishes as the evidentiary standard for proving a causation-in-fact claim.

CONCLUSION

Because Petitioner did not preponderantly demonstrate that the flu vaccine could cause her movement disorder, the claim is dismissed.

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.¹⁴

IT IS SO ORDERED.

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

¹⁴ 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.