In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 16-634V
(to be published)

* *
WEI-TI CHEN, *
Petitioner, *
v. *
SECRETARY OF HEALTH AND HUMAN SERVICES, *
Respondent. *
* *

Filed: April 19, 2019

Decision; Denial of Entitlement; Neuromyelitis Optica Spectrum Disorder ("NMOSD"); Influenza ("flu") Vaccine; Onset; Causation Theory

John Robert Howie, Jr., Howie Law, P.C., Dallas, TX, for Petitioner.

Christine M. Becer, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On May 27, 2016, Wei-Ti Chen filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"[2]). Petition ("Pet.") (ECF No. 1). Petitioner alleges that she developed Neuromyelitis Optica Spectrum Disorder ("NMOSD") as a result of the influenza "(flu") vaccine she received on November 1, 2013. Petition (ECF No. 1) at 1.

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[1] This Decision will be posted on the United States Court of Federal Claims' website, and in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means 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 published Decision's inclusion of certain kinds of confidential information. Specifically, 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 entire Decision will be available in its current 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. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

Following the filing of Petitioner's medical records, and expert reports from both parties, I scheduled the matter for hearing. However, Petitioner subsequently requested that I resolve this matter via ruling on the record, filing a brief in support of her claim on September 21, 2018 (ECF No. 45) ("Mot."). Respondent thereafter opposed Petitioner's entitlement to a damages award by brief dated October 29, 2018 (ECF No. 46) ("Opp."). Petitioner also filed a reply on November 16, 2018 (ECF No. 47) ("Reply"). Having completed my review of the evidentiary record and the parties' filings, I hereby DENY Petitioner's request for compensation, for the reasons stated below.

I. Factual Background

Vaccine and Preexisting Symptoms

Ms. Chen received a flu vaccine on November 1, 2013, at a booth on the campus of Yale University. Ex. 2 at 1-2. At the time, Petitioner was forty-two years old, and she was employed at Yale's School of Nursing as an Assistant Professor. *Id.* at 1. She had a past medical history significant for hypertension, headaches, glaucoma, gestational diabetes, and asymptomatic Hepatitis B. Ex. 1 at 3; Ex. 2 at 3-111; Ex. 3 at 1-9; Ex. 5 at 158; Ex. 11 at 2. She also had a seven to eight-year history of lower back and buttock pain (possibly related to a prior epidural injection or childbirth), for which she routinely sought treatment from a chiropractor. Ex. 4 at 3. No adverse reaction was noted at the time of vaccine administration.

That October (and thus immediately prior to the flu vaccine's administration), Petitioner had been receiving bi-weekly chiropractic treatment for her pre-existing back/buttock pain. Ex. 4 at 1-3. In particular, on October 25, 2013 (roughly one week prior to her receipt of the flu vaccine), Petitioner reported to her chiropractor, Dr. Leo Zygelman, D.C.P.C., that she was experiencing tingling in both her inner thighs (in addition to her persistent lower back and buttock pain). *Id.* at 2. The record referencing this complaint is undetailed, however, and provides no insight into the basis for this complaint or its possible etiology.

Three days after receipt of the flu vaccine, Ms. Chen returned to Dr. Zygelman on November 4, 2013, complaining again of lower back/buttock pain, along with persistent tingling in the inner thighs (similar to those symptoms reported in late October of that year). Ex. 4 at 1. Petitioner returned another time on November 11, 2013, for treatment related to the above-mentioned symptoms. *Id.* The treatment notes from her November 11th visit indicate that she also was now experiencing new onset of tingling in her toes. *Id.* At a third chiropractic visit thereafter on November 19, 2013, Petitioner also reported "thigh pain." *Id.* As with the October chiropractic records, however, these notations contain no explanations for such symptoms.

Onset of Symptoms Identified as Neurologic in Origin

On November 21, 2013, Ms. Chen took a trip to Taiwan. Upon arrival on November 23, 2013, Petitioner began to experience right-side, lower extremity numbness and paresthesias in her legs ascending to the abdomen and right hand. Ex. 5 at 12, 18. She presented to the Taipei Veterans General Hospital in Taipei, Taiwan, on November 25, 2013, and was evaluated by the orthopedic out-patient department. *Id.* at 12, 144-45. During the visit, she reported her history of lower back pain (consistent with her pre-vaccination records). *Id.* at 144. She also informed hospital treaters that the bilateral leg numbness she was experiencing had begun one week prior to her presentation (and thus in the days immediately before her flight). *Id.* at 12. Apart from the above complaints, her physical exam was otherwise normal, and an EMG and nerve conduction study (conducted during a follow-up appointment on November 27, 2013) produced normal results. *Id.* at 12, 96, 144. Petitioner was discharged and prescribed Acemet[3] and Benzoflex[4] for her symptoms. *Id.* at 12. Records reveal treater awareness that Ms. Chen had received the flu vaccine earlier that month. *Id.*

On November 29, 2013, Petitioner returned to Taipei Veterans General with worsening symptoms. Ex. 5 at 4-11, 12. Ms. Chen now reported feeling increasing numbness in the extremities and scalp, and an unsteady gait. *Id.* at 4. Her neurological exam, however, showed normal deep tendon reflexes, albeit with decreased sensation to pinprick on neck and scalp. *Id.* The ER physicians diagnosed her with cervical stenosis, and admitted Petitioner for further evaluation. *Id.* Upon admission, Petitioner had a cervical MRI of her spine. *Id.* at 12. It showed a mild hyper-intense lesion at C2-C3, plus a crescent shape lesion outside the dural sac. *Id.* In addition, Petitioner's physical exam evidenced an abnormal stance, dysuria, and chest tightness, but was otherwise normal (revealing no fever, nausea/vomiting, motor swelling, swallowing difficulties, or blurred vision). *Id.* at 12, 15. Petitioner's diagnosis was changed to cervical myelopathy. *Id.* at 15.

On December 1, 2013, Petitioner had an MRI of the thoracic spine which showed several areas of high signal changes (with "very faint enhancement"), suggestive of an existing demyelinating process. Ex. 5 at 20. On December 2, 2013, Petitioner had an MRI of her brain that identified a small lesion in the subcortical white matter of the left high parietal, left dorsal aspect of the pons, and left middle cerebellar peduncle, with high signal on T2 compatible with a demyelinating process. *Id.* at 165. A "tiny focus of enhancement" was also noted on in the left

[3] "Acemet" or Acemetacin is a non-steroidal anti-inflammatory drug used to treat rheumatoid arthritis, osteoarthritis, and low back pain, as well as for postoperative pain. *Acemetacin: Compound Summary*, PubChem, NIH, https://pubchem.ncbi.nlm.nih.gov/compound/acemetacin (last accessed on April 1, 2019). It is not currently approved by the FDA for use in the United States. *Id.*

[4] "Benzoflex" or Ciprofloxacin is an antibiotic used to treat mild-to-moderate urinary and respiratory tract infections. *Ciprofloxacin: Compound Summary*, PubChem, NIH, https://pubchem.ncbi.nlm.nih.gov/compound/ciprofloxacin (last accessed on April 1, 2019).

middle peduncle. *Id.* Petitioner was treated with methylprednisolone pulse therapy from December 4, 2013 through December 8, 2013, with good improvement. *Id.* at 19. After treatment, she reported some residual tingling in the distal extremities. *Id.* at 19, 25-26. Petitioner was discharged from Taipei Veterans General on December 9, 2013, with a diagnosis of multiple sclerosis ("MS"), although ADEM and NMOSD were also included in the differential. *Id.* at 16, 22-25.

Progression of Petitioner's Neurologic Symptoms

After her return to the United States, Ms. Chen was evaluated at the office of her primary care physician at Yale Health on February 21, 2014, for evaluation of her hospitalization abroad, the symptoms she had experienced, and the tentative diagnosis of ADEM versus MS. Ex. 2 at 170. Petitioner received pulse therapy with nearly complete resolution of her symptoms. *Id.* Upon exam, it was noted that Petitioner continued to report intermittent numbness and tingling in her right lower extremity, and a feeling of not fully emptying her bladder. *Id.*

On March 13, 2014, Petitioner presented to a neurologist at Yale Health, Dr. Richard Nowak. Ex. 2 at 182. Petitioner reported that she had experienced numbness in both legs beginning a few days after her receipt of the flu vaccine (although the medical record discussed above does not itself relate the vaccine to these symptoms, which were also experienced immediately prior to vaccination), progressing to the point where she could not walk. *Id.* Upon evaluation, Dr. Nowak noted that Petitioner was ambulating unassisted, but still had some numbness in her legs as well as constipation and urinary retention, although she denied vision loss. *Id.* Dr. Nowak opined that Petitioner had likely experienced post-vaccinal ADEM. *Id.* at 186. A follow-up appointment was recommended in six to eight weeks, and additional radiologic testing for inflammatory markers was scheduled. *Id.*

On May 1, 2014, Petitioner returned to see Dr. Nowak. Her status and exam were unchanged. Ex. 2 at 194-98. An MRI of Ms. Chen's brain, cervical spine, and thoracic spine performed on April 25, 2014, did not show any residual or new/enhancing lesions (a finding consistent with a one-time demyelinating event like ADEM). *Id.* at 194, 309-10. A blood work-up to test for inflammation biomarkers (including testing for elevated ANA, ENA, ESR, CRP, and serum NMO) was also unremarkable. *Id.* at 194. A physical exam, however, revealed persistent decreased sensation in the right leg, along with decreased vibration in the toes and fingertips. *Id.* at 198. Dr. Nowak's impression remained post-vaccinal ADEM, and he instructed Petitioner to follow up with him in one year (or sooner should her symptoms change). *Id.*

On September 16, 2014, Petitioner returned to Yale Health and was evaluated by Jonathan Merritt, PA. Ex. 2 at 212. Her diagnosis of ADEM following a flu vaccine in late 2013 was again noted. *Id.* Petitioner denied worsening weakness, numbness, and tinging. *Id.* Additional complaints at this time included constipation and recurrent URIs, but her condition otherwise remained

relatively stable, and it was recommended she schedule a follow-up appointment in six months. *Id.*

Several months later, Petitioner was seen by medical professionals in the emergency room at the Queens Medical Center in Honolulu, Hawaii on December 22, 2014. Upon presentation, Petitioner reported that she had arrived in Hawaii for a business trip, but that on or about December 20, 2014, began to experience dizziness and diplopia (the first time she experienced any symptoms affecting or connected to her vision). Ex. 6 at 2. Her health history noted that she had been diagnosed with ADEM secondary to a flu vaccine (approximately one year prior). *Id.*

An MRI with contrast performed during the visit showed small, enhancing lesions in the left bronchium pontis, although cerebrospinal fluid testing was unrevealing. Ex. 6 at 7-8. Petitioner was also evaluated by a neurologist, Dr. Rony Salem, during her hospital stay. *Id.* at 23-25. She was now noted to have impaired abduction of her left eye with nystagmus – the first record evidence of any ophthalmic symptoms (apart from her pre-existing glaucoma) – but her physical exam was otherwise normal (revealing no motor, sensory, or gait abnormalities). *Id.* at 24. Petitioner received solumedrol treatment, with noted improvement. *Id.* Given her history, Dr. Salem felt her course was "concerning for MS." *Id.* at 25. It was recommended that she follow-up with her primary care physician upon return home. *Id.* at 55.

Competing Diagnoses: ADEM vs. MS. vs. NMOSD

On January 8, 2015, Ms. Chen returned to Dr. Nowak for evaluation of her diplopia, which she explained had begun around the time of her trip to Hawaii. Ex. 2 at 217, 221. Repeat MRIs of the brain, cervical, and thoracic spine were conducted on January 6, 2015, and revealed no new areas of abnormal enhancement. *Id.* at 217, 311-12. Dr. Nowak noted a concern for ADEM with possible additional episodes consistent with an MS diagnosis, and recommended that Petitioner be evaluated by the Yale MS clinic. *Id.* at 221.

Thereafter, on January 29, 2015, Petitioner was evaluated by Dr. Mary Bailey in the Yale MS clinic in New Haven, Connecticut. Ex. 9 at 110-14. Based on review of Petitioner's history, Dr. Bailey diagnosed her with MS – most likely (as indicated in an addendum to her notes on February 5, 2015) relapsing-remitting MS ("RRMS"). *Id.* at 111-13. *Id.* Dr. Bailey based this diagnosis on her interpretation of the radiologic evidence, back to Petitioner's initial MRI in 2013. *Id.* at 112. In her view, Petitioner's cervical cord lesions, juxta cortical lesion, and location of her lesion on the left brachium pontis were consistent with what would be often seen in an MS diagnosis *Id.* By contrast, Dr. Bailey proposed that Petitioner's clinical history was (at least as of that point in time) inconsistent with NMOSD or opticospinal MS (given that her spinal lesion was relatively nonextensive, and she had no history of optic neuritis, despite her recent eye-related symptoms). *Id.* at 113. Moreover, Dr. Bailey noted that Petitioner's symptoms were quite responsive to steroid treatment (which would also be consistent with MS). *Id.*

On April 1, 2015, Petitioner returned for a follow-up visit with Dr. Bailey. Ex. 9 at 114. Her NMOSD antibody levels were noted to be negative at this time. *Id.* Dr. Bailey suggested she begin treatment for RRMS, but Petitioner declined and opted to seek a second opinion *Id.* To that end, on May 6, 2015, Ms. Chen saw Dr. Aaron Miller at the Mt. Sinai MS clinic in New York, NY, for an evaluation of her health course. Ex. 7 at 1-4. Petitioner reported a health history consistent with the above (including her onset of ascending numbness and tingling in Taiwan, plus the recent hospitalization in Hawaii for diplopia/dizziness). *Id.* at 1. It was also noted that she had received a flu shot on November 1, 2013. *Id.* at 1, 4. Upon presentation, Petitioner complained of some persistent urinary urgency and hesitancy, and altered sensation in her ankle, but her neurologic exam was otherwise noted to be normal. *Id.* at 1-2. After review of Petitioner's lab results and radiological studies from 2013 to the present, Dr. Miller noted that Petitioner's treaters in Taiwan suspected she likely had antibody-negative NMOSD. *Id.* at 4-5. It was noted, however, that Dr. Bailey had been more concerned for MS. *Id.* at 4. It is not clear from Dr. Miller's notes that he reached a firm conclusion regarding diagnosis at this visit.

The subsequent progression of Petitioner's symptoms seemed to better support the prior MS diagnosis. In mid-May 2015, Ms. Chen went to the emergency room at Yale Hospital with a three-day history of swallowing difficulties, dysarthria, and slurred speech. Ex. 9 at 1; Ex. 2 at 235-38. A brain MRI conducted during the visit revealed a cystic lesion in the left precentral gyrus, which was felt to represent a new demyelinating lesion (consistent with a prior MS diagnosis). Ex. 9 at 27. Dr. Bailey now more forcefully opined that, based on Petitioner's course, MS was the appropriate diagnosis, but Petitioner again declined MS disease modifying therapy. Ex. 9 at 116. Instead, she returned to Dr. Miller that August, who (after review of Petitioner's most recent symptoms and all MRI evidence to date)[5] concluded that her most likely diagnosis was NMOSD. Ex. 7 at 7-8.

In so proposing, Dr. Miller acknowledged that Ms. Chen's NMOSD antibody test had been negative, but found compelling the fact that her CSF studies were negative for oligoclonal banding (which would be more consistent with MS), along with her Chinese ancestry (making her more susceptible to NMOSD).[6] Ex. 7. at 8; Ex. 6 at 26. Dr. Miller also noted that Petitioner's forebrain lesion with aphasia and "long (albeit not quite 2 segment) spinal cord lesion" were also characteristic of NMOSD. Ex. 7 at 8. Dr. Miller recommended treatment with Rituximab (given its beneficial effects for both NMOSD and MS). *Id.* Dr. Bailey, however, continued to maintain

[5] At Petitioner's initial consult with Dr. Miller, it appears he did not have all the MRI evidence from her hospitalization in Taiwan. Ex. 7 at 4.

[6] Petitioner's expert treater, Dr. Kon-Ping Lin, filed literature from the Taiwan Multiple Sclerosis Association suggesting that sixty percent of Taiwanese patients originally diagnosed with MS eventually are later found more likely to be suffering from NMOSD. *See Know Multiple Sclerosis* (Feb. 21, 2017), http:www ms.org.tw/ap/news_view.aspx?bid=57&sn=f7221a45-603f-455c-ad14-9254ece31aef (last accessed by Petitioner on Mar. 23, 2017), filed as Ex. 14 (ECF No. 21-1).

that MS was the proper diagnosis, based on her symptoms as well as follow-up MRIs. Ex. 9 at 118-121, 124, 157.

More Recent Medical Records and Evidence of Proper Diagnosis

Petitioner has continued to receive treatment for the constellation of neurologic symptoms she experiences. In the course of such treatment, some treaters (including Dr. Bailey) began to allow for the possibility that Ms. Chen might have NMOSD, albeit a relapsing-remitting form like RRMS, or even some combination of the two. *See, e.g.*, Ex. 9 at 136-47 (April 26, 2016 visit with Dr. Bailey); Ex. 29 at 32-53 (February 15, 2017, visit to Yale MS Center). Other treaters have characterized her condition as a general, central nervous system ("CNS")-oriented white matter disease, finding significant the lack of strongly-corroborative ophthalmologic symptoms that would be consistent with NMOSD. *See, e.g.*, Ex. 8 at 19-20 (April 28, 2016 visit to Yale Eye Clinic). However, certain treaters maintained the view that Petitioner was experiencing NMOSD, even though in certain respects she did not display clinical indicia of the condition. *See* Ex. 28 at 1-3 (March 6, 2017 visit to Columbia University Medical Center).[7] Treaters have subsequently expressed greater confidence in the accuracy of the NMOSD diagnosis. *See, e.g.*, Ex. 29 at 54-69 (August 30, 2017 appointment at Yale MS center) (finding that evidence of the presence of anti-MOG (myelin oligodendrocyte glycoprotein) antibodies[8]); Ex. 49 at 1-9 (April 13, 2018 visit to UCLA MS Center).

II. Expert Reports

A. *Petitioner's Expert – Dr. Kon-Ping Lin*

Dr. Lin treated Petitioner during her initial hospitalization in Taiwan. He authored three expert reports in support of Petitioner's claim that the flu vaccine caused her NMOSD. *See* Exhibit 12, dated Mar. 10, 2017 ("First Lin Rep.") (ECF No. 20-1); Ex. 30, dated July 31, 2017 (ECF No. 28-1) ("Second Lin Rep."); Ex. 40, dated Oct. 23, 2017 ("Third Lin Rep") (ECF No. 31-1).

Dr. Lin is a board-certified neurologist in Taiwan. *See* CV, filed as Exhibit 13, dated Mar. 23, 2017 (ECF No. 20-2) ("Lin CV"). He received his medical degree from Kaohsiung Medical College, in Kaohsiung, Taiwan. *Id.* at 1. He thereafter completed a residency in neurology at Veterans General Hospital in Taipei, Taiwan, followed by a fellowship in clinical neuroscience at

[7] Such treaters did not, however, propose that the November 2013 flu vaccine was likely causal of Petitioner's NMOSD, despite Petitioner's speculation. Ex. 28 at 3.

[8] The relevant literature filed in this case suggests that NMOSD (while traditionally associated with the AQP4 antibody) can be clinically associated with a different autoantibody, MOG-IgG, in some instances. *See* B. Weinshenker, et al., *Neuromyelitis Spectrum Disorders*, 92 Mayo Clin. Proc. 663, 667 (2017), filed as Ex. 37 (ECF No. 29-7); S. Hamid, et al., *What Proportion of AQP4-IgG-Negative NMO Spectrum Disorder Patients Are MOG-IgG Positive?: A Cross Sectional Study of 132 Patients*, 264 J. Neurol. 2088 (2017), filed as Ex. 43 (ECF No. 33-2) (42% or 15/36 of AQP4-IgG-negative patients in the UK tested positive for MOG-IgG).

the Royal Free Hospital in London, UK. *Id.* Dr. Lin also served as a research fellow in the Department of Hematology and Oncology at the Texas Medical Center in Houston, TX. *Id.* Currently, he serves as a senior attending neurologist at Veterans General Hospital in Taipei, Taiwan. *Id.* Dr. Lin's CV does not establish that he possesses notable training in the field of immunology – though his CV suggests he has "expertise" in immuno-neurology with a "focus" on immune-mediate neuropathies. *Id.* His CV also notes that he has published various articles involving neuromuscular disorders and topics relating to other neuropathic conditions. *Id.* at 7-14.

To begin, Dr. Lin reviewed Petitioner's symptoms and the progression of her condition compared to the varying diagnoses discussed in her medical records. Based on his review of the relevant records, Dr. Lin categorized Ms. Chen's health course as consistent with NMOSD (rather than MS). First Lin Rep. at 1. The typical diagnostic criteria for NMOSD include: 1) evidence of at least one core clinical characteristic (i.e., optic neuritis, acute myelitis, area postrema syndrome/episode of unexplained hiccups or nausea/vomiting, acute brainstem episode, symptomatic narcolepsy syndrome or acute diencephalic clinical syndrome, or symptomatic cerebral syndrome with NMOSD-typical brain lesions); 2) testing positive for the AQP4-IgG antibody; and 3) exclusion of alternative diagnoses. *See* D. Wingerchuk, et al., *International Consensus Diagnostic Criteria for Neuromyelitis Optica Spectrum Disorders*, 85 Neurology 177 (2015), filed as Ex. 19 (ECF No. 21-6) ("Wingerchuk").

Antibody testing (via cell-based assay) can also help distinguish between NMOSD and MS. As noted above, NMOSD is associated specifically with the AQP4-IgG pathogenic autoantibody biomarker. First Lin Rep. at 5. NMOSD's diagnostic criteria, however, allows for the possibility that a patient could be diagnosed with a seronegative (meaning negative for the AQP4 antibody) form of the disease. *Id.*; *see* Wingerchuk at 3. In such cases, the diagnosis is applicable only if a patient has experienced two core clinical characteristics (occurring as one or more clinical attacks) and meet the following requirements: 1) at least one core clinical characteristic *must* be optic neuritis, acute myelitis with LETM, or area postrema syndrome; 2) dissemination in space (i.e., two or more different core clinical characteristics; and 3) fulfillment of additional MRI requirements. First Lin Rep. at 6; Wingerchuk at 3. The additional MRI evidence for acute myelitis/LETM requires a greater-than-three vertebral segment lesion in the spinal cord. Wingerchuk at 3. Area postrema syndrome requires evidence of dorsal medulla/area postrema lesions, and acute brainstem syndrome requires associated periependymal brainstem lesions. *Id.* Other alternative diagnoses must also be excluded. *Id.*

As Dr. Lin explained, Ms. Chen's first clinical episode was thought to reflect an acute myelitis (with accompanying walking difficulties and numbness ascending to the chest). First Lin Rep. at 1; Second Lin Rep. at 2. Dr. Lin acknowledged Petitioner's cervical MRI conducted at presentation did not evidence a three-segment LETM spinal cord lesion (a feature required by the accepted diagnostic criteria noted above). First Lin Rep. at 1 ("her . . . MRI presented close to three vertebral segments"). This factor, however, did not alter his opinion, because Petitioner's brain MRI also revealed demyelinating lesions "located at the pons and the left side deep cerebellar

hemisphere[,]" which was in his view sufficient to meet the additional radiologic requirements. *Id.*

Dr. Lin also found Petitioner's second and third episodes of recurrent symptoms, and the MRIs obtained in this period, to be supportive of an NMOSD diagnosis, since the results were inconsistent with MS. While in Hawaii on a business trip, Petitioner had experienced what Dr. Lin characterized as a brainstem episode (presenting as diplopia, nystagmus, and unsteady gait). First Lin Rep. at 2; Second Lin Rep. at 2. A second brain MRI revealed a "12mm focal enhancement" surrounding the T2 signal and "asymmetric enlargement of the left brachium pontis." First Lin Rep. at 2. Petitioner experienced a third clinical episode roughly six months later when she developed speaking difficulties (aphasia), and her third brain MRI revealed a "heterogeneous enhanced lesion" on the left side along with additional nodule enhancing lesions.[9] *Id.* By contrast, her lumbar puncture had been negative for oligoclonal banding, which would have confirmed MS. *Id.*

Petitioner's later-in-time clinical lab tests also supported the NMOSD diagnosis. Third Lin Rep. at 1. In particular, by late August 2017, repeat testing revealed the presence of MOG antibodies, which Dr. Lin deemed as equally consistent with NMOSD. Third Lin Rep. at 1; *see* Ex. 29 at 56-57; B. Weinshenker, et al., *Neuromyelitis Spectrum Disorders*, 92 Mayo Clin. Proc. 663, 668 (2017), filed as Ex. V (ECF No. 40-12) ("Weinshenker") (suggesting that the MOG antibody can be pathologic in nature, thereby serving as an alternative mediator to AQP4). Neurologists "globally" agree, Dr. Lin maintained, that the MOG antibody is representative of a form of NMOSD. *See* M. Jurynczyk, et al., *Brain Lesion Distribution Criteria Distinguish MS from AQP4-Antibody NMOSD and MOG-Antibody Disease*, 88 J. Neurol. Neurosurg. Psychiatry 132 (2017), filed as Ex. 44 (ECF No. 34-1); M. Bouzar, et al., *Neuromyelitis Optica Spectrum Disorder with Antibodies to Myelin Oligodendrocyte Glycoprotein or Aquaporin-4: Clinical and Paraclinical Characteristics in Algerian Patients*, 381 J. Neuro. Sci. 240 (2017), filed as Ex. 42 (ECF No. 33-1); S. Hamid, et al., *What Proportion of AQP4-IgG-Negative NMO Spectrum Disorder Patient are MOG-IgG positive? A Cross Sectional Study of 132 Patients*, 264 J. Neurol. 2088 (2017), filed as Ex. 43 (ECF No. 33-2).[10]

Dr. Lin next attempted to explain how the flu vaccine could have caused Ms. Chen's NMOSD. He proposed that her illness had occurred through the biologic mechanism of molecular mimicry. This is a concept that has been largely accepted in the medical community (and often in the Vaccine Program as well): that antibodies produced to fight off a foreign infectious antigen (or

[9] An MRI conducted one month earlier, however, revealed stable (or unidentifiable lesions). First Lin Rep. at 2; Ex. 9 at 36).

[10] Dr. Lin also offered some suggestion that Petitioner's ancestry played a role in his opinion concerning Petitioner's appropriate diagnosis. First Lin Rep. at 2. In his view, Taiwanese patients are more prone to have NMOSD instead of MS. *See Know Multiple Sclerosis* (Feb. 21, 2017), http:www.ms.org.tw/ap/news_view.aspx?bid=57&sn=f7221a45-603f-455c-ad14-9254ece31aef (last accessed by Petitioner on Mar. 23, 2017), filed as Ex. 14 (ECF No. 21-1) (suggesting that 60% of Taiwanese patients diagnosed with MS are later diagnosed with NMOSD in the alternative).

generated in response to a vaccine) can mistakenly attack, or cross-react with, myelin basic protein ("MBP") (a primary protein component of human nerves) or oligodendrocytes, causing damage to the nerve's myelin sheath and resulting in disease. First Lin Rep. at 4-5. Relevant medical literature, Dr. Lin maintained, supports the contention that the flu vaccine contains fourteen antigens that display cross-reactivity potential with MBP. *Id.* at 5.[11]

To establish a more direct connection between the flu vaccine and Petitioner's illness, Dr. Lin referenced a few scientific articles involving different CNS demyelinating injuries. *See, e.g.*, A. Shoamanesh, et al., *Acute Disseminated Encephalomyelitis Following Influenza Vaccination*, 29 Vaccine 8182 (2011), filed as Ex. 25 (ECF No. 22-2) ("Shoamanesh"). Shoamanesh, for example, catalogued case reports of ADEM with onset following flu vaccine administration, observing that the wild influenza *virus* had been shown to contain fourteen antigens that display cross-reactivity potential with MBP. *Id.* at 8182-83. Based on the above, Shoamanesh proposed that the flu *vaccine* could similarly elicit autoimmunity in the same manner as post-infectious ADEM (via "killed or live attenuated virus" proteins interaction with myelin protein). *Id.* at 8183.

In addition, Dr. Lin cited various case reports of ADEM following influenza vaccination to support his theory. First Lin Rep. at 5; *see, e.g.*, S. Lee, et al., *An Adverse Event Following 2009 H1N1 Influenza Vaccination: A Case of Acute Disseminated Encephalomyelitis*, 54 Korean J. Pediatrics 422 (2011), filed as Ex. 23 (ECF No. 21-10) ("Lee"); J. Machicado, et al., *Acute Disseminated Encephalomyelitis Following Seasonal Influenza Vaccination in an Elderly Patient*, 20 Clin. & Vaccine Immunol. 1485 (2013), filed as Ex. 21 (ECF No. 21-8) ("Machicado"); K. Maeda, et al., *Acute Disseminated Encephalomyelitis Following 2009 H1N1 Influenza Vaccine*, 51 Internal Med. 1931 (2012), filed as Ex. 22 (ECF No. 21-9) ("Maeda"); W. Huynh, et la., *Post-Vaccination Encephalomyelitis: Literature Review and Illustrative Case*, 15 J. Clin. Neurosci. 1315 (2008), filed as Ex. 24 (ECF No. 22-1) ("Huynh"). Machicado, for example, concluded that a diagnosis of post-vaccination ADEM was "possible" based on the World Health Organization (WHO) criteria for causality assessment. *See* First Lin Rep. at 3; Machicado at 1486.[12]

Dr. Lin also offered literature that allegedly more directly involved NMOSD, although it largely consisted of additional case studies. Second Lin Rep. at 3; D. Karussis, et al., *The Spectrum of Post-Vaccination Inflammatory CNS Demyelinating Syndromes*, 13 Autoimmune Rev. 215

[11] Dr. Lin's report also briefly referenced the concept of bystander activation as a possible secondary mechanism that could facilitate an immune response resulting in NMOSD. First Lin Rep. at 4. He proposed that components of the flu vaccine might precipitate or exacerbate an autoimmune reaction from immune cells *not* specifically responding directly to the vaccine's antigens (as in the case with molecular mimicry), thereby producing myelin damage through a secondary process. *Id.* His report, however, cited no literature in support of any role played by bystander activation in directly causing NMOSD, and he offered no further explanation apart from above-noted statement.

[12] Respondent filed the WHO causality assessment as Exhibit H. *See Causality Assessment of an Adverse Event Following Immunization (AEFI)*, WHO, Mar. 2013, filed as Ex. H (ECF No. 25-8). Petitioner's motion explains that Dr. Lin cited to the WHO criteria as supportive of his opinion that Petitioner's flu vaccine could be linked to her onset of NMOSD (even though the document itself does not discuss NMOSD). *See* Motion for Ruling on Record, filed Sept. 21, 2018 (ECF No. 45) ("Mot.") at 56-61.

(2014), filed as Ex. 33 (ECF No. 29-3) ("Karussis").[13] Karussis, for example, was a review article that considered all PubMed[14] reported cases of CNS disease from 1979 to 2013 in which onset followed any kind of vaccine administration. Out of a total of seventy-one instances, Karussis identified eight cases of post-vaccination NMOSD. Karussis at 218-19, 220. Notably, however, none followed the flu vaccine. *Id.* at 218-19.[15] Another article evaluated reports of CNS disease in the Taiwanese population after administration of the H1N1 flu vaccine (for a total of 3.5 million doses, both adjuvanted and nonadjuvanted). *See* W. Huang, et al., *Safety of Pandemic (H1N1) 2009 Monovalent Vaccines in Taiwan: A Self-Controlled Case Series Study*, 8 Plos One E58827 (2013), filed as Ex. 20 (ECF No. 21-7) ("Huang"). Huang observed a small, "nonsignificant" increase in risk of GBS and encephalitis/myelitis post-vaccination following vaccination with the nonadjuvanted H1N1. Huang at 3. Twelve cases of demyelinating CNS disease were also reported, but this number was not deemed statistically significant, and Huang otherwise makes no mention of NMOSD. *Id*.

Besides offering a causation opinion, Dr. Lin attempted to rebut evidence from Petitioner's medical record suggesting that she had experienced neurologic symptoms *prior* to, or at the time of, her receipt of the flu vaccine, arguing that they were inconsistent with NMOSD. Second Lin Rep. at 1; *see* Ex. 4 at 1-2 (noting "inner thigh tingling" on 10/25/2013 and 11/1/2013). Significantly, Dr. Lin's opinion on onset changed in the course of the filing of his expert reports. Dr. Lin's first report suggested that Petitioner's documented, post-vaccination instances of thigh and toe tingling (recorded in her chiropractic notes on 11/4/2013 and 11/11/2013) were the initial signs of her NMOSD. First Lin Rep. at 1. In his subsequent reports, however (prepared in response to Dr. Raabe – who pointed out that there was record evidence of earlier, pre-vaccination thigh tingling), Dr. Lin asserted that only the November 11, 2013 toe tingling was the initial episode. Second Lin Rep. at 1; Third Lin Rep. at 1-2.

Dr. Lin's revised onset argument was dependent on diminishing the significance of the recorded pre-vaccination instances of thigh tingling. Arm/leg weakness associated with myelitis, Dr. Lin proposed, usually originates in the distal extremities (i.e., the feet) before ascending to the upper extremities. Second Lin Rep. at 1. He also cited authority to support this position. *See* J. Rosenfeld, et al., *Chapter Three – Numbness: A Practical Guide for Family Physicians*, Am. Acad. Neuro. 6-7 (2013), filed as Ex. 31 (ECF No. 29-1) ("Rosenfeld"). While the passage referenced in

[13] Karussis was published in "Autoimmunity Reviews," a bimonthly peer-reviewed medical journal publishing review articles pertaining to autoimmunity, and edited by Drs. Eric Gershwin and Yehuda Shoenfeld – both of whom frequently offer expert opinions in Vaccine Program cases on behalf of petitioners.

[14] PubMed is a free, online searchable database comprising more than 29 million citations to biomedical literature from Medline, life science journals, and online books. It is maintained by the United States National Library of Medicine at the National Institute of Health (NIH). The database can be accessed at: https://www.ncbi.nlm.gov/pubmed.

[15] Karussis observed three instances of NMOSD following administration of the HPV vaccine, with the remaining five following the Japanese encephalitis, rubella, yellow fever, rabies, and meningococcal C vaccines.

Rosenfeld discusses distal tingling in the context of a progressive peripheral disease (i.e., neuropathy or radiculopathy), however, it does not say explicitly that a CNS demyelinating condition like NMOSD would *not* present with such symptoms, or that CNS demyelinating illnesses generally are never associated with such symptoms. *Id.*

Dr. Lin also identified an alternative health condition revealed by Petitioner's records that in his view better explained her pre-existing inner thigh tingling: a bulging disc. Second Lin Rep. at 1. A CT scan conducted during Ms. Chen's initial hospital presentation in November 2013 revealed a bulging disc in the spinal cord between the L4-5 and L5-S1 vertebra. *Id.*; *see also* Ex. 5 at 146. The literature filed on this point by Dr. Lin, however, references symptoms related to a "herniated disc," a distinguishable condition that can cause pain/numbness/tingling consistent with what Petitioner experienced (although it does not also establish that a bulging disc is equivalent to a herniated disc). *See Herniated Disc*, Mayo Clinic (last accessed by expert on Nov. 23, 2016), filed as Ex. 34 (ECF No. 29-4) ("Mayo"). Dr. Lin's report otherwise does not attempt to relate the tingling symptoms Petitioner actually suffered with a "bulging" disc.

Dr. Lin went on to explain how the timing of Petitioner's injury was consistent with his contention that her NMOSD was indeed vaccine-caused. In his reading of the record, Petitioner developed myelitis symptoms (i.e., toe tingling and numbness) on November 11, 2013, or eleven days following her receipt of the flu vaccine. Third Lin Rep. at 2. Relevant scientific literature supported an onset as reasonably occurring within a period of five to twenty-eight days post-vaccination, making the timeframe in this case medically appropriate. *Id.*; *see* R. Baxter, et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis*, 63 Clin. Infect. Diseases 1456 (2016), filed as Ex. 41 (ECF No. 32-1) ("Baxter"); Karussis at 216 (noting average reported onset would be 14.2 days).

Baxter is an interesting choice to support Petitioner's argument. This article is a large-scale retrospective epidemiologic study in which researchers considered all cases of TM as well as ADEM in the United States (both acute CNS demyelinating conditions) that were recorded to have occurred in a population of nearly 64 million vaccine dose recipients, including over one million recipients of the flu vaccine, within two primary exposure windows: 5-28 days and 2-42 days. Baxter at 1456. Notably, however, Baxter observed *no* statistically significant heightened risk of TM in the 5-28 day exposure interval following *any* vaccination (as compared to the nine months after), or the longer 2-42 day time period. ADEM, by contrast, was noted to have some association with only the Tdap vaccine, and within the shorter 5-28 day interval. *Id.* at 1460. Baxter also makes no mention at all of NMOSD (or MS for that matter). Dr. Lin nevertheless maintained, based upon Baxter's findings with respect to acute-onset CNS demyelinating illnesses like ADEM and TM, that the 5-28 day exposure window was medically appropriate for NMOSD as well.

B. *Respondent's Expert – Dr. Winfried Raabe*

Respondent's expert, Winfried Raabe, M.D., submitted two expert reports in this case. *See* Ex. A, dated June 30, 2017 (ECF No. 25-1) ("First Raabe Rep."); Ex. K, dated Jan. 12, 2018 (ECF No. 40-1) ("Second Raabe Rep.").

Dr. Raabe received his undergraduate and medical degrees from the University of München in München, Germany. CV, filed as Ex. B (ECF No. 25-1) ("Raabe CV"). Following medical school, Dr. Raabe completed a doctoral fellowship in the Laboratory of Neurophysiology at the Institute for Psychiatry, also in München, Germany. *Id.* at 2. From 1972-1973, he worked as a research fellow in the Department of Neurology at the University of Minnesota, Minneapolis, and as an Instructor of Neurology thereafter. *Id.* Dr. Raabe then completed a residency in neurology at the University of Minnesota from 1974-1977. *Id.* Since 1977, Dr. Raabe has remained employed at the University of Minnesota and has served in various roles over his tenure, including as a staff physician in the neurology department and director of the EMG laboratory. *Id.* at 1-2. He has extensive teaching experience in clinical neurology and neuromuscular disease. *Id.* at 5-6. At present, he serves as an Adjunct Professor of Neurology for the university, as well as a consulting neurologist for the Stillwater Medical Group. *Id.* at 1. Dr. Raabe is board certified in neurology and currently holds a license to practice medicine in the state of Wisconsin. *Id.* at 2. He has also published on various neuropathic conditions (such as encephalopathy and spinal cord disease processes). *Id.* at 6-8. His CV does not suggest that he has received any training in immunology, however, and it does not appear that he has actively treated patients since 2007.

Contrary to Dr. Lin, Dr. Raabe did not deem Petitioner's symptoms course to be consistent with NMOSD, but instead opined that she more likely had MS. First Raabe Rep. at 5-6, 7. Petitioner's clinical and laboratory abnormalities did not fulfill the accepted diagnostic criteria for NMOSD – and thus, her symptoms could not be definitively confirmed as such.

In support of this argument, Dr. Raabe referenced the same diagnostic criteria set forth in Wingerchuk also relied upon by Dr. Lin. Dr. Raabe deemed Petitioner's MRI imaging studies as inconsistent with those typically seen in patients suffering from seronegative NMOSD. In particular, he found no evidence of specific NMOSD-related brain abnormalities reported in any of her scans.[16] First Raabe Rep. at 5. He also maintained that Petitioner had not experienced two or more of the core clinical criteria associated with NMOSD: optic neuritis, acute myelitis with LETM (MRI lesions extending $\geq$3 continuous spinal segments), an area postrema syndrome with hiccups or nausea/vomiting, or symptomatic narcolepsy/acute diencephalic syndrome. *Id.* Dr.

[16] Dr. Raabe defined the appropriate MRI evidence as revealing: 1) periependymal lesions surrounding the ventricular system; 2) diencephalic lesions surrounding the third ventricles and cerebral aqueduct; 3) dorsal brainstem lesions adjacent to the fourth ventricle; or 4) periependymal lesions surrounding the lateral ventricles. First Raabe Rep. at 5; *see* H. Kim, et al., *MRI Characteristics of Neuromyelitis Optica Spectrum Disorder: An International Update*, 84 Neurology 1165 (2015), filed as Ex. D (ECF No. 25-4).

Raabe's report, however, did not explain why Petitioner's brain lesion evidence better supported an MS diagnosis. *Id.* He otherwise noted that Petitioner also suffered from pre-existing glaucoma (not due to demyelinating disease affecting the optic nerve), which might better explain the vision problems evidenced in the record. *Id.*

The fact that Ms. Chen tested positive for the MOG antibody did not alter Dr. Raabe's opinion regarding Petitioner's proper diagnosis. Second Raabe Rep. at 4-5. Although he agreed that NMOSD could be subdivided into variants dependent upon the presence of AQP4 versus MOG antibodies, Dr. Raabe found significant the fact that Petitioner was never diagnosed with optic neuritis – a "hallmark" of MOG-positive NMOSD based on his review of the relevant literature. *Id.* at 5; *see* S. Ramanathan, et al., *Clinical Course, Therapeutic Responses and Outcomes in Relapsing MOG Antibody-Associated Demyelination, J. Neruol. Neruosurg. Psychiatry* 1 (2013), doi:10.1136/jnnp-2017-316880, filed as Ex. R (ECF No. 40-8); Weinshenker at 664, 667. Dr. Raabe also admitted, however, that the MOG autoantibody is rarely present in individuals with confirmed diagnoses of MS. Second Raabe Rep. at 5; *see* S. Kim, et al., *Central Nervous System Neuroinflammatory Disorders in Asian/Pacific Regions*, 29 Co-Neurology 372, 376 (2016), filed as Ex. Q (ECF No. 40-7).

Yet the dispute concerning Petitioner's symptomatology course and proper diagnosis ultimately did not matter, Dr. Raabe proposed, given the lack of direct medical evidence proffered by Petitioner supporting any link between the flu vaccine and onset of NMOSD *or* MS. Second Raabe Rep. at 5-6. In support, Dr. Raabe referenced two somewhat-recent articles authored by the Institute of Medicine, both of which assessed the mechanistic evidence regarding an association between the influenza vaccine and onset of NMOSD and MS. *See* K. Stratton, et al., *Adverse Effects of Vaccines: Evidence of Causality: Neuromyelitis Optica*, IOM 314 (2012), filed as Ex. F (ECF No. 25-6) ("Stratton I"); K. Stratton, et al., *Adverse Effects of Vaccines: Evidence of Causality: Multiple Sclerosis*, IOM 314 (2012), filed as Ex. E (ECF No. 25-5).

Stratton I surveyed the medical literature but found no studies even evaluating the risk of NMOSD following flu vaccine administration. Stratton I at 314. The article also identified no literature reporting clinical, diagnostic, or experimental evidence associating any mechanistic process (i.e., autoantibodies, T cells, complement activation, or molecular mimicry) or activity with onset of NMOSD following receipt of a flu vaccine. *Id.* Another article identified 780 cases of CNS disease (compared to 3885 controls) but found no association between *any* vaccine and onset of CNS disease (including MS) within a three-year period following administration. *See* A. Langer-Gould, et al., *Vaccines and the Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases*, 7 JAMA 1506 (2014), filed as Ex. G (ECF No. 25-7) ("Langer-Gould").

Besides offering literature that he maintained rebutted any association between the flu vaccine and NMOSD, Dr. Raabe disputed the persuasiveness of the scientific literature proffered by Petitioner for this same point. He noted that much of Petitioner's literature involved not NMOSD but ADEM (an acute CNS disease distinct in presumed etiology and course). First Raabe Rep. at 7; *see also* D. Pohl, et al., *Acute Disseminated Encephalomyelitis: Updates on an Inflammatory CNS Syndrome*, 87 Neurology S38 (2016), filed as Ex. I (ECF No. 25-9); A. Javed, et al., *Acute Disseminated Encephalomyelitis: Handbook of Clinical Neurology*, 123 Neurovirology 705 (2014), filed as Ex. J (ECF No. 25-10) (Table 35.3). In addition, literature purportedly evaluating the existence of a relationship between vaccination and NMOSD, like Karussis, involved the HPV rather than flu vaccine. Second Rabbe Rep. at 5; *see* Karussis at 218.

Dr. Raabe further emphasized record evidence suggesting that Petitioner's symptoms predated vaccination. First Raabe Rep. at 5. In particular, he pointed out the tingling/numbness referenced in two chiropractic notes from before, as well as at the time of, Petitioner's receipt of the flu vaccine. *Id.* at 5-6; *see* Ex. 4 at 1-2 (noting "inner thigh tingling" on 10/25/2013 and 11/1/2013). And he contested Dr. Lin's effort to distinguish thigh tingling symptoms as not evidence of a CNS demyelinating condition, arguing that this contention was unsupported by the filed scientific literature. Second Raabe Rep. at 1-2. Rosenfeld, he maintained, discussed distal extremity numbness as a presenting symptom only in the context of a peripheral nerve disease (i.e., neuropathy), and thus could not be read as supporting onset of CNS disease like NMOSD. *Id.*

Dr. Raabe further disputed Dr. Lin's suggestion that Petitioner's inner thigh tingling and numbness could be attributed to her preexisting bulging disc. Second Raabe Rep. at 2. To begin, Dr. Raabe pointed out that the literature cited by Dr. Lin in support of Petitioner's bulging disc theory actually involved the distinguishable condition of a "herniated" disc. *Id.*; *see* Ex. 34. In Dr. Raabe's view, a herniated (or "displaced") disc can compress the nerve root and result in tingling/pain. Second Raabe Rep. at 2. A bulging disc (or the presence of additional disc tissue extending beyond the edges of the disc), by contrast, is *not* considered a form of herniation, and in many instances does not even cause adverse symptoms. *Id.* at 2; *see* D. Fardon, et al., *Lumbar Disc Nomenclature: Version 2.0*, 39 Spine E1448 (2014), filed as Ex. O (ECF No. 40-5) ("Fardon"); *see* S. Boden, et al., *Abnormal Magnetic-Resonance Scans of the Lumbar Spine in Asymptomatic Individuals*, 72 J. Bone Joint Surg. 403 (1990), filed as Ex. M (ECF No. 40-3) ("Boden"); M Jensen, et al., *Magnetic Resonance Imaging of the Lumbar Spine in People Without Back Pain*, 331 New Eng. J. Med. 69 (1994), filed as Ex. N (ECF No. 40-4).

In fact, Dr. Raabe maintained that the record itself rebutted Dr. Lin's effort to attribute Petitioner's pre-vaccination thigh tingling to a bulging disc, pointing to Petitioner's CT scan of her lumbar spine conducted on November 26, 2013 (during her initial hospital presentation in Taiwan). Second Raabe Rep. at 2; *see* Ex. 5 at 146. The bulge revealed on that scan was located at the L4-L5 (which separates the L4 vertebral body from the L3 nerve root by roughly 2.5cm). Second

Rabbe Rep. at 2. The inner thighs, however, are innervated by the L2 and L3 nerve roots. *Id.* Thus, because of the distance (≥2.5cm) between the bulging disc and the nerve root affecting the inner thigh, Dr. Raabe opined that it would not be possible for Petitioner's observed bulging disc to have caused the tingling she was experiencing in her thighs. *Id.*

III. Procedural Background

After initiating this action in May 2016, Ms. Chen began filing medical records in support of her claim, completing the process three months later. *See* Statement of Completion, dated Aug. 25, 2016 (ECF No. 12). Respondent filed his Rule 4(c) Report thereafter, on October 24, 2016 (ECF No. 13). Petitioner filed an initial expert report from Dr. Lin on March 23, 2017 (ECF No. 20). Respondent thereafter filed his initial expert report from Dr. Raabe on June 30, 2017 (ECF No. 25). Supplemental experts were filed by Petitioner on October 26, 2017 (ECF No. 28), and October 27, 2017 (ECF No. 31), followed by a supplemental report from Respondent on January 12, 2018 (ECF No. 40).

Upon review of the records and the expert reports, I set this matter for hearing to take place on November 9, 2018 (ECF No. 38). In the interim period, however, Petitioner requested the matter be instead resolved via ruling on the record, filing a motion dated September 21, 2018 (ECF No. 45). Respondent submitted a response on October 29, 2018 (ECF No. 46). On November 16, 2018, Petitioner submitted her reply (ECF No. 47). The matter is now ripe for adjudication.

IV. Parties' Respective Arguments

Petitioner relies on Dr. Lin's immunological conclusions that the flu vaccine's components can cause the production of antibodies that, via the mechanistic process of molecular mimicry, damage the nerve's myelin sheath and result in NMOSD. Mot. at 45-46. Petitioner maintains that her causation contentions are well-supported by the filed medical literature and Program case law, and thus her receipt of the November 2013 flu vaccine likely caused damage resulting in NMOSD (the diagnosis best supported by the medical record and treater opinions). *Id.* at 31-45, 46-50, 56-61, 63, 78-80; *see also Day v. Sec'y of Health & Human Servs.*, No. 12-630V, 2015 WL 8028393 (Fed. Cl. Spec. Mstr. Nov. 13, 2015).[17]

In addition, Petitioner argues that Respondent's expert has not offered a persuasive rebuttal in response to the theory proffered by Dr. Lin. Mot. at 45-46. Petitioner directly disputes Respondent's contention that the relevant scientific literature best supports the conclusion that the flu vaccine cannot cause NMOSD. *Id.* at 50-56, 80-81. Rather, Petitioner argues that Dr. Lin provided ample support for the concept that vaccines can cause autoimmune CNS disorders

[17] Pages 1-29 of Petitioner's motion are dedicated to a factual review of the record (along with a section dedicated to describing the credentials of Petitioner's treating physicians). Mot. at 1-29.

(including ADEM/TM). *Id.* at 46. She otherwise contends that Dr. Raabe relies solely on evidence tending to prove statistically that the flu vaccine cannot cause NMOSD, without directly addressing the ability of the vaccine to cause an injury via Petitioner's proffered biologic theory. *Id.* at 45-50, 51-56.

Consistent with Dr. Lin's opinions set forth above, Petitioner maintains that her pre-vaccination sensory symptoms (i.e., inner thigh tingling) were not related to her NMOSD diagnosis thereafter (but were more likely attributable to a lower back problem and/or too vague in nature to indicate a deeper neurological problem was occurring). Mot. at 63-78. In her view, the toe tingling she experienced eleven days following her receipt of vaccination constituted the more likely onset of her NMOSD-related symptoms. *Id.* at 78-80.

Petitioner's motion otherwise posits that Dr. Raabe is not qualified and/or lacks the appropriate treatment experience to render an opinion on causation in this matter. Mot. at 29-31. Rather, based on a review of Dr. Raabe's CV, Petitioner argues that Dr. Raabe only holds expertise in "general neurology" or electro-diagnostics. *Id.* at 30. But his CV, she maintains, is devoid of evidence of expertise in the field of neuro-immunology. *Id.* In so stating, she asserts that Dr. Raabe's reports provide no evidence that he has experience evaluating or treating patients with either NMOSD (or MS for that matter). *Id.*

In response, Respondent argues that Petitioner has failed to establish that the flu vaccine was responsible for Petitioner's onset of neurologic symptoms, whatever the proper diagnosis was.[18] Opp. at 9-13. Respondent dismissed Dr. Lin's molecular mimicry theory, arguing that it was not adequately supported by the medical literature filed in the case. *Id.* at 10. Rather, Respondent posited that the medical articles relied on by Petitioner discussed illnesses (ADEM and/or GBS) distinct in nature from those considered in Petitioner's medical records, and thus not comparable to the present matter. *Id.* Respondent maintains that the available epidemiologic evidence strongly suggests no correlation between the flu vaccine and onset of NMOSD (or MS). *Id.* at 10-11. Otherwise, Respondent argues that Petitioner's records evidence an onset of disease symptoms (i.e., inner thigh tingling documented on 10/15/2013) prior to her receipt of the flu vaccine, and thus could not logically be associated with a cause and effect relationship. *Id.* at 14-15.

Petitioner's reply restated the medical theory of causation set forth in the motion for ruling on the record. Reply at 11-13. It also reiterated Petitioner's contention that her NMOSD diagnosis was both proper and supported by the medical records discussed above. *Id.* at 13-18. In addition, the reply further discussed the dispute regarding onset of Petitioner's symptoms, albeit mainly by restating the arguments proffered in the original motion. *Id.* at 17-21. Petitioner also maintained

[18] Respondent nevertheless maintains that Petitioner's medical records best support an MS diagnosis. Opp. at 13-14.

that Dr. Raabe's qualifications to opine in the matter are lacking, and that his reports otherwise failed to articulate a credible rebuttal. *Id.* at 1-11.

V. Applicable Law

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 & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[19] In this case, Petitioner does not assert a Table claim.

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

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

[19] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human 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 & Human 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 & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

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 & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[20]

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

[20] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

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

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing 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 & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 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 & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd 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, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than

those which are internally consistent") (quoting *Murphy*, 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 & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records 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 & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial for a (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health*

& Human Servs., 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). 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 & Human 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 every filed item factors into the outcome of this decision. While I have reviewed all of 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 & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered").

E. *Resolution of Case Via Ruling on Record*

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

ANALYSIS

I. Overview of CNS Demyelinating Conditions and Relevant Prior Decisions

Despite disputing Petitioner's proper diagnosis, the parties' experts agreed that MS and NMOSD are distinct CNS demyelinating illnesses. In fact, there are notable distinctions not just between the two, both of which are chronic, but also between longer-term conditions like NMOSD and more acute forms of CNS demyelination that are highly relevant to this matter's resolution.

In prior cases, I have found that a variety of acute CNS diseases (such as ADEM or TM) are distinguishable (whether by clinical presentation, radiological findings, and/or treatment protocol) from those deemed to be more progressive or multiphasic in character, like MS or NMOSD. *See, e.g., Taylor v. Sec'y of Health & Human Servs.*, No. 13-700V, 2018 WL 2050857, at *28-29 (Fed. Cl. Spec. Mstr. Mar. 9, 2018) (distinguishing ADEM from MS); *Caruso v. Sec'y of Health & Human Servs.*, No. 15-200V, 2017 WL 5381154, at *12-13 (Fed. Cl. Spec. Mstr. Oct. 18, 2017) (same), *mot. for review den'd*, 137 Fed. Cl. 386 (2018). The relevant literature filed in the case also recognizes this distinction – as does Program case law. *See, e.g.*, Karussis at 216-17 (discussing the "spectrum" of CNS demyelinating syndromes and the variances between ADEM, ON, MS, myelitis, and NMOSD); *Davis v. Sec'y of Health & Human Servs.*, No. 07-451V, 2010 WL 1444056 (Fed. CL. Spec. Mstr. Mar. 16, 2010) ("ADEM and [MS] appear to differ from NMO[SD] in some respects"), *aff'd*, 94 Fed. Cl. 53, *aff'd*, 420 F. App'x 973 (Fed. Cir. 2011).

Conditions like ADEM or TM are understood to occur rapidly and often resolve without recurrence (even though they can leave lasting sequelae). *See* Karussis at 216-17; *Palattao v. Sec'y of Health & Human Servs.*, No. 13-591V, 2019 WL 989380, at *11 (Fed. Cl. Spec. Mstr. Feb. 4,

2019) (describing TM's course as "abrupt[]" and "monophasic"); *Taylor*, 2018 WL 2050857, at *20 ("ADEM is . . . characterized by an acute onset and monophasic course"). By contrast, relapsing conditions like MS can initially *present* as if they were ADEM or TM , but will invariably recur. *See, e.g.*, *Hunt v. Sec'y of Health & Human Servs.*, No. 12-232V, 2015 WL 1263356, at *11 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) (noting that an MS diagnosis traditionally requires "at least two events disseminated in time and space") (internal quotation marks omitted)), *mot. for review den'd*, 123 Fed. Cl. 509 (2015). NMOSD, while distinct from MS, is similarly understood to be a relapsing disease (and hence distinguishable from monophasic conditions like ADEM, even though both involve CNS demyelination). Wingerchuk at 9 (noting only "5%-10% of contemporary cases are described as monophasic" and requiring five years of relapse-free clinical observation in order to confirm a monophasic course).

These distinctions are critical for purposes of evaluating causation in this case. Program petitioners have on many occasions successfully established that an acute form of a CNS demyelinating condition, such as TM or ADEM, could be vaccine-caused. *See, e.g.*, *Raymo v. Sec'y of Health & Human Servs.*, No. 11-0654V, 2014 WL 1092274, at *23 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) (TM injury found to be vaccine caused); *Brown v. Sec'y of Health & Human Servs.*, No. 09-426V, 2011 WL 5029865, at *41 (Fed. Cl. Spec. Mstr. Sept. 30, 2011) (flu vaccine caused petitioner's ADEM injury); *Banks v. Sec'y of Health & Human Servs.*, No. 02-0738V, 2007 WL 2296047, at *25 (Fed. Cl. Spec. Mstr. July 20, 2007) (awarding compensation for ADEM linked to MMR vaccine); *Kuperus v. Sec'y of Health & Human Servs.*, No. 01-0060V, 2003 WL 22912885, at *11 (Fed. Cl. Spec. Mstr. Oct. 23, 2003) (awarding compensation for ADEM linked to DTaP vaccine); *but compare Caruso v. Sec'y of Health & Human Servs.*, No. 15-200V, 2017 WL 5381154 (Fed. Cl. Spec. Mstr. Oct. 18, 2017) (petitioner successfully established a plausible mimicry theory involving the capacity of different vaccines, including the flu vaccine, to cause ADEM and/or a myelitis, although petitioner ultimately did not establish that his ADEM was vaccine-caused).

By contrast, Program claimants have had less consistent success in establishing that a vaccine (including the flu vaccine) could cause a person to develop MS or NMOSD.[21] *See, e.g.*, *Day*, 2015 WL 8028393 (awarding entitlement where HPV and Flumist vaccines were shown to have caused petitioner to develop NMOSD); *Calise v. Sec'y of Health & Human Servs.*, No. 08-

[21] For cases discussing MS, *see Heddens v. Sec'y of Health & Human Servs.*, No. 15-734, 2018 WL 5726991 (Fed. Cl. Spec. Mstr. Oct. 5, 2018) (HPV vaccine cannot cause or aggravate MS); *Giannetta v. Sec'y of Health & Human Servs.*, No. 13-215V, 2017 WL 4249946 (Fed. Cl. Spec. Mstr. Sept. 1, 2017) (MS found to be caused by meningococcal vaccine); *Smith v. Sec'y of Health & Human Servs.*, No. 08-864V, 2016 WL 2772194 (Fed. Cl. Spec. Mstr. Apr. 18, 2016) (Hep B vaccine found to be causal of MS); *Fisher v. Sec'y of Health & Human Servs.*, No. 99-432V, 2009 WL 2365459 (Fed. Cl. Spec. Mstr. July 13, 2009) (same). It does not appear, however, that past case law has addressed the capacity of the flu vaccine to cause MS directly, as most successful such claims have been alleged in the context of other vaccines also deemed causal, or a more acute CNS disease process (like TM). *See, e.g.*, *Ruppert v. Sec'y of Health & Human Servs.*, No. 13-869V, 2018 WL 4561276 (Fed. Cl. Spec. Mstr. Aug. 28, 2018); *Williams v. Sec'y of Health & Human Servs.*, No. 10-843V, 2016 WL 3027778 (Fed. Cl. Spec. Mstr. Apr. 27, 2016).

85V, 2011 WL 1230155 (Fed. Cl. Spec. Mstr. Mar. 14, 2011) (awarding entitlement for flu vaccine/NMOSD injury); *but compare Davis*, 2010 WL 1444056, *aff'd*, 94 Fed. Cl. 53 (upholding special master's decision that the flu vaccine did not cause NMOSD). Although the results of some of these decisions are consistent with Petitioner's favored outcome, the theories offered are not.

In *Calise* and *Davis*, for example, petitioners alleged that the flu vaccine caused NMOSD, but the theories offered in both cases centered on the concept that components of the flu vaccine first cause direct injury to the endothelial cells in the body, thereby producing a breach in the blood brain barrier, and resulting in further injury via a subsequent antibody attack on the myelin sheath (absent any cross-reactivity via molecular mimicry). *See Calise*, 2011 WL 1230155, at *12-21; *Davis*, 2010 WL 1444056, at *8-9. Here, by contrast, Petitioner simply proposes that molecular mimicry between antigens in the vaccine and self structures in the MBP of nerves caused harm, with less explanation as to how the process occurred.

Day, on the other hand, involved a causation theory centered on molecular mimicry, but featured two vaccines acting in concert (i.e., the HPV and Flumist[22] vaccines). The presiding special master decided the claim for petitioner in that case based primarily on record evidence supporting the potential of components of the *HPV* vaccine to cause a cross-reaction spurred on by AQP4 (the traditional NMOSD autoantibody). *See Day*, 2015 WL 8028393, at *14. Here, it is undisputed that Ms. Chen has never tested positive for the AQP4 autoantibody (the autoantibody most associated with NMOSD), and did not receive the HPV vaccine. *Day* did not otherwise specifically address the role the flu vaccine might have played in contributing to the petitioner's disease course. *Day*, 2015 WL 8028393, at *14.

II. The Medical Record Best Supports an NMOSD Diagnosis

The parties strenuously disagree on the proper diagnosis for Ms. Chen. Although my ultimate analysis does not turn on resolution of this point, it bears some brief discussion.

It is indisputable that Petitioner's treaters considered both MS and NMOSD diagnoses over the course of her illness (and followed appropriate treatment protocol for both diseases). Petitioner maintains that her health course is better characterized by an NMOSD diagnosis. Even though Petitioner tested negative for the AQP4 autoantibody (the biomarker most often associated with NMOSD), an individual can still be properly diagnosed with a seronegative form of NMOSD if other criteria are established. In reaction, Respondent points to certain of Petitioner's MRI imaging

[22] The Flumist vaccine contains live, attenuated (or reduced in virulence) strains of the wild flu virus (unlike an inactivated version of the vaccine), and is administered intranasally as a spray rather than being injected. *See D'Toile v. Sec' of Health & Human Servs.*, 132 Fed. Cl. 421, 426 n.3 (2017), *aff'd*, 726 F. App'x 809 (2018); *see also Influenza Virus Vaccine, Live (Nasal Route)*, Mayo Clinic, https://www.mayoclinic.org/drugs-supplements/influenza-virus-vaccine-live-nasal-route/description/drg-20066943 (last accessed Apr. 11, 2019).

studies that he argues are inconsistent with the more stringent diagnostic criteria for NMOSD patients negative for AQP4. Dr. Lin acknowledged that Petitioner's myelitis scans were somewhat atypical, but maintained that an almost three-segment spinal cord lesion would be sufficient to meet the NMOSD criteria from a treatment perspective. Petitioner also identifies some later-in-time lab results revealing that she tested positive for MOG antibodies – an alternative NMOSD biomarker that treating physicians deemed significant. Dr. Raabe's second expert report conceded, at a minimum, that MOG antibodies are not indicative of MS (Respondent's preferred diagnosis), though he continued to dispute the NMOSD diagnosis given the lack of optic neuritis evidence in the record.

The overall record in this case makes it difficult to firmly establish Petitioner's correct diagnosis (a task that, to some extent, I am not even called upon to perform, since diagnosing illness falls well beyond the purview of the special masters in resolving Vaccine Act claims). However, the evidence ultimately preponderates in favor of the NMOSD diagnosis. Even though Petitioner's history does not present a classic form of the condition – it unquestionably did not present with any ophthalmologic symptoms in the fall of 2013, and lacks the most common autoantibody evidence – the most recent treater views (which take into account Petitioner's overall medical history) seem to accept the diagnosis. I also give weight to Dr. Lin's views as a treater[23] who saw Ms. Chen at the very outset of her neurologic condition.

III. Petitioner Has Not Satisfied the *Althen* Prongs

A. *Althen Prong One*

As noted above, Petitioner has offered various medical and scientific literature (and employed a treating expert) to support her claim, and her theory has elements that are routinely deemed valid in the Vaccine Program. Petitioner's proposed mechanism (molecular mimicry) has repeatedly been embraced in Program cases as pertinent to immune-mediated conditions, and could plausibly explain the genesis of many demyelinating disorders. *See, e.g., Tompkins v. Sec'y of Health & Human Servs.*, No. 10-261V, 2013 WL 3498652, at *22 (Fed. Cl. Spec. Mstr. June 21, 2013) ("[t]he molecular mimicry theory is the one most widely accepted for the agents most frequently accepted as causal"), *mot. for review den'd*, 117 Fed. Cl. 713 (2014). Nevertheless, I do not find the overall theory as proposed *in this case* was sufficiently reliable, or bulwarked in crucial places by reliable evidence.

[23] In so finding, I accept some of Petitioner's arguments about Dr. Lin's superior qualifications over Dr. Raabe to opine on diagnostic issues – although I do not find that the experts were similarly uneven in their qualifications when commenting on the likelihood of vaccine causation generally. Indeed, too much of Petitioner's motion for a ruling on the record was devoted to unnecessary credibility attacks that did not meaningfully alter my assessment of the strength of her showing,

For molecular mimicry to credibly and reliably explain how the flu vaccine could cause NMOSD, there should be some evidence that the relevant autoantibodies that are known to drive, or are at least associated with, the resulting disease are likely produced as a result of vaccination (or at least the wild virus) – and it is reasonable to require a petitioner to offer some evidence in support of such a contention when evaluating the success of the claimant's prong one showing. *See, e.g., W.C.*, 704 F.3d at 1361; *Hunt v. Sec'y of Health & Human Servs.*, 123 Fed. Cl. 509, 523-34 (2015) (discussing *W.C.*). Petitioner could have established this with a variety of circumstantial evidence involving the flu vaccine (or wild flu virus) and its association with MS or NMOSD, or proof that immune system stimulation can at least *initiate* a chronic process that would indirectly result in the down-stream production of the relevant autoantibodies. But Petitioner offered little such evidence. Rather, and as discussed above, most of the scientific evidence presented in this case involved either peripheral neuropathies, like GBS, or acute CNS disease processes (i.e., ADEM) following administration of the flu vaccine. *See, e.g.*, Shoamanesh; Lee; Machicado; Huynh; Huang. This evidence had some limited circumstantial value, since it involves demyelinating conditions, but was not sufficiently bulwarked with evidence relevant to a chronic CNS demyelinating disease like NMOSD.

Moreover, although Dr. Lin did attempt to establish that there was some possible homology between antigens in the flu vaccine and MBP components, he did *not* identify the antigenic source in the flu vaccine responsible for this autoimmune process resulting in NMOSD, and cited no medical or scientific literature involving experimentation on the subject. He also offered no evidence tending to suggest that the flu vaccine might produce, directly or indirectly, *any* NMOSD-associated autoantibodies – but at a minimum the MOG autoantibodies, since that was the sole relevant biomarker for which Petitioner tested positive. By citing scientific literature in support of distinguishable, acute CNS injuries, Dr. Lin erroneously assumed that the homology/cross-reactivity potential studied between the flu vaccine and self-structures in the body resulting in *other* kinds of demyelinating illnesses are automatically relevant to NMOSD simply because they are all demyelinating.

Petitioner's ample case study evidence was little better. Much of it involved distinguishable conditions, like ADEM. *See, e.g.*, Shoamanesh; Lee; Machicado; Maeda. The only case report study directly addressing NMOSD was Karussis, but *none* of the eight post-vaccination case-report instances of NMOSD it identified involved the flu vaccine. Karussis at 218-19. And in any event, case studies as a class of evidence are not typically given great weight in Program cases. *Doe/16 v. Sec'y of Health & Human Servs.*, No. 06-670, 2008 WL 2390064, at *14 (Fed. Cl. Spec. Mstr. June 2, 2008) (citing *Daubert*, 509 U.S. at 594-96 ("[c]ausal attribution based on case studies must be regarded with caution, largely because they lack control and thus do not provide the level of information or detail found in epidemiologic studies")).

In response, Respondent referenced some larger epidemiologic studies in an effort to show that the flu vaccine has not been credibly associated with NMOSD (or other CNS demyelinating conditions, for that matter). *See, e.g.*, Stratton I; Langer-Gould. Stratton I surveyed the available medical literature and found no studies evaluating the risk of onset of NMOSD following flu vaccine administration. Stratton I at 314. Langer-Gould similarly identified 780 cases of CNS disease following vaccination, but observed no association between disease onset and *any* vaccine (including the flu vaccine). Langer-Gould at 1506. I am mindful of the fact that petitioners need not offer epidemiologic evidence in support of their claims, and I cannot require it in reaching my conclusions. *See Harris v. Sec'y of Health & Human Servs.*, No. 10-322V, 2014 WL 3159377, at *11 (Fed. Cl. Spec. Mstr. June 10, 2014) (epidemiologic studies cannot absolutely refute causal connections, because it is possible that a larger study could always detect an increased risk). But the Federal Circuit has repeatedly noted that where epidemiologic evidence exists, and where it is reliable and relevant, it may be considered in evaluating the strength of a petitioner's causation showing. *See, e.g., D'Tiole v. Sec'y of Health & Human Servs.*, No. 15-085V, 2016 WL 7664475 (Fed. Cl. Spec. Mstr. Nov. 26, 2016), *mot. for review den'd*, 132 Fed. Cl. 421 (2017), *aff'd*, 726 F. App'x 809, 811-12 (Fed. Cir. 2018).

Notably, even epidemiologic evidence filed by the *Petitioner* undercuts her argument for associating the flu vaccine with NMOSD. Baxter, for example – a retrospective epidemiologic study that reviewed nearly 64 million vaccine doses (including over one million flu vaccine recipients) – found no significant association between the flu vaccine and onset of even *acute* forms of CNS demyelinating diseases, like ADEM or TM (suggesting an association with more chronic forms of demyelination was even less likely). Baxter at 1456. Petitioner also offered Huang, a large-scale study which similarly reviewed over 3.5 million doses of the H1N1 vaccine in the Taiwanese population but found no significant increase in CNS disease (as opposed to peripheral neuropathies like GBS) onset post-vaccination. Huang at 3.

All in all, Petitioner has not offered sufficient reliable and persuasive evidence suggesting that the flu vaccine could cause a chronic form of CNS demyelinating disease such as NMOSD, that would unfold over a lengthy period of time. The scientific and medical evidence offered in support of her theory best supports associating the flu vaccine with acute CNS demyelinating processes – not ones like NMOSD, in which specific autoantibodies are understood to be causal. And Dr. Lin's expertise, while sufficient to explain his theory (and more than sufficient to offer persuasive testimony on Petitioner's proper diagnosis), was not enough (based on his actual practice experience with CNS disorders) to fill in the theory's many evidentiary gaps.

B. *Althen Prong Two*

As noted, the evidence in the present matter establishes that Petitioner suffers from some form of CNS disease (more likely NMOSD). However, my findings with respect to the medical theory proffered in the case (along with timing of onset) make it impossible for me to conclude that Petitioner successfully established a logical cause-and-effect sequence – that in this case the flu vaccine "did cause" Petitioner's NMOSD, as reflected in the record before me. Without being able to establish a reliable medical theory (and onset *after* vaccination), Petitioner cannot show that the vaccine more likely than not caused her illness thereafter.

But even had I determined that the flu vaccine could cause NMOSD, the record in this case is not preponderantly supportive of the conclusion that Ms. Chen's illness was attributable to her November 1st vaccination. Although some treaters allowed for the possibility that her initial symptoms were vaccine-caused, they did so based on the assumption that she had experienced a single occurrence of an acute demyelinating condition like ADEM, rather than a recurring, chronic form of CNS demyelination that would subsequently wax and wane over the course of the next several years. As noted above, the scientific evidence linking the flu vaccine to an acute form of CNS demyelination is much stronger. No treaters since appear to have strongly embraced an association between the vaccine and Ms. Chen's subsequent NMOSD diagnosis. *See, e.g.*, Ex. 2 at 186; *but compare* Ex. 9 at 110-13; Ex. 7 at 1, 4; Ex. 28 at 3.

Admittedly, the evidence from the records of Petitioner's initial medical workup and evaluation (in the first month to six weeks post-vaccination) is mixed. Ignoring the evidence of thigh tingling (which, as noted above, likely preceded vaccination), the first set of alarming symptoms appeared between (or right prior to) November 21-23, 2013, at the time of Petitioner's trip to Taiwan. But EMG and nerve conduction studies from this period were normal, and there are no other lab results that would suggest that Petitioner's demyelinating process was at this time rampant (although it likely existed). Ex. 5 at 12, 96, 144. By contrast, MRIs performed in late November/early December were not only corroborative of the nature of her illness, but their "enhancing" quality suggested they were more recent in origin (which would be more consistent with Petitioner's argument that her disease process began post-vaccination). *Id.* at 12, 20.[24]

[24] As other decisions have discussed, demyelinating lesions observed from radiologic scans can precede discovery by a substantial period of time, measured in weeks or even months. *See, e.g., L.Z. v. Sec'y of Health & Human Servs.*, No. 14-920V, 2018 WL 5784525, at *17 (Fed. Cl. Spec. Mstr. Aug. 24, 2018); *Borrero v. Sec'y of Health & Human Servs.*, No. 01-417V, 2008 WL 4527837, at *21 (Fed. Cl. Spec. Mstr. Sept. 24, 2008); *Stevens v. Sec'y of Health & Human Servs.*, No. 99-594V, 2006 WL 659525, at *23 (Fed. Cl. Spec. Mstr. Feb. 24, 2006). But lesions that appear "enhanced" on MRI can reflect a disease process far more recent in origin. *See, e.g., Maciel v. Sec'y of Health & Human Servs.*, No. 15-362V, 2018 WL 6259230, at *2 n.5 (Fed. Cl. Spec. Mstr. Oct. 12, 2018) (citing *W.C. v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 440, 444 (2011), *aff'd*, 704 F.3d 1352 (Fed. Cir. 2013)), *mot. for review den'd*, slip op. (Fed. Cl. Apr. 1, 2019); *Borrero*, 2008 WL 4527837, at *21 (suggesting that an enhancing lesion takes on average three to four weeks to develop).

However, it is also significant that Petitioner *never* tested positive for any of the autoantibodies associated with NMOSD at any time even within the *first year* of vaccination – even though her causation theory supposes that a molecular mimicry-derived cross-reactive attack by vaccine antigen-induced autoantibodies should have been occurring in the first month after receipt of the flu vaccine. At most, she established that acute onset of symptoms in Taiwan occurred in a medically appropriate timeframe relevant to *other* kinds of CNS illnesses considered acute, like ADEM – conditions parallel to, but not congruent with, what she experienced in this case. Petitioner cannot prevail simply because her CNS demyelination was discovered within a month of vaccination. *See, e.g.*, *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014) ("[a] temporal correlation alone is not enough to demonstrate causation").

C. *Althen Prong Three*

As set forth above, establishing the third *Althen* prong requires preponderant evidence of a medically-acceptable temporal relationship between a vaccination and alleged illness. *Althen*, 418 F.3d at 1281. A mere temporal association is not by itself sufficient to carry a petitioner's burden of proof for a non-Table claim. *Grant*, 956 F.2d at 1148. At bottom, a Vaccine Act claimant must establish that the injury in question did not *precede* the relevant vaccine's administration (except in the case of a significant aggravation claim, which has not been alleged herein). *See, e.g.*, *Shalala v. Whitecotton*, 514 U.S. 268, 273-274 (1995).

The parties generally agree that the evidentiary record establishes that Petitioner experienced *some* neurologic and/or sensory symptoms (i.e., numbness/tingling) that were related to her more obvious subsequent manifestations around the time of her trip to Taiwan. Petitioner and her treating expert argue for an onset of symptoms eleven days post-vaccination, at which time chiropractic records suggest she had experienced notable sensory issues (specifically, toe tingling) that she argues are reasonably associated with a CNS myelitis due to their distal origin. Petitioner disputes, however, that the inner thigh tingling referenced in those same records – both pre-vaccination and post – was also an initial manifestation of NMOSD, arguing instead that such symptoms were wholly the product of her preexisting back problems.

In support of this assertion, Dr. Lin referenced Rosenfeld, which generally stands for the proposition that numbness (and its various descriptors) *can* be associated with CNS disorders. Rosenfeld at 1. But Rosenfeld more discusses distal extremity sensory issues associated with *peripheral* neuropathies (characterized by leg and arm symptoms that unfold in a slow, progressive course), as opposed to CNS diseases involving the brain or spinal cord (in which sensory issues would be usually expected to present acutely). Rosenfeld at 6. Rosenfeld does not stand for the proposition that the distal situs of tingling invariably establishes its CNS character, and is therefore weak support for Petitioner's contention that onset of her NMOSD was reflected only in her toe tingling symptoms (although it is not strong support for Respondent's position either, since this entire constellation of symptoms would be more associated with peripheral than CNS neuropathies

– allowing for the conclusion that such symptoms say nothing about Petitioner's onset either way). *Id.* at 3-4.

Respondent, by contrast, argues for an onset pre-dating vaccination, pointing to Petitioner's medical records for support. Petitioner lodged complaints of sensory issues, including paresthesias (i.e., tingling in the legs) and/or numbness in the lower extremities, *before* vaccination that are arguably consistent with the symptoms that later led her to seek emergency treatment in Taiwan. *See, e.g.*, Ex. 4 at 1-2 (10/25/2013 and 11/4/2013 notations of inner thigh tingling; 11/11/2013 notation of toe tingling); Ex. 5 at 12 (11/25/2013 notation of paresthesia and leg numbness), 4 (11/29/2013 notation of numbness in arms/legs), 26 (12/9/2013 hospital noting "residual distal limbs tingling" at discharge). Over the course of her illness, Petitioner also continued to report to her treaters that she was experiencing residual tingling and numbness in the lower extremities attributable to her condition. Ex. 2 at 170 (2/21/2014 notation of intermittent numbness/tingling of right lower extremity), 182 (3/13/2014 notation of numbness/tingling in legs, knees down). Nothing in the medical record suggests any treaters deemed these symptoms to be unrelated to her NMOSD, and/or the product of her preexistent back pain issues.

To distinguish these symptoms, Dr. Lin opined that Petitioner's inner thigh tingling could best be attributed to a bulging disc (concurrently revealed on Petitioner's CT scan conducted during her initial hospitalization). However, although it is not disputed that Petitioner's scan revealed a disc bulge, the scientific and medical literature relied on by Dr. Lin for this point only discussed symptoms of numbness/tingling relating to a "herniated" disc. *See* Mayo at 1. To rebut Dr. Raabe's contentions on this subject, Petitioner seems to have adopted the position that the terms are interchangeable (in which case both problems can cause numbness/tingling *or* be asymptomatic). *See* Mot. at 74-77. Petitioner otherwise suggests that "inner thigh tingling" is a vague term, thereby making it impossible to tell which nerve root ending would be affected without more information. *Id.* at 77-78. Notably, however, Petitioner offered *no* literature on the topic of nerve innervation is it relates to inner thigh tingling (or distinguishing a herniation from a bulge in that context).

Dr. Raabe,[25] by contrast, persuasively established the contrary, offering literature suggesting that a bulge and a herniation are indeed different (*see, e.g.*, Fardon), and that bulging disc cases tend to be asymptomatic in nature. *See, e.g.*, Boden. Dr. Raabe also persuasively established with record proof, unrebutted by Petitioner, that Petitioner's bulging disc could not have resulted in Petitioner's inner thigh tingling given the location of the bulge on his spinal

[25] I take note of Petitioner's suggestion that Dr. Raabe's CV does not establish that he currently treats patients with NMOSD, nor is he a specialist in back pain and its explanations. In the context of this case (i.e., one weighing heavily on evidence of causation rather than a dispute among treater conclusions), however, I find no reason to disregard (or offer less weight) to Dr. Raabe's opinion on this subject. In essence, it was a reasonable point raised in response to Dr. Lin's contention – and despite being on notice of it, Petitioner did not persuasively rebut it.

column (when compared to the location of the nerve root ending). Second Raabe Rep. at 2. The distance between the bulge and the nerve root affecting the inner thigh (i.e., ≥2.5cm) made Petitioner's contention implausible.

I acknowledge that the record does not illuminate the precise nature of Petitioner's pre-vaccination tingling, and it is not strong evidence for pre-vaccination onset. But it was nevertheless unsupportive of Petitioner's position on onset, and ineffectively rebutted.[26] Thigh tingling – which even Dr. Lin initially deemed significant (*see* First Lin Rep. at 1), excising it as a manifesting symptom for Ms. Chen's NMOSD only when it was revealed that she had experienced the same complaint *before* vaccination – is reasonably associated with CNS myelitis, and was never established by the record to be a product of Petitioner's preexisting chiropractic problems.[27] Dr. Lin's assertions to the contrary were unmoored from identifiable scientific or record support, and instead reflected conclusory reasoning that does not merit great weight merely on account of his status as an otherwise credible treating expert. *Cedillo*, 617 F.3d at 1339 ("a Special Master need not credit expert opinion testimony that is connected to the existing data or methodology 'only by the *ipse dixit* of the expert,'") (quoting *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997)). I thus cannot conclude it more likely than not that Petitioner's illness only began after vaccination.

IV. Petitioner Has Not Carried Her Overall Burden of Proof

Although each individual *Althen* prong focuses on a different mix of legal and factual matters, in the end *all* Petitioners must establish that a given vaccine "more likely than not" caused an alleged injury. *W.C.*, 704 F.3d at 1356. Here, there is some objective evidence supporting Petitioner's claim, and given the timing of the more severe manifestation of her symptoms it was more than reasonable for her to suspect that the vaccine could have played a role in her condition. Petitioner was also successful in establishing that the record evidence best supports her preferred diagnosis – although that issue was not dispositive of causation.

But I do not find that Petitioner has carried her preponderant burden overall. Her causation theory relies too heavily on literature involving acute CNS demyelinating conditions, and the limited existing Program case law involving the capacity of any vaccine to cause NMOSD is distinguishable. The medical record further only demonstrates that Petitioner's severe symptoms began temporally after vaccination – not that the theory she embraces (an inflammatory autoimmune process resulting in the production of MOG autoantibodies) happened to her in real

[26] Petitioner does not in this case allege in the alternative that the flu vaccine exacerbated or aggravated a preexisting case of NMOSD, and I do not otherwise find the record would support such a contention.

[27] For example, a treater opinion set forth in a contemporaneous record that the thigh tingling Petitioner reported was not attributable to demyelination would have aided her argument.

time due to vaccination. Indeed, the record suggests her first neurologic symptoms likely preceded vaccination.

CONCLUSION

The Vaccine Act permits me to award compensation only if a Petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. Here, there is insufficient evidence to support an award of compensation, leaving me no choice but to hereby **DENY** this claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of Court), the Clerk shall enter judgment in accord with this decision.[28]

IT IS SO ORDERED.

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

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