In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 19-647V
Filed: December 12, 2024

LYNN ACTON,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Patricia Ann Finn, Patricia Finn Attorney, P.C., Nanuet, NY, for petitioner.
Benjamin Patrick Warder, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On May 1, 2019, petitioner, Lynn Acton, filed a petition for compensation under the National Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that her receipt of an influenza ("flu") vaccination on November 30, 2016 caused a significant aggravation of her pre-existing conditions of chronic fatigue syndrome and Lyme disease, resulting in myoclonus, tremors, fasciculations, and muscle atrophy, which "has been identified by her team of physicians as a post-vaccination syndrome." (ECF No. 1.) She subsequently indicated that she suffered from "immune activation syndrome to a previous vaccination resulting in chronic fatigue syndrome and brain injury" and that her flu vaccination significantly aggravated her condition "causing her current injuries, i.e., myoclonus and accompanying muscular weakness and muscular wasting." (ECF No. 87, p. 2.)

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

For the reasons set forth below, petitioner has been unsuccessful in seeking to prosecute her case with respect to the full scope of her alleged syndrome through her retained expert. However, petitioner's medical records, and the medical opinion contained therein by movement disorder specialist Duarte G. Machado, M.D., are sufficient to entitle her to a more limited award of compensation for her post-vaccinal myoclonus *only.*

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect

showing that the vaccination was the reason for the injury[,]" with the logical sequence being supported by "reputable medical or scientific explanation, *i.e*., evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Ultimately, petitioner must satisfy what has come to be known as the *Althen* test, which requires: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.[3] *Id*.

A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. § 300aa-13(b)(1). A petitioner may also rely upon circumstantial evidence. *Althen*, 418 F.3d at 1280. The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. While scientific certainty is not required, that expert's opinion must be based on "sound and reliable" medical or scientific explanation. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359 (Fed. Cir. 2019).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3. Special masters must ensure each party has had a "full and fair opportunity" to develop the record but are empowered to determine the format for taking evidence based on the circumstances of each case, including having the discretion to decide cases without an evidentiary hearing. Vaccine Rule 3(b)(2); Vaccine Rule 8(a); Vaccine Rule (d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental

[3] Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a preexisting injury, as petitioner has pleaded, the petitioner must establish the three *Althen* prongs along with three additional factors described in the prior *Loving* case. *See Loving ex rel. Loving v. Sec'y of Health & Human Servs*., 86 Fed. Cl. 135, 144 (2009) (combining the first three *Whitecotton* factors for claims regarding aggravation of a Table injury with the three *Althen* factors for off table injury claims to create a six-part test for off-Table aggravation claims); *see also W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part *Loving* test). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee's condition prior to the administration of the vaccine, (2) the vaccinee's current condition, and (3) whether the vaccinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. *Loving*, 86 Fed. Cl. at 144.

fairness to both parties. Vaccine Rule 8(b)(1). 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." § 300aa-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).

In the pleadings, petitioner presented a significant aggravation claim under *Loving v. Secretary of Health & Human Services*. (ECF No. 1.) Specifically, petitioner argued that the subject flu vaccination resulted in overstimulation of her immune system due to her preexisting autoimmune conditions of chronic fatigue syndrome and Lyme disease, causing increased inflammation and new onset of neurologic symptoms, namely, myoclonus, tremors, fasciculations, and muscle wasting. (ECF No. 1, p. 4: ECF No. 73, p. 14; ECF No. 87, p. 2.) During the hearing, however, petitioner's expert, Dr. Neuenschwander, explained that, although petitioner's alleged preexisting condition is relevant to his causal theory, he does not opine that petitioner's post-vaccination condition is an exacerbation of her preexisting condition. (Tr. 66, 69-70.) Accordingly, this case is properly evaluated under the *Althen* test for causation-in-fact.

II. Procedural History

The case was initially assigned to another special master. (ECF No. 5.) On May 2, 2019, petitioner filed medical records, marked as Exhibits 1-9 and 11-20, as well as a Statement of Completion.[4] (ECF Nos. 7-9.) The case was subsequently reassigned to the undersigned on August 26, 2019. (ECF No. 11.) Over the course of the following year, petitioner continued to file medical records requested by respondent.[5] (ECF Nos. 21-22, 24-25, 27, 32, 35; Exs. 21-31.)

Respondent filed his Rule 4(c) report on October 22, 2020, recommending against compensation. (ECF No. 39.) Respondent noted petitioner's failure to show that her symptoms would not be expected in the natural course of chronic fatigue syndrome or Lyme disease, notwithstanding the subject vaccination, though he also

[4] There were a few errors in the labeling of petitioner's exhibits: Exhibit 4 was incorrectly marked as Exhibit 5, Exhibit 6 was incorrectly marked as Exhibit 7, Exhibit 7 was incorrectly marked as Exhibit 8, Exhibit 8 was incorrectly marked as Exhibit 9, and Exhibit 9 was incorrectly marked as Exhibit 10. (ECF No. 7.) Exhibits 4 and 9 were subsequently refiled with the correct marking. (ECF Nos. 18, 20.) Throughout this ruling, citations to Exhibit 6 refer to the exhibit filed at ECF No. 7-6, citations to Exhibit 7 refer to the exhibit filed at ECF No. 7-7, and citations to Exhibit 8 refer to the exhibit filed at ECF No. 7-8.

[5] Exhibit 21 is a compact disc containing a series of photos and videos depicting petitioner's alleged symptoms. (ECF No. 21.) The Notice accompanying the exhibit lists the 3 videos as depicting myoclonic jerks of the legs on December 2, 2016; October 27, 2017; and February 1, 2018, although the videos themselves are unmarked. (*Id.*) As part of this filing, petitioner also submitted 17 photographs to demonstrate her alleged muscle wasting. These photographs appear to be taken from an iPad camera roll and include date stamps.

questioned whether petitioner ever actually had Lyme disease in light of negative testing. (*Id.* at 17-18 & n.12.) He also noted conflicting opinions among petitioner's treaters regarding vaccine causation and asserted that there was no evidence of a causal connection between petitioner's vaccination and the alleged significant aggravation of her pre-existing conditions. (*Id.* at 18-19.) Finally, respondent noted that petitioner's alleged symptoms of myoclonus, tremors, and fasciculations are non-specific symptoms with no evidence they are related to either vaccine-induced neuroinflammation or structural neurologic pathology. (*Id*. at n.15.)

Petitioner subsequently filed updated medical records, the file of her workers' compensation claim relative to her alleged injury, and expert opinion by James Neuenschwander, M.D.[6] (ECF Nos. 41-43, 47-48, 50, 51-56, 69, 72; Exs. 31-91.) Respondent filed a responsive opinion by neurologist Norman S. Werdiger, M.D. (ECF Nos. 52, 58; Exs. A-C.)

A one-day entitlement hearing was held on June 27, 2023. (Transcript of Proceedings ("Tr."), at ECF No. 84.) Following the hearing, the parties were permitted to file post-hearing briefs limited to the issue of how much weight may be given to Vaccine Adverse Event Reporting System ("VAERS") reports regarding myoclonus, responsive to a question that arose during the hearing. (ECF No. 83.) This briefing was completed between August and October of 2023. (ECF Nos. 87-90.)

Accordingly, this case is now ripe for resolution.

III. Factual History

a. As reflected in the medical records

i. Pre-vaccination

The medical records filed in this case begin with a follow up encounter of May 30, 2013, regarding ongoing fatigue, arthralgia, and swollen lymph nodes (Ex. 31, p. 25); however, around that time, petitioner was also reporting a prior history of an apparent viral thyroiditis occurring sometime in 2012 (Ex. 19, p. 6). It was noted that, earlier that month, petitioner presented to primary care with complaints of fatigue and joint pains.

[6] When petitioner was ordered to file an expert report, she was directed to ensure that if her expert relied on the presence of Lyme disease, such reliance would need to be substantiated. (ECF No. 40.) Dr. Neuenschwander's first report asserted the presence of Lyme disease but did not explain why the diagnosis was appropriate. (Ex. 53, p. 3.) A subsequent order provided an opportunity for petitioner to correct that omission (ECF No. 49); however, in a supplemental report, Dr. Neuenschwander removed all reference to Lyme disease from his report and instead opined that petitioner was experiencing chronic immune activation from "any number of other possible pathogens for which she was not tested" (Ex. 69, p. 1).

(Ex. 31, p. 25.) She was empirically treated with a two-week course of doxycycline[7] and reported feeling "significantly better" with this treatment. (*Id*.) However, she continued to feel fatigue and aching in her ankles, feet, and hands. (*Id*.) Petitioner was concerned she had Lyme disease due to what she suspected had been a tick bite (Ex. 19, p. 6; Ex. 31, p. 22); however, she had twice tested negative for Lyme serology (Ex. 31, p. 25). Her physical examination was normal with the exception of non-tender, swollen lymph nodes. (*Id.* at 26-27.) Petitioner was assessed with lymphadenopathy. (*Id.* at 27.) An ultrasound of petitioner's neck and right auxiliary lymph nodes was ordered, and she was advised to continue taking doxycycline for an additional week. (*Id.*)

Petitioner underwent various examinations and tests in June 2013. Her chest PA and lateral x-ray results were normal. (Ex. 31, p. 37.) Her thyroid ultrasound results were normal with no definitive evidence of abnormal lymph nodes. (*Id.* at 38-40.) Her musculoskeletal limited examination was also normal. (*Id.* at 40.)

Petitioner had a primary care follow up for her ongoing symptoms with Dana Ranani, M.D., on June 22, 2013. (Ex. 31, p. 22.) She complained of increased joint pain in her neck, aching in her wrists and ankles, and paresthesia in her left leg and collar bone area, but reported having more energy. (*Id.*) It was noted that petitioner suffered from a prolonged course of symptoms relating to arthralgias. (*Id.*) Petitioner's physical examination was normal with no lymphadenopathy. (*Id.* at 24.) Petitioner's joints were not swollen and appeared stable, and her muscle strength and tone were normal. (*Id.*) Petitioner was assessed as having fatigue and arthralgias in multiple places, though the etiology of the arthralgias was unclear. (*Id.*) It was noted that the doxycycline seemed to treat "something," but it was unclear whether petitioner suffered from Lyme disease. (*Id.*) Dr. Ranani felt post-infectious arthralgias was possible and ordered serology tests for other tick-borne illnesses. (*Id.*) She prescribed meloxicam[8] and ordered a series of laboratory tests, including ANA, babesia microti, IgM and IgG western blot, and parvovirus b-19 antibodies. (*Id.*)

On July 15, 2013, petitioner visited rheumatologist Robert T. Schoen, M.D., for an evaluation of arthralgias. (Ex. 19, p. 6.) Dr. Schoen did not believe that petitioner suffered from Lyme disease. (*Id.*) Instead, Dr. Schoen diagnosed petitioner with inflammatory arthritis and noted that her medical history was "consistent with a viral syndrome." (*Id.*) In a follow-up examination on August 26, 2013, Dr. Schoen noted petitioner's history of arthralgias and improvement on meloxicam. (*Id.* at 5.) Her physical examination was normal. (*Id.*) However, Dr. Schoen advised petitioner to discontinue meloxicam in preparation for an upcoming surgical procedure. (*Id.*) On October 17, 2013, petitioner visited Dr. Schoen for her "widespread musculoskeletal pain and possible viral arthritis." (*Id.* at 4.) Petitioner reported that she was "generally

[7] Doxycycline is an orally administered antibacterial treatment. *Doxycycline*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=14859 (last visited Oct. 3, 2024).

[8] Meloxicam is an orally administered non-steroidal anti-inflammatory drug that is used to treat osteoarthritis. *Meloxicam*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=30286 (last visited Nov. 14, 2024).

feeling better" but had developed some tingling in her hands and apparent ganglion cyst. (*Id.*)

Petitioner saw Stephanie Parrillo, P.A., for an annual primary care examination on January 20, 2014. (Ex. 31, p. 18.) She described intermittent joint pain and swelling that was primarily in her ankles. (*Id.*) It was noted that petitioner's blood work did not uncover an autoimmune process and that petitioner was diagnosed with inflammatory arthritis, though it was unclear whether the inflammatory arthritis was the result of a viral illness. (*Id.*) Petitioner complained of a "flare up" in her arthritis but admitted that she was exerting herself more and that taking Advil provided some relief. (*Id.*) Her physical examination was normal, and she was assessed in pertinent part with arthralgias in multiple locations. (*Id.* at 20-21.) Petitioner's January 22, 2014 laboratory results were normal with the exception of an elevated low-density lipoprotein (LDL) level at 153 md/dL (reference range of 0-100 mg/dL). (*Id.* at 122.)

Petitioner returned to her primary care physician on March 5, 2014. (Ex. 31, p. 15.) It was noted that the pain in her wrists and ankles was improving on meloxicam. (*Id.*) Her physical examination was otherwise normal, and Dr. Ranani refilled her meloxicam prescription. (*Id.* at 17.) However, petitioner's joint pain returned in April 2014. On April 8, 2014, petitioner saw Dr. Schoen with complaints of pain in her ankles, wrists, and neck, though she reported less fatigue. (Ex. 19, p. 3.) Petitioner was restarted on meloxicam and diagnosed with unspecified arthritis. (*Id.*) In his notes, Dr. Schoen stated his belief that petitioner either had a self-limiting viral arthritis or an early inflammatory arthritis. (*Id.*) Petitioner returned Dr. Schoen on May 5, 2014, for her joint pain, as well as pain in the right side of her neck and carotid swelling. (Ex. 31, p. 125.) Her right carotid was larger than her left and "somewhat tender to palpation." (*Id.*) Subsequent imaging uncovered no evidence of hemodynamically significant stenosis. (*Id.* at 32-33.) Dr. Schoen noted that petitioner's lab results were unremarkable. (*Id.* at 125.) Specifically, her test results were negative for antinuclear antibody (ANA) and rheumatoid factor. (Ex. 19, p. 10.) Dr. Schoen's impressions were unspecified arthritis, anxiety, and right carotid swelling. (Ex. 19, p. 2.) Dr. Schoen suggested the possibility of fibromyalgia. (*Id.*) At a follow-up appointment on June 3, 2014, Dr. Schoen noted that petitioner was "doing much better" on a gluten-free diet and that she was no longer taking meloxicam. (*Id.* at 1.) Her swelling had gone down, her physical examination was unchanged, and her carotid ultrasound was unremarkable. (*Id.*) Dr. Schoen maintained his impression of unspecified arthritis. (*Id.*)

On June 10, 2014, petitioner saw naturopath Jeffrey J. Klass, N.D., with complaints of joint swelling, joint pain, bloated stomach, palpitations, unexplained cough, "foggy" mind, and "carotid bulb swollen." (Ex. 22, pp. 59-60.) In her symptom survey, petitioner also checked off the following past symptoms: tired, weak, lack of energy; irritability; frequent coughing; noises or ringing in the ears; swollen, painful or stiff joints; bone pains; painful feet, ankles or calves; gas or belching; bloating; constipation; foul odor of stool or gas hemorrhoids; reflux; heart beats fast or irregular; and swollen ankles. (*Id.* at 60-61.) Petitioner further reported suffering from the following symptoms at the time that she completed the survey: skin rashes; dryness,

roughness or scaling skin, scalp, elbows, knees, around nose, ears, etc.; dry eyes; loss of strength in her hands; inability to eat fats first thing in the morning post-gull bladder removal; avoiding certain foods that contain gluten; and irregular menstruation. (*Id.*) In handwritten notes in the margins of the survey, petitioner explained that the pain in her joints, bones, feet, ankles, and calves dissipated after four days of following a gluten-free diet and that the skin issues and irregular bowl movements arose when she did not adhere to the gluten-free diet. (*Id.*)

There are records suggesting that Dr. Klass thereafter ordered a series of tests. (Ex. 31, pp. 59-69.) Petitioner tested positive for Epstein-Barr virus[9] and Bartonella henselae[10] on July 8, 2014. (*Id.* at 59, 64-65.) Her results for Babesia microti[11] were "[e]quivocal." (*Id.* at 66.) Dr. Klass noted these results in a letter, dated January 13, 2015. (Ex. 22, p. 58.) He also noted that petitioner's cortisol and dehydroepiandrosterone ("DHEA") levels were low.[12] (*Id.*) Dr. Klass explained that petitioner's chief complaints were fatigue, joint pain, paresthesia, and peri-menopausal

[9] Epstein-Barr virus, or human herpesvirus 4, is a virus that causes, for example, infectious mononucleosis, which is a common, acute, and usually self-limited infectious disease that is generally characterized by *inter alia* fever and lymph node enlargement. *Epstein-Barr virus*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=118260 (last visited Oct. 3, 2024); *Human herpesvirus 4*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=80849 (last visited Oct. 3, 2024); *Infectious mononucleosis*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=89566 (last visited Oct. 3, 2024).

[10] Bartonella henselae is the etiologic agent of cat-scratch disease, which is a generally benign, self-limited infectious disease of the regional lymph nodes that is usually characterized by fever and lymph node inflammation. *Bartonella henselae*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=60252 (last visited Oct. 3, 2024); *Cat-scratch disease*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=70170 (last visited Oct. 3, 2024). Bartonella henselae is also the primary cause of bacteremia (bacteria in the blood) in immunocompromised patients, as well as bacterial endocarditis. *Bartonella henselae*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=60252 (last visited Oct. 3, 2024); *Bacteremia*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=5343 (last visited Oct. 3, 2024).

[11] Babesia microti is a parasite that is normally found in rodents and causes human babesiosis, which is usually characterized by anemia, hemoglobinemia, hemoglobinuria, and a malaria-like fever will chills, sweats, myalgia, nausea and vomiting, hemolytic anemia, and splenomegaly. *Babesia microti*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=59806 (last visited Oct. 3, 2024); *Human babesiosis*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=59816 (last visited Oct. 3, 2024). However, Babesia microti can also be transmitted by tick Ixodes scapularis, which is also the principal vector of Lyme disease. *Babesia microti*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=59806 (last visited Oct. 3, 2024); *Lxodes scapula'ris*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=83375 (last visited Oct. 3, 2024).

[12] According to the results of petitioner's blood work, her cortisol levels were within the normal range at 9.8 ug/dL (reference range of 7.0-25.0 ug/dL), as was her DHEA level at 74 ug/dL (reference range of 35-430 ug/dL).

symptoms and that he had been treating her with "various nutritional, herbal supplements" since July 2014. (*Id.* at 58.)

On January 19, 2015, petitioner saw P.A. Parrillo for an annual exam. (Ex. 31, p. 11.) She reported that the swelling in her ankles and wrists had gone down since starting a gluten free diet and obtaining treatment from Dr. Klass. (*Id.* at 11, 14.) However, a subsequent celiac panel was negative. (*Id.* at 78.) Her physical examination was normal with the exception of some minor swelling in her right ankle and bilateral wrists. (*Id.* at 13-14.) Petitioner was assessed as having arthralgias in multiple locations. (*Id.* at 14.) Dr. Klass authored another letter, dated October 2, 2015, in which he diagnosed petitioner with chronic fatigue syndrome. (Ex. 22, p. 57.) As a result of this diagnosis, Dr. Klass advised the petitioner forego vaccination due to compromised immune system. (*Id.*)

On January 18, 2016, petitioner returned to P.A. Parrillo for an annual exam. (Ex. 31, p. 7.) Petitioner reported that she was seeing Dr. Klass on a regular basis "for ongoing management of lyme and joint aches," and that, under Dr. Klass's treatment, her joint swelling had been reduced and she could tolerate small amounts of gluten. (*Id.* at 7.) Her physical examination was normal. (*Id.* at 9-10.) Petitioner was assessed as having arthralgia in multiple places, hyperlipidemia, and an abnormal thyroid blood test. (*Id.* at 10.) There is no mention of chronic fatigue syndrome, despite the inclusion of fatigue as one of petitioner's active problems. (*Id.* at 8.) On March 25, 2016, petitioner was seen in follow-up for "Lyme & co-infection" with complaints of a frequent twitch in her right eye on a daily basis, joint swelling, and muscle pain. (Ex. 22, p. 55.) She indicated that she presented for Rife treatment and reported that she had been "feeling pretty good until last week," that she had been "very red/toxic [for the] last 4 days," and that her sleep had been disrupted. (*Id.* at 26.) On June 2, 2016, petitioner returned to her primary care physician because her LDL level had increased. (Ex. 31, p. 3.) Though fatigue was listed as an active problem, petitioner was assessed as only having hyperlipidemia. (*Id.* at 6.) Dr. Klass authored another letter, dated November 8, 2016, again advising against vaccination due to petitioner's chronic fatigue syndrome. (Ex. 22, p. 54.)

i. Post-vaccination

Petitioner received the flu vaccine on November 30, 2016, as an employment requirement for her position as a speech pathologist at Yale New Haven Hospital.[13]

[13] In addition to petitioner's regular medical care as discussed below, petitioner also initiated a workers compensation claim for her alleged vaccine injury that included numerous follow up evaluations. The encounter records relating to petitioner's workers' compensation claim are in Exhibits 9 and 33. Although I have carefully reviewed these records, it is not necessary to summarize them in light of the analysis that follows. Petitioner also sat for a deposition in connection with her workers' compensation claim. (Ex. 34.) Again, it is not necessary to separately summarize this testimony, though I have carefully reviewed it. During the hearing in this case, petitioner confirmed she did not wish to amend or recant any of her deposition testimony. (Tr. 33.) Ultimately, petitioner's workers compensation proceedings do not lend any significant clarity to her medical history. The respondent's medical examination concluded that petitioner was not suffering any neurologic injury at all. (Ex. 33, pp. 8-10.) However, Dr. Russi of the

(Ex. 4; Ex. 26, p. 1; Ex. 20, ¶ 9.) She indicated that her employer had not accepted Dr. Klass's vaccination exemption letters. (Ex. 20, ¶¶ 7-8.) At the time of vaccination, petitioner was 52 years old. (Ex. 1; Ex. 34, p. 26.)

The following day, December 1, 2016, petitioner initially arrived at work, but she was subsequently sent home by the occupational health department at Yale New Haven Hospital. (Ex. 9, p. 73.) She was instructed to reach out to her primary care provider if her symptoms did not improve. (*Id*.) Thereafter, petitioner contacted her primary care provider, reporting "a lot of joint pain" throughout her body, but primarily in her hands, which began around 6:00 p.m. on November 30, 2016. (Ex. 5, p. 1.) Specifically, she observed that she noticed her pain when she was tying her son's karate belt at about 6:30 p.m. on the day of the vaccination and, by the morning of December 1, 2016, she was struggling to open a water bottle with her right hand. (*Id.*) She noted her concern that she was experiencing a "flare" of her prior joint pain and explained that she had been reluctant to receive the flu vaccine because of her history of Lyme disease. (Ex. 5, p. 1.) P.A. Parrillo recommended that petitioner treat the inflammation with Tylenol and Motrin and follow up with Dr. Klass for naturopathic options. (*Id.*) She also reassured petitioner that her symptoms were "not contraindication for future immunizations" and advised that she take Tylenol or Motrin before future vaccinations. (*Id.*)

On December 2, 2016, petitioner returned to her primary care provider, complaining of an acute reaction to the flu vaccine that she received two days prior. (Ex. 5, p. 3.) Specifically, she complained of pain in her hands and twitching in her thigh muscles without pain or weakness. (*Id.*) She described how the twitching in her thighs woke her up in the middle of the night but spontaneously subsided after thirty minutes. (*Id.*) However, she was concerned about Guillian-Barré syndrome ("GBS"). (*Id.*) She indicated that she had not taken Tylenol or Motrin as advised because she wanted to track whether she improved without the aid of anti-inflammatory medications, and that she had contacted Dr. Klass, who was "not surprised with her reaction" but reassured her that "it would pass after a few days." (*Id.*) Petitioner's physical examination was normal except for slight swelling in the right pointer finger. (*Id.* at 4.) She was assessed as having reactive arthropathy and muscle twitching. (*Id.* at 3.) For the reactive arthropathy, P.A. Parrillo reassured petitioner that her symptoms would improve and advised her to take the anti-inflammatory medication as previously prescribed. (*Id.*) With regard to the muscle twitching, P.A. Parrillo reassured petitioner that this symptom was not consistent with GBS (reflexes within normal limits and normal strength throughout) and would also improve. (*Id.*) She was directed to stretch and remain active, which would also help with stress management. (*Id.*)

Yale New Haven Hospital occupational health department evaluated petitioner multiple times and repeatedly diagnosed "miscellaneous neurological devices associated with adverse incidents, not elsewhere classified." (*See, e.g.*, Ex. 9, pp. 27, 55.) Petitioner settled her workers' compensation claim for $5,000.00. (Ex. 43.) In reaching the settlement, Yale New Haven Hospital admitted that petitioner suffered an adverse reaction to the flu vaccine but contested the extent of petitioner's alleged disability and need for medical treatment. (*Id*. at 4-5.)

On December 3, 2016, petitioner called the "After Hours Nurse Call Line" at her primary care office, complaining of uncontrollable shaking in her hands, and it was recommended that she visit Express Care. (Ex. 5, p. 7.) That same day, petitioner presented to her primary care office with complaints of tremors and uncontrolled jerking movements in her arms and legs. (*Id.* at 8.) Petitioner was in "extreme emotional distress" and indicated that she wanted to go to the emergency room. (*Id.*) The twitching appeared to decrease significantly once petitioner calmed down. (*Id.*) Her physical examination revealed decreased reflexes in the upper extremities with no signs of swelling. (*Id.*) Her grip strength was normal but associated with pain. (*Id.*) Petitioner was transported by ambulance to the emergency room for further evaluation, and it was suggested that she should undergo testing to determine if an electrolyte abnormality was causing her symptoms. (*Id.*)

Walter Green, M.D., treated petitioner once she arrived at the emergency room. (Ex. 23, p. 1.) Petitioner reported a 3-day history of bilateral leg tremors and muscle spasms since receiving a flu vaccination. (*Id.*) Petitioner reported that her symptoms began with bilateral hand pain that progressed to tremors in the upper extremities over the past few days, but her symptoms had "been resolving over the past couple of hours." (*Id.*) Dr. Green noted that petitioner had received the flu vaccine in the past without issue, as well as her "remote history" of Lyme disease. (*Id.*) Her neurologic and physical examinations appeared normal with no focal deficits and no evidence of swelling in her hands or tremor in her extremities. (*Id.*) Petitioner's lab results were also unremarkable with no evidence of electrolyte abnormality, and she was subsequently discharged home. (*Id.*)

Petitioner called her primary care office on December 5, 2016, reporting that she was "still having some neurological effects," that she had a headache, and that her legs were "still moving." (Ex. 5, p. 2.) However, her symptoms were improving, and at the time, P.A. Parrillo did not believe that petitioner needed to be seen again. (*Id.*) Petitioner visited Dr. Klass later that day with complaints of brain fog, constipation, fatigue, headaches, increased stress, insomnia, joint pain, joint swelling, and numbness/tingling. (Ex. 6, p. 1; Ex. 22, p. 51.) She reported that her pain was a five out of ten, and her symptoms were primarily affecting her hands. (Ex. 22, p. 52.) Dr. Klass' notes read: "VEGA Findings (electro-diagnostic testing, which is for investigational use only): Toxicity – 15 (scale 0-21)." (Ex. 6, p. 1.) As treatment, Dr. Klass prescribed the following: Bromelain, Curcumin, and Quercetin (BCQ) capsules for inflammation and joint pain; Detoxosode OS for "detoxification"; Metabiarex drops for "bug killer"; Neuroantitox CAN drops for "detoxification" and "bug killer"; and Red Clover Compound drops for "detoxification". (*Id.*)

On December 6, 2016, petitioner self-reported an adverse vaccine reaction through VAERS. (Ex. 23, pp. 3-6.) As a pre-existing condition, petitioner reported that she had a compromised immune system due to chronic fatigue syndrome and that she had Lyme disease in the past. (*Id.* at 5.) She described her alleged post-vaccine symptoms as the following: She noticed joint pain and swelling at around 4:30 p.m. on November 30, 2016, followed by a right-sided headache at around 8:00 p.m. that same

day. At approximately 9:45 a.m. on December 1, 2016, petitioner began feeling "extreme fatigue," followed by muscle twitched beginning at 2:30 p.m. Her joint issues and muscle twitching continued through December 2, 2016. At around 9:00 a.m. on December 3, 2016, petitioner had a "severe headache" and, by 11:21 a.m., she began experiencing "Parkinson hand tremors." At 12:20 p.m., she noticed "severe flailing of lower extremities," which was allegedly witnessed by medical staff at an urgent care facility. Petitioner then went to the emergency room, but her blood work was normal and she was discharged by 4:30 p.m. On December 5, 2016, petitioner saw Dr. Klass, who witnessed her legs "moving uncontrollably." (*Id.* at 6.)

Petitioner saw neurologist Duarte G. Machado, M.D., on December 8, 2016. (Ex. 7, p. 1.) In petitioner's documented medical history, Dr. Machado listed "a history of chronic fatigue and Lyme disease with Babesia coinfection." (*Id.*) Dr. Machado reported that petitioner was without joint pain and in her usual state of health when she received the flu vaccine on November 30, 2016. (*Id.*) Petitioner's history of present illness included joint pain and headache on November 30, 2016; "extreme exhaustion" and twitching in her legs on December 1, 2016; and severe headache and hand tremors on December 3, 2016, prompting an urgent care visit. (*Id.*) At urgent care, petitioner's "lower external knees were moving uncontrollable," and she subsequently transferred to the emergency room but was eventually discharged after her lab results returned within normal limits. (*Id.*) Dr. Machado noted that petitioner was taking supplements that had helped in "reducing her movements." (*Id.*) However, Dr. Machado noted that petitioner "continued to experience involuntary jerking of her legs and a sensation of worms under skin." (*Id.*) She was also experiencing eyelid twitching. (*Id.*) These involuntary movements were hindering petitioner's sleep, which contributed to her exhaustion. (*Id.*) Petitioner's physical examination was normal with the exception of rare and intermittent fasciculations in her right lower leg, as well as provoked myoclonic jerks in both legs. (*Id.* at 3.) Petitioner showed Dr. Machado videos demonstrating myoclonic jerks in her legs and fasciculations of her orbicularis oculi muscle. (*Id.*) Dr. Machado assessed petitioner's predominate movement disorder as myoclonus. (*Id.* at 4.) He explained that "post infectious and post vaccination myoclonus is a well described clinical entity where the myoclonus is the sole manifestation." (*Id.*) Dr. Machado ordered serum studies to rule out other possibilities but maintained that "the timeframe and description of her condition" pointed to petitioner suffering a "postvaccination myoclonus." (*Id.*) He expected that petitioner's condition would be benign and her prognosis was good. (*Id.*) Petitioner refused Dr. Machado's prescription of clonazepam[14] for the myoclonus. (*Id.*)

[14] Clonazepam is an orally administered benzodiazepine (depressant of the central nervous system) that is used as an anticonvulsant in the treatment of myoclonic seizures and as an antipanic agent in the treatment of panic disorders. *Clonazepam*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=10139 (last visited Sept. 30, 2024); *Benzodiazepine*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=5838 (last visited Sept. 30, 2024).

Petitioner saw Moshe Hasbani, M.D.,[15] for a neurological consultation on December 20, 2016. (Ex. 11, p. 11.) Dr. M. Hasbani noted that petitioner developed myalgia, arthralgia, headache, fasciculations primarily in her eyelids and thighs, and tremors in her hands, after receiving the flu shot. (*Id.*) Petitioner showed Dr. M. Hasbani videos of the myoclonus, which were irregular. (*Id.* at 12.) She again described the feeling of "warm worms crawling under her skin." (*Id.* at 11.) Petitioner's medical history over the prior two to three years included chronic fatigue and "Lyme syndrome co-infection with babesiosis," which was being treated with naturopathic medicine. (*Id.*) Petitioner's review of systems was "positive for Tinnitus, chest pain, hypertension, wheezing, chronic fatigue, [and] chronic Lyme." (*Id.*) Her neurological and physical examinations were generally unremarkable. (*Id.* at 12.) Petitioner's muscle tone and strength were normal; however, "[e]liciting reflexes provoked intermittently a monoclinic jerk with a certain amount of delay." (*Id.*) These jerks were irregular. (*Id.*) No tremors were observed during the examination. (*Id.*) Dr. M. Hasbani concluded that petitioner developed post-vaccination myalgia and arthralgia after receipt of the flu vaccine, but any tremors and fasciculations had mostly subsided. (*Id.*) The fasciculations were nonspecific because they were not found to be associated with atrophy or weakness. (*Id.*) The myoclonus appeared to be precipitated by deep tendon reflex examination. (*Id.*) Dr. M. Hasbani ordered an EEG and recommended that petitioner start walking regularly. (*Id.*) At this time, he found her to be completely incapable of performing her job; however, he stated that her prognosis for recovery was "quite good." (*Id.*)

On December 22, 2016, petitioner presented to Dr. Klass for a Rife treatment and completed a visit questionnaire, in which she claimed that her symptoms were improving. (Ex. 22, p. 49.) She reported that the myoclonus was less frequent and less severe, but it was still affecting her ability to sleep. (*Id.*) She further complained of cough/wheezing on inhalation, fatigue, increased stress, insomnia due to the myoclonic jerks, joint pain, and joint swelling. (*Id.*) She reported her pain was at a three out of ten. (*Id.*)

Neurologist M. Joshua Hasbani, M.D., performed an EEG on January 5, 2017. (Ex. 9, p. 15; Ex. 11, p. 10.) He assessed petitioner's results as normal. (Ex. 11, p. 10.) Myoclonic jerks of petitioner's legs were noted during the recording, but were not associated with any electrographic correlate. (*Id.* at 10.) Petitioner returned to Dr. J. Hasbani on January 17, 2017, and reported that she had more energy and her overall condition had "improved by about 50%." (*Id.* at 9.) Her neurological examination was normal. (*Id.*) Dr. J. Hasbani's assessment was myoclonus and a reaction to the flu vaccine. (*Id.*) He determined that petitioner was "gradually improving" and noted his anticipation that petitioner's symptoms "should hopefully fully resolve." (*Id.*)

On January 20, 2017, petitioner presented to Dr. Klass and completed a visit questionnaire, in which she claimed that her energy had increased, but the

[15] Petitioner sought treatment from both Moshe Hasbani, M.D., and M. Joshua Hasbani, M.D. For the sake of clarity, Moshe Hasbani, M.D., is hereinafter referred to as Dr. M. Hasbani, and M. Joshua Hasbani, M.D., is subsequently referred to as Dr. J. Hasbani.

"movements" were aggravated by increased activity. (Ex. 22, p. 47.) She further complained of bloating/gas, fatigue, insomnia, joint pain, joint swelling, and an "electrical like pain" in the tips of her toes. (*Id.*) She reported her pain as being between two and four out of ten and primarily affecting her hands and toes. (*Id.* at 48.)

Petitioner returned to Dr. Machado on January 24, 2017. (Ex. 7, p. 4.) Dr. Machado noted that petitioner's EEG results were unremarkable and that her serum studies were normal or negative. (*Id.* at 5.) Petitioner's energy and sleep were both improved, but she was still dealing with fatigue. (*Id.*) Her myoclonus was milder in both frequency and intensity, which she attributed to the beneficial effects of the supplements prescribed by Dr. Klass; however, the movements continued to impair her sleep, which contributed to her exhaustion. (*Id.*) She was still experiencing intermittent fasciculations of all limbs and sharp pain at the tips of her toes. (*Id.*) Her physical and neurological examinations were normal, including normal muscle bulk and tone. (*Id.* at 7.) There were no fasciculations observed during the examination. (*Id.*) However, petitioner showed him a video that demonstrated myoclonic jerks in both legs. (*Id.*) Dr. Machado's assessment was "[i]solated post infectious and post vaccination myoclonus." (*Id.* at 8.) He again noted his expectation petitioner's condition would be benign with a good prognosis. (*Id.*)

Petitioner saw Dr. Klass on February 16, 2017, with complaints of bloating/gas, anger, fatigue, insomnia due to the myoclonic jerks, joint pain, joint swelling, cognitive issues, and rashes. (Ex. 22, pp. 44-45.) Petitioner reported that she "had naturopathic lyme disease treatment (RIFE)" on February 21, 2017, and received some relief until February 24, 2017, when she began experiencing hard, painful bumps that limited her manual activities. (Ex. 11, p. 7.)

Petitioner saw Dr. J. Hasbani on March 2, 2017. (Ex. 11, p. 7.) It was noted that the jerking was limited to petitioner's right eyelid and left quadricep when she took the naturopathic supplements. (*Id.*) When she did not take the supplements, the jerking and fasciculations spread "diffusely" and she experienced confusion with "divided attention." (*Id.*) She maintained that she was losing between one and three hours of sleep per night due to the myoclonus in her upper extremities. (*Id.*) Petitioner reported feeling decreased ability to concentrate despite taking naturopathic supplements. (*Id.*) Her physical and neurological examinations were normal, and she was assessed with fasciculations and reaction to the flu vaccine. (*Id.* at 8.)

Less than a week later, on March 7, 2017, petitioner saw Dr. Machado. (Ex. 41, p. 8.) Petitioner maintained that she was losing sleep due to the myoclonus, and she continued to experience fasciculations of all limbs, which were improved when taking her supplements. (*Id.* at 9.) She also complained of sharp pain at the tips of her toes and heaviness in her chest at rest. (*Id.*) Her physical and neurological examinations were normal with no sign of fasciculations. (*Id.* at 11.) Dr. Machado reviewed petitioner's videos and determined that they displayed myoclonic jerks in both legs. (*Id.*) He again diagnosed petitioner with post-vaccination myoclonus. (*Id.* at 12.) To treat the

myoclonus, Dr. Machado prescribed clonazepam. (*Id.*) He again stated his expectation that petitioner's condition would be benign and her prognosis was good. (*Id.*)

Petitioner saw Dr. Klass on March 16, 2017. (Ex. 22, p. 42.) She reported that her symptoms had improved and that she was feeling "cognitively clearer" after Rife treatment. (*Id.* at 42-43.) She stated that she felt tired, her eyes were tearing, and her pain was at a three out of ten; however, her body felt lighter and her legs felt better on the stairs. (*Id.*) She complained of the following symptoms: bloating/gas, constipation, anger, dizziness while walking, fatigue, insomnia, joint pain, joint swelling, heart palpitations, chest heaviness/pain, and numbness/tingling. (*Id.* at 42.)

On April 17, 2017, petitioner saw naturopath Matthew Fisel, N.D., and described a history of present illness that tracked her previous descriptions of her clinical course following vaccination. (Ex. 13, p. 1.) During this appointment, petitioner complained of joint swelling, fatigue, sudden jerking in her muscles, smaller fasciculations, and "entire body twitching." (*Id.*) Petitioner reported that her symptoms were "definitely worse with stress." (*Id.*) Petitioner's physical examination showed left basal joint edema with pain on active and passive range of motion but no joint crepitus. (*Id.*) It was noted that petitioner continued to take the naturopathic supplements, as well as Lipitor.[16] (*Id.*) Dr. Fisel's assessment was "adverse effect of other viral vaccines, sequela." (*Id.*) He prescribed thirty minutes of acupuncture, a magnesium supplement, and a liposomal glutathione supplement. (*Id.*)

Petitioner returned to Dr. Fisel on April 26, 2017. (Ex. 13, p. 2.) She reported that the jerking in her legs seemed to be worse right after acupuncture but then improved for a couple of days. (*Id.*) She was able to sleep through the night for a couple of nights and the joint pain and swelling decreased for about a week, which she stated was a "big improvement." (*Id.*) However, petitioner claimed that her symptoms worsened with increased activity. (*Id.*) Dr. Fisel provided the same diagnoses as the April 17, 2017 appointment and again prescribed thirty minutes of acupuncture. (*Id.*)

The following day, petitioner saw Dr. J. Hasbani and reported that she was still suffering from daily fasciculations and myoclonic jerks, though her physical and neurological examinations were normal. (Ex. 39, p. 11.) Petitioner showed Dr. J. Hasbani a video to demonstrate her symptoms. (*Id.*) Dr. J. Hasbani's assessment was "postvaccination movement disorder." (*Id.*) He further noted his "hope for resolution of her symptoms over time." (*Id.*)

Petitioner presented to Mark Russi, M.D., in the occupational health department at Yale New Haven Hospital on April 28, 2017. (Ex. 9, p. 40.) Petitioner informed Dr. Russi that she awoke on April 16, 2017, with "more intense intermittent leg jerking." (*Id.*

[16] Lipitor is the trademark name for atorvastatin calcium, which is an orally administered treatment for hypercholesterolemia and other forms of dyslipidemia. *Atorvastatin calcium*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=4739 (last visited Nov. 18, 2024); *Lipitor*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=28396 (last visited Nov. 18, 2024).

at 41.) She noticed that the pain and swelling in her hands, as well as the "internal buzzing" that she feels, were decreased after acupuncture. (*Id.*) The twitching was also associated with an "intermittent electric shock feeling in toes." (*Id.*) Petitioner's physical examination was normal. (*Id.* at 42.) Dr. Russi noted that acupuncture appeared to help with her symptoms. (*Id.* at 41.)

Petitioner saw Dr. Fisel three times in May of 2017. On May 2, 2017, petitioner complained of increased fatigue and achiness, but she noticed some relief with acupuncture. (Ex. 13, p. 3.) Dr. Fisel noted that the frequency and intensity of petitioner's myoclonic jerks seem to be correlated with activity. (*Id.*) His assessment was flu vaccine adverse reaction, and he again prescribed thirty minutes of acupuncture. (*Id.* at 5.) A week later, on May 9, 2017, petitioner reported that she was still dealing with myoclonic jerks in her lower extremities, which were worse at night. (*Id.* at 7.) In his review of symptoms, Dr. Fisel noted fatigue, intermittent myalgia, myoclonic jerks, and anxiety. (*Id.*) His assessment and plan remained the same. (*Id.* at 8.) On May 16, 2017, petitioner complained of twitching, an "electrical sensation" in her lower extremities, and right-sided neck lymph node swelling. (*Id.* at 9.) However, she reported that she was feeling more benefits from acupuncture. (*Id.*) In his review of symptoms, Dr. Fisel noted fatigue, recent murmurs or palpitations, intermittent myalgia throughout the body, myoclonic jerks, and anxiety. (*Id.*)

The following day, on May 17, 2017, petitioner saw Dr. Machado with complaints of worsened myoclonus, persistent fatigue, and intermittent fasciculations of all extremities, which were more prevalent when she was not taking her supplements. (Ex. 41, pp. 17-18.) Petitioner complained of sharp pain at the tips of her toes and the sensation of pins and needles at her left shoulder blade. (*Id.* at 18.) She reported that she was seeing a cardiologist regarding her feeling of chest heaviness when at rest. (*Id.*) Petitioner was recorded as taking Lipitor, as well as the following supplements on a daily basis: magnesium glycinate, Lyme D., BCQ, Detoxosode, Neuroantitox, Microbojen, Neuroantitox CNS, Vax Reaction, red clover leaf extract, and Viracon, Mono-Lauarin. (*Id.* at 18-19.) Though previously prescribed, petitioner opted against taking clonazepam. (*Id.* at 18.) Petitioner's physical examination was normal with no sign of fasciculations. (*Id.* at 20-21.) Dr. Machado noted that petitioner displayed a video demonstrating a "clear example of myoclonic jerks involving both legs." (*Id.* at 21.) His assessment was post-vaccination myoclonus and prescribed propranolol.[17] (*Id.*) He again noted his expectation that petitioner's condition would be benign and her prognosis would be good. (*Id.*)

On June 6, 2017, petitioner saw Dr. J. Hasbani for a neurological reevaluation. (Ex. 11, p. 6.) Petitioner complained of persistent fatigue and exhaustion, as well as myoclonic jerks before falling asleep. (*Id.*) Her neurological examination was normal,

[17] Propranolol is a medication that is a nonselective beta-adrenergic blocking agent that lacks intrinsic sympathomimetic activity, decreases cardiac rate and output, reduces blood pressure, and is effective in the prophylaxis of migraine. *Propranolol*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=41268 (last visited Nov. 18, 2024.)

and Dr. J. Hasbani's assessment was myoclonic jerks. (*Id.*) His plan was to continue monitoring petitioner. (*Id.*)

On June 27, 2017, petitioner wrote an email to Dr. Klass, in which she complained of bruising on her upper right arm and left forearm. (Ex. 22, p. 37.) She was concerned that the bruising could be the result of an iron deficiency or "from the Bartonella." (*Id.*) Dr. Klass responded that "Bartonella doesn't usually cause bruising" and that he would order blood tests to measure iron "and a few other vitamins." (*Id.*) Petitioner's test results were normal with a high level of ferritin and a slightly elevated mean platelet volume. (*Id.* at 38.) On July 31, 2017, petitioner sent another email to Dr. Klass, in which she complained that she was "missing a big chunk of muscle" in her calves. (*Id.* at 35.) She inquired into whether Dr. Klass believed that she should hold off on taking one of her supplements until she could talk to her neurologist. (*Id.*)

On August 2, 2017, petitioner saw Dr. Machado with complaints of "muscle wasting in her legs starting at the end of July." (Ex. 41, p. 22.) Her physical examination showed normal muscle bulk and tone and no signs of fasciculations but positive postural tremors. (*Id.* at 24-25.) Dr. Machado's assessment remained post-vaccination myoclonus; however, he ordered an electromyograph ("EMG") to determine whether petitioner was "truly experiencing muscle atrophy." (*Id.* at 25-26.) Petitioner's August 8, 2017 EMG was normal. (Ex. 11, pp. 1-4.)

On August 13, 2017, petitioner wrote another email to Dr. Klass, complaining that she was "[m]issing [a] chunk under [her] knee cap" and a "large portion of [her] calf." (Ex. 22, p. 34.) She wanted to ensure that the supplements that she was talking were not the cause of these issues. (*Id.* at 34.) Petitioner presented to neuromuscular and EMG consultant Kevin J. Felice, D.O., approximately two weeks later, on August 30, 2017. (Ex. 42, p. 1.) Intermittent myoclonus of the left arm and bilateral lower extremities were observed on physical examination. (*Id.*) It was noted that the myoclonic jerks occurred spontaneously and with certain stimuli, such as reflex testing and nerve stimulation. (*Id.*) However, petitioner's limb muscle, bulk, tone, and reflexes were normal. (*Id.*) Petitioner's EMG results were also noted to be normal. (*Id.* at 1-5.)

Petitioner underwent a muscle biopsy on her left thigh on September 11, 2017. (Ex. 14, p. 1.) The report noted that the sections studied were structurally unremarkable with no sign of significant inflammation; however, a subset of myofibers showed a mild increase of internalized nuclei, which is often a non-specific finding seen in a variety of conditions, including myotonic dystrophy if in the appropriate clinical context. (*Id.*) The report cautioned that increased internalized nuclei cannot be seen in isolation and close clinical correlation is necessary. (*Id.*) The final diagnosis was "skeletal muscle with mild non-specific changes." (*Id.*)

On September 25, 2017, petitioner sent an email to Dr. Klass. (Ex. 22, p. 33.) She informed Dr. Klass that Dr. Machado ordered genetic testing but did not believe that petitioner suffered from myotonic dystrophy. (*Id.*) She further informed Dr. Klass that she started taking prednisone and felt "a world of better." (*Id.*) She reported

substantially less muscle burning and an ability to sleep through the night. (*Id.*) Though she maintained her belief that her symptoms were the result of the flu vaccine, petitioner complained that she had "thrown [away] $4000 in supplements" while her symptoms were "getting worse." (*Id.*) She hoped that taking prednisone would "break the chain of [her] downward spiral." (*Id.*) Petitioner sent another email to Dr. Klass on September 26, 2017, complaining that she "lost another part of [her] facial muscle" during the night and that she had some sort of growth on her face. (*Id.* at 32.) She asked Dr. Klass to confirm that the prescribed supplements were safe to take with prednisone. (*Id.*)

On September 29, 2017, petitioner saw Dr. J. Hasbani. (Ex. 39, p. 19.) Dr. J. Hasbani noted that petitioner's EMG results were normal and her muscle biopsy showed non-specific changes in the muscles with no other findings. (*Id.*) As a result, a definitive muscle disease could not be identified. (*Id.*) A second opinion from Dr. Felice did not provide any further diagnosis. (*Id.*) Petitioner's neurological examination was normal. (*Id.*) Dr. J. Hasbani's assessment was muscle weakness, but he could not provide a specific diagnosis for why petitioner had developed muscle atrophy. (*Id.*)

Petitioner saw Dr. Machado on October 3, 2017. (Ex. 41, p. 26.) Petitioner complained of an increase in muscle atrophy and reported that she began taking a low dose of prednisone on September 23, 2017, which enabled her to stand and walk with less muscle pain. (*Id.* at 27.) She also reported continued, intermittent myoclonus of all limbs, which was "more prevalent after she ran out of her supplements," as well as persistent fatigue. (*Id.* at 26-27.) Petitioner's physical examination was normal with the exception of a reduction is muscle bulk with some atrophy in the leg muscles and right masseter and minimal postural tremors. (*Id.* at 29.) Dr. Machado's assessment remained post-vaccination myoclonus. (*Id.* at 30.) He noted petition's muscle biopsy revealed a subset of myofibers showing a mild increase of internalized nuclei. (*Id.*) "[I]n the appropriate clinical context, this change has been observed in cases of a chronic neuropathic or myopathic process where 10% to 30% of fibers may have internalized nuclei." (*Id.*) Because it was unclear if this chronic neuropathic or myopathic process was the result of petitioner's vaccination, Dr. Machado indicated his intent to obtain a second opinion from a neuromuscular specialist colleague. (*Id.*)

On October 5, 2017, petitioner saw David Minkoff, M.D.,[18] at Lifeworks Wellness Center in Clearwater, Florida. (Ex. 16, p. 1.) Dr. Minkoff recorded a history of chronic fatigue syndrome, chronic pain, Lyme disease, and sequela from flu vaccine reaction. (*Id.*) Petitioner's physical examination was normal with the exception of jerks and

[18] In his Rule 4 Report, respondent noted that Dr. Minkoff has been previously disciplined by the State of Florida Board of Medicine in 2001. (ECF No. 39.) Respondent attached to his report the Final Order suspending Dr. Minkoff's medical license for one year after he prescribed controlled substances to a patient without personal knowledge of her condition or medical history and submitted fraudulent prescriptions to obtain those medications for the patient in violation of Florida law. (ECF No. 39-1, pp. 2-3, 66-79.) Dr. Minkoff was also subject to a 2-year probation following his suspension and required to pay a fine of $10,000.00 to the Board. (*Id.* at 2-3.) Respondent also noted that Dr. Minkoff "advertises a number of scientifically discredited treatments" on the website for the Lifeworks Wellness Center that petitioner visited, "including ozone treatments and homeopathy." (ECF No. 39, p. 18 (citing https://www.lifeworkswellnesscenter.com/therapies.html).)

clonus. (*Id.* at 2.) Petitioner returned to Dr. Minkoff on November 14, 2017, and reported that she was feeling "pretty good" and experiencing less jerking. (*Id.* at 3.) A few days later, on November 20, 2017, Dr. Minkoff wrote a letter to petitioner's health insurance company. (*Id.* at 5.) He outlined petitioner's medical history, explicitly stating that petitioner was "treated for," rather than diagnosed with, Lyme disease in May 2013. (*Id.*) He claimed that, during the October 5, 2017 appointment, he noticed muscle atrophy in all of petitioner's limbs and the masseter muscles in her face. (*Id.*) Dr. Minkoff discussed petitioner's lab results before diagnosing her with "chronic fatigue, chronic pain and Lyme disease." (*Id.* at 5-6.) He stated that he had designed an "intensive treatment plan" involving nine IV treatments, three "ozone saunas," and three "allergy elimination treatments." (*Id.* at 6.) These treatments "and other treatments" were to be administered on a weekly basis for an undetermined period of time. (*Id.*) Dr. Minkoff reported that petitioner was "showing improvement" during the follow up appointment on November 14, 2017. (*Id.*) However, Dr. Minkoff opined that "curtailing the intensive level of treatment would further delay and exacerbate a critical situation." (*Id.*)

Petitioner returned to see Dr. Minkoff on December 13, 2017. (Ex. 16, p. 4.) It was noted that petitioner's weight was stable on a ketosis diet, that she was having less myoclonic jerking, and that the "fat atrophy" was "better." (*Id.*) Petitioner's physical examination was normal with the exception of jerks. (*Id.*) The diagnostic assessment was "post flu vaccine injury" and Lyme disease. (*Id.*) About a week later, on December 19, 2017, Dr. Minkoff wrote a letter stating that petitioner continued to suffer from chronic fatigue syndrome and Lyme disease, despite nearly completing her treatment plan, and that he had provided petitioner with a "home program of prescription medications, supplements and dietary changes." (Ex. 9, p. 58.) She was to follow-up with him in 2-3 months. (*Id.*)

Petitioner's next encounter was in June of 2018, when she presented to Dr. Klass with reports that the jerking had increased. (Ex. 22, p. 22.) She stated that she "felt very toxic." (*Id.*) While her fatigue was improving, petitioner complained of muscle pain in her left extremities and joint swelling. (*Id.*) She further complained of bloating/gas, constipation, increased stress, and insomnia. (*Id.*)

Petitioner saw Dr. Machado a week later, on June 13, 2018. (Ex. 35, p. 1.) Dr. Machado briefly described petitioner medical history. (*Id.*) He characterized Dr. Minkoff's conclusion as "muscle wasting . . . from a severe autoimmune reaction to the flu vaccine." (*Id.*) Dr. Machado noted that petitioner had undergone "183 treatments from 10/16/17 – 12/19/17, as well as ozone tx x 2, ultraviolet blood irradiation x 1, Myers cocktail x 3, glutathione x 3 (per week) and hyperthermic ozone and carbonic acid transdermal therapy saunas x 3," that she was still "being treated for chronic fatigue and Lyme/coinfections by Dr. Kloss [*sic*]" with monthly Rife treatments and supplements, and that she had "spent tens of thousands of dollars trying to recover from her vaccine injury." (*Id.* at 1-2.) He further noted that petitioner was following a ketogenic diet, "which appears to have stopped her muscle loss." (*Id.*) Petitioner claimed that her energy was improving but that she still needed to rest for one hour per day. (*Id.* at 2.)

She complained of intermittent myoclonus of all limbs and reported that her myoclonus would become more prevalent when she did not follow a ketogenic diet or when she was resting. (*Id.*) Petitioner further complained of occasional muscle pain primarily in her left arm and left leg. (*Id.*) Her physical examination was normal with the exception of minimal postural tremors, as well as the following notation: "Reflexes 3+ throughout with crossed reflexes, such that striking the right suprapatellar location causes bilat[eral] legs to move." (*Id.* at 4-5.) Dr. Machado opined that "[t]he timeframe and description of her condition thus far again points to this being a post-vaccination induced myoclonus and muscle atrophy." (*Id.* at 5.) He again indicated that petitioner's muscle biopsy showed a mild increase of internalized nuclei, a result that has been observed in cases of chronic neuropathic or myopathic processes. (*Id.*) In petitioner's case, Dr. Machado opined that the muscle biopsy results were "likely the result of an autoimmune reaction to her vaccination." (*Id.*) He ordered another set of laboratory tests to "track inflammatory markers." (*Id.*) Petitioner's subsequent bloodwork showed a borderline-high cholesterol level, a normal triglycerides level, and a slightly elevated LDL level. (Ex. 22, pp. 19-20.) Dr. Machado also wrote a letter, dated July 5, 2018, in which he responded to a letter, dated June 22, 2018, that does not appear in the record. (Ex. 36.) He stated: "It is in my medical opinion that Ms. Acton's current diagnosis of myoclonus is a result of the flu vaccine she received on November 30, 2016. It is also in my medical opinion that the muscle atrophy is a result of the same vaccine." (*Id.*)

Petitioner continued to see Dr. Klass throughout the rest of 2018 and until August of 2019. On August 8, 2018, petitioner reported that she was experiencing bicycle-like jerking of her legs and "intermittent ridges" on her arms, but her fatigue was improving. (Ex. 22, p. 21.) On September 12, 2018, petitioner complained of bicycle-like jerking of her lower limbs, as well as anxiety, bloating/gas, fatigue, increased stress, insomnia, occasional muscle pain, and numbness/tingling in her left hand. (*Id.* at 18.)

On November 13, 2018, petitioner wrote an email to Dr. Klass, in which she attached test results for celiac disease genotyping. (Ex. 22, pp. 14-16.) Petitioner tested negative for Celiac (HLA-DQB1*05) and positive for Celiac (HLA-DQB1*02). (*Id.* at 15.) It was noted that the presence of the HLA-DQB*2 allele, without the HLA-DQB*05 allele, is rarely observed in individuals with celiac disease.[19] (*Id.*) Petitioner stated that Dr. Machado informed her that she had the celiac "gene" and, "in the right environment (vaccine injury)," celiac disease "will manifest." (*Id.* at 14.) Petitioner stated that she believed that she had a "gluten sensitivity related to lyme" and avoided gluten for a few years. (*Id.*) She was eventually able to eat gluten "without symptoms" but stopped eating gluten when she started to notice "muscle disintegration." (*Id.*) She asked for Dr. Klass's opinion on whether she has celiac disease. (*Id.*)

On November 28, 2018, petitioner reported less bicycle-like jerking of her legs; however, she complained of anxiety, bloating/gas, depression, fatigue, increased stress,

[19] Celiac disease is an autoimmune malabsorption syndrome precipitated by ingestion of gluten-containing foods and characterized by gastrointestinal issues; vitamin B, D, and K deficiencies; and electrolyte depletion. *Celiac disease*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=70171 (last visited Oct. 3, 2024).

insomnia, joint swelling, muscle pain, numbness/tingling in her left arm and both hands, and rashes. (Ex. 22, p. 13.) A few weeks later, on December 17, 2018, petitioner again reported a slight decrease in the bicycle-like jerking of her legs. (*Id.* at 17.) However, she was experiencing increased numbness in her left arm, as well as a "new neuropathy" in her right middle finger. (*Id.*) Dr. Klass wrote a letter, dated January 25, 2019, in which he stated that petitioner's blood test results had "in the past been positive for Babesia and Epstein Barr Virus." (*Id.* at 10.) He stated that he was still treating petitioner for Babesia, chronic fatigue syndrome, and fibromyalgia. (*Id.*)

On August 1, 2019, petitioner reported that she was still feeling fatigued but experienced relief when her diet contained a certain amount of vegetables per day. (Ex. 22, p. 5.) She further reported anxiety, bloating/gas, constipation, increased stress, and weight loss. (*Id.*) In a letter, dated August 9, 2019, Dr. Klass stated that he saw petitioner on August 1, 2019, and noted that her symptoms were fatigue, anxiety, and occasional muscle spasms. (*Id.* at 4.) Though she was improving, Dr. Klass reported that petitioner was still suffering from these symptoms, which he conclusively stated were "related to her vaccination reaction." (*Id.*) Dr. Klass indicated his intent to "continue to treat her nervous system." (*Id.*)

There are no medical records for the next several years. Petitioner had a dental appointment on May 5, 2022, in which it is noted that petitioner's legs were jerking during the appointment. (Ex. 91.)

b. Testimony

Petitioner filed an affidavit and provided testimony at the entitlement hearing. (Ex. 20; Tr. 6.) In her affidavit, petitioner avers that, prior to vaccination, she was "in good health and suffered from no medical conditions, other than Lyme disease." (Ex. 20, ¶¶ 2, 4-5.) She was able to work as a health care worker at Yale New Haven Hospital and care for her family "without any problems, medical issues or disabilities." (*Id.* ¶¶ 4-5, 7.) Prior to vaccination, petitioner was receiving treatment for presumed co-infections of Lyme and Babesia with naturopath Dr. Klass. (*Id.* ¶ 5.) She never missed a day of work due to her Lyme disease. (*Id.* ¶¶ 6, 30.) Petitioner states that, by the fall of 2016, her condition had improved. (*Id.* ¶ 5.) However, due to her compromised immune system as a result of her Lyme disease, Dr. Klass authored a letter excusing her from an employer-mandated flu vaccination. (*Id.* ¶ 7.) Her medical exemption request was ultimately denied. (*Id.* ¶ 8.)

Petitioner avers that she received the subject flu vaccine at 1:00 p.m. on November 30, 2016. (Ex. 20, ¶ 9.) By 4:30 p.m. on that same day, she began experiencing joint pain and swelling throughout her body, and by 8:00 p.m., she had an intense, right-sided headache that was unlike anything she had ever experienced before. (*Id.* ¶ 10.) Her symptoms continued through the next day and were "getting worse." (*Id.* ¶ 11.) By 9:45 a.m. on December 1, 2016, petitioner states that she was "in extreme pain and experiencing extreme fatigue," requiring that she leave work early. (*Id.* ¶ 12.) By 2:30 p.m. on that same day, petitioner's muscles began twitching and she

contacted her primary care physician. (*Id.*) On the following day, December 2, 2016, petitioner presented to her primary care physician for joint issues and muscle twitching. (*Id.* ¶ 13.) By 9:00 a.m. on December 3, 2016, petitioner's headache was "incapacitating." (*Id.* ¶ 14.) She began experiencing "Parkinson's like hand tremors" at 11:20 a.m. and presented to urgent care at 12:20 p.m., where "the medical staff witnessed my severe flailing of all limbs." (*Id.*) Petitioner was subsequently transferred to the emergency department; however, she was discharged home at around 4:30 p.m. that same day after her bloodwork returned normal. (*Id.* ¶ 15.)

Petitioner states that she was subsequently diagnosed with post-vaccination inflammation of the peripheral nervous system and three movement disorders: fasciculations, tremors, and myoclonus. (Ex. 20, ¶¶ 2, 16.) Due to her symptoms, petitioner was completely unable to work for nearly two months, before returning on a part-time basis. (*Id.* ¶ 17.) By July 31, 2017, petitioner states that she was back to working full-time; however, "the disintegration of the muscle in my legs made it difficult for me to stand. I had to stand with my legs three feet apart in order to keep my balance and avoid falling." (*Id.* ¶ 18.) In October of 2017, petitioner was diagnosed by Dr. Minkoff with "severe autoimmunity reaction from the flu shot," which caused muscle loss in her arms, legs, and face. (*Id.* ¶ 21.) She describes receiving a PICC line insertion and "183 treatments (IV ozone, HOCATT sauna, etc.)" by Dr. Minkoff from October 16, 2017, to December 19, 2017. (*Id.* ¶ 22.) She avers that "Dr. Minkoff was able to stop the autoimmunity reactions, and prevented further muscle loss with the above described treatments he prescribed, and a six month ketogenic diet." (*Id.*) Although she reports that the muscle disintegration has stopped, she claims that she has not regained the muscle that was lost "from the severe autoimmune reaction to the flu shot leading to disability." (*Id.*) Petitioner was also unable to work during her treatment with Dr. Minkoff. (*Id.* ¶¶ 22-23.) However, she returned to work full-time on April 20, 2018. (*Id.* ¶ 25.)

Petitioner avers that she continues to experience "chronic fatigue, joint pain, muscle loss and daily severe myoclonic jerking of my limbs and neck." (Ex. 20, ¶ 26.) She reports the need to take frequent breaks to rest and to sit during certain activities of daily living as her "endurance for standing is decreased." (*Id.* ¶ 27.) Her myoclonus continues on a daily basis "when resting and when trying to fall asleep." (*Id.* ¶ 28.) These movements are violent and disrupt her sleep. (*Id.*) She describes, "My legs move like I am pedaling a bicycle or in unison, like a hopping motion. My head bangs on the pillow." (*Id.*) She further avers that she was receiving Lyme treatments once every four months prior to receiving the subject vaccine, but the frequency of her treatments has been increased to once-a-month post-vaccination. (*Id.* ¶ 24.)

During the hearing, petitioner attested to the accuracy of her previously submitted affidavit. (Tr. 33.) The testimony that she provided at the hearing was substantially the same as the allegations contained within her affidavit. She added that, on top of the joint pain and swelling, petitioner noticed difficulty tying her son's taekwondo belt at around 6:00 p.m. on November 30, 2016. (*Id.* at 9.) She further described the myoclonic jerking that led her to visit urgent care. (*Id.* at 15.) She stated,

"When they took me to the treatment room, two people were holding my shoulders while my legs were kicking over my head. . . . I was sitting down at the time, but they were actually holding me down because my legs were flailing uncontrollably." (*Id.*) She also described muscle wasting in her masseter, jaw, arms, biceps, left calf, and legs, beginning in July of 2017. (*Id.* at 18-19.) On top of the balance difficulties, petitioner also reported only being able to walk for short periods of time. (*Id.* at 19.) She testified, "I had been to 12 doctors over 10 months and no one was really helping me to stop the jerking, and I was very concerned about the muscle disintegration." (*Id.* at 21.)

By January of 2017, when petitioner returned to work part-time, the myoclonus was persistent in her arms and legs but somewhat improved. (Ex. 34, p. 101.) However, she reported that her symptoms worsened after returning to work. (*Id.* at 102.) She stated that the myoclonus would wake her up and keep her awake for one-to-three hours in the middle of the night. (*Id.*) She acknowledged that the myoclonic jerks were reduced in duration and severity but not frequency. (*Id.* at 103-04.) Regarding the fatigue, petitioner stated, "I was tired but able to work the limited schedule." (*Id.* at 103.) She also described muscle atrophy in her legs, arms, and face. (*Id.* at 105-12.) She explained that a muscle biopsy uncovered increased internalized nuclei, which suggested two potential explanations for the muscle atrophy: an environmental toxin or a continuation of a current process. (*Id.* at 112.)

IV. Expert Reports

a. Petitioner's Expert, James R. Neuenschwander, M.D.[20]

Dr. Neuenschwander authored three reports on behalf of petitioner in his case. (Exs. 53, 69, 71.) He also testified on petitioner's behalf during the entitlement hearing. (Tr. 38.) Dr. Neuenschwander described petitioner's claimed injury as "a classic vaccine injury resulting from overstimulation of her immune system." (Ex. 53, p. 2.) He stated that the immediate onset of symptoms suggests "exacerbation of a pre-existing condition along with brain inflammation." (*Id.*)

Dr. Neuenschwander began his analysis with a discussion of "immunotolerance" and "immune reactivity." (Ex. 53, p. 2.) He explained that the concept of immunotolerance refers to the immune system's ability to tolerate non-threatening antigens, or agents that might induce an immune response, and the immune system's ability to react to threatening antigens. (*Id.*) Dr. Neuenschwander described three

[20] Dr. Neuenschwander received his medical degree from the University of Michigan Medical School in 1985, before going on to a residency in general surgery. (Ex. 70, p. 1; Tr. 40.) Dr. Neuenschwander "left [the residency] voluntarily to pursue integrative medicine practice." (Ex. 70, p. 1; Tr. 40.) He is board certified in both emergency medicine and integrative medicine. (Ex. 70, p. 3; Tr. 40.) He is the founder and owner of an integrative medicine practice and has over thirty years of experience in dealing with chronically ill patients, particularly those whose illness is associated with a vaccine injury. (Ex. 70, p. 1; Ex. 53, p. 1; Tr. 38.) His office sees roughly 8,000 patients, 20-30% of which are vaccine injured. (Tr. 38, 43-44.) Dr. Neuenschwander was proffered as an expert in emergency and integrative medicine without objection. (*Id.* at 43, 46-47.)

types of "loss of immunotolerance": loss of immunotolerance to environmental agents, loss of immunotolerance to self, and loss of immunotolerance to potentially infectious agents. (*Id.* at 3.) He claimed that petitioner suffered from loss of immunotolerance to potentially infectious agents, which occurs when "a person develops a reaction to organisms that may have once been infectious but have become part of their ecosystem." (*Id.*)

Initially, Dr. Neuenschwander stated that petitioner's "history of 'chronic Lyme disease'" is an example of this sort of loss of immunotolerance, explaining that patients who suffer from chronic Lyme "have a loss of immunotolerance to the Lyme spirochete (from a prior exposure) as a cause of their symptoms" and how "[t]his is manifested by persistent immune activation and loss of their natural killer cells." (Ex. 53, p. 3.) With regard to petitioner, Dr. Neuenschwander conceded that he did "not have all of the lab values" and that he understood petitioner's Lyme diagnosis to be based on her clinical presentation alone. (*Id.*; Tr. 57.) He indicated that he was primarily relying on Dr. Minkoff's notation of "decreased CD57 (which are activated natural killer cells)." (Ex. 53, p. 3.) Based on this, Dr. Neuenschwander initially argued that, given petitioner's "history of chronic Lyme, she was already exhibiting immune system issues with a loss of immunotolerance and was at risk of having an adverse immune response to vaccination." (*Id.*)

However, in his supplemental expert reports and during the hearing, Dr. Neuenschwander abandoned his reliance on petitioner's supposed history of Lyme disease in favor of petitioner's purported history of chronic fatigue syndrome to support his position that her immune system was "primed" for overreaction to vaccination. (Ex. 69; Tr. 106.) Dr. Neuenschwander also later amended his discussion of petitioner's alleged loss of immunotolerance to potentially infectious agents. (Ex. 69, p. 3.) He stated that petitioner's medical history suggested loss of immunotolerance "to some type of pathogen." (*Id.*) To support this claim, Dr. Neuenschwander pointed to Dr. Klass's mention of "prior positive testing for Babesia and Epstein-Barr virus in his letter dated January 25, 2019," and how petitioner was "still under treatment for Babesia, Chronic Fatigue Syndrome, and fibromyalgia." (*Id.*) However, Dr. Neuenschwander stated that whether petitioner "has (or had) Babesia is irrelevant to her current condition." (*Id.*) He opined that "it is not the organism that matters in these cases, it is the immune response." (*Id.*)

Dr. Neuenschwander opined that petitioner has a history of chronic fatigue syndrome; however, he does not utilize published diagnostic criteria for chronic fatigue syndrome. (Tr. 53, 55.) He assesses chronic fatigue syndrome when there is: (1) persistent fatigue (2) lasting for longer than three-to-six months (3) without another cause. (*Id.* at 55.) He stated that chronic fatigue syndrome is a subset of immune activation syndrome.[21] (Ex. 71, p. 2.) He explained that "chronic fatigue syndrome"

[21] In the same vein, Dr. Neuenschwander suggested that chronic immune activation could explain the chronic Lyme disease "[i]f that was indeed the case in this situation." (Tr. 57.) In fact, he explained that "immune activation could have been eczema or it could have been a chronic fatigue syndrome or it could

refers to a constellation of symptoms, while "chronic immune activation" refers to the cause of the symptoms. (Tr. 56.) The symptoms indicate which system is being targeted by the immune activation. (*Id.* at 60-61.) Dr. Neuenschwander cited five articles to support his position that immune activation and chronic inflammation is "at the heart of" chronic fatigue syndrome. (Ex. 71, p. 2. (citing Adriano José Maia Chaves-Filho et al., *Shared Microglial Mechanisms Underpinning Depression and Chronic Fatigue Syndrome and Their Comorbidities*, 372 BEHAVIORAL BRAIN RES. 111975 (2019) (Ex. 72); Gerwyn Morris et al., *The Neuro-Immune Pathophysiology of Central and Peripheral Fatigue in Systemic Immune-Inflammatory and Neuro-Immune Disease*, 53 MOLECULAR NEUROBIOLOGY1195 (2016) (Ex. 73); Roald Omdal, *The Biological Basis of Chronic Fatigue: Neuroinflammation and Innate Immunity*, 33 CURRENT OP. NEUROLOGY 391 (2020) (Ex. 74); Geir Bjørklund et al., *Environmental, Neuro-Immune, and Neuro-Oxidative Stress Interactions in Chronic Fatigue Syndrome*, 57 MOLECULAR NEUROBIOLOGY 4598 (2020) (Ex. 75); Gerwyn Morris & Michael Maes, *Mitochondrial Dysfunctions in Myalgic Encephalomyelitis / Chronic Fatigue Syndrome Explained by Activated Immune-Inflammatory, Oxidative and Nitrosative Stress Pathways*, 29 METABOLIC BRAIN DISEASE 19 (2014) (Ex. 76)).) Dr. Neuenschwander opined that petitioner suffered from an immune activation syndrome, which is characterized by chronic elevation of inflammatory cytokines and persistent alteration of the normal systems designed to respond to injury or infection, resulting in persistent microglia activation in the brain. (Ex. 69, p. 3; Ex. 71, p. 2.)

Dr. Neuenschwander further opined that vaccines necessarily stimulate an immune response through activation of T and B lymphocytes. (Ex. 71, p. 3; Tr. 48, 58.) He continued that a review of "all vaccine trials" reveals a subset of individuals that "under-responds" to vaccination and that "physiological common sense" dictates that there must be a corresponding group that "over-respond[s]" to vaccinations. (Ex. 53, p. 3 (citing Li-Yu Wang et al., *Response to Hepatitis B Vaccination Is Co-Determined by* HLA-DPA1 *and* -DPB1, 37 VACCINE 6435 (2019) (Ex. 54); Nao Nishida et al., *Key* HLA-DRB1-DQB1 *Haplotypes and Role of the* BTNL2 *Gene for Response to a Hepatitis B Vaccine*, 68 HEPATOLOGY 848 (2018) (Ex. 55); Shady Z. K. Estfanous et al., *Inflammasome Genes' Polymorphisms in Egyptian Chronic Hepatitis C Patients: Influence on Vulnerability to Infection and Response to Treatment*, MEDIATORS INFLAMMATION, Jan. 9, 2019, at 1 (Ex. 56); Jussi Leppilahti et al., *Associations Between Glutathione-S-Transferase Genotypes and Bronchial Hyperreactivity Patients with Di-isocyanate Induced Asthma. A Follow-Up Study*, FRONTIERS MED., Oct. 9, 2019, at 1 (Ex. 57); S. Wilson et al., *Role of the NLRP3 Inflammasome in Vaccine Responses*, J. ALLERGY & CLINICAL IMMUNOLOGY, Feb. 2012, at AB162 (Ex. 58)).) Although Dr. Neuenschwander acknowledged that petitioner was never evaluated for any genetic "risk factors" for abnormal immune response, he claimed that petitioner likely "has some of these risk factors based on her clinical history." (*Id.*) He cited studies observing "chronic fatigue type symptoms" following flu vaccination and finding that patients with chronic fatigue syndrome experienced altered immune responses to vaccination, as well as greater complaints without any obvious cause and despite lower antibody response.

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have been a chronic Lyme or a chronic Epstein-Barr kind of syndrome. All of these are immune activation syndromes, and they would predispose somebody to have an injury." (*Id.* at 60.)

(Ex. 71, p. 3 (citing Ashkan Shoamanesh et al., *Postvaccination Miller Fisher Syndrome*, 68 ARCHIVES NEUROLOGY 1327 (2011) (Ex. 60); Makoto Hara et al., *Miller Fisher Syndrome Associated with Influenza A Infection*, 51 INTERNAL MED. 2621 (2012) (Ex. 61); Heidrun H. Krämer et al., *Postvaccination Miller Fisher Syndrome After Combined Pertussis, Diphtheria and Tetanus Toxoid Vaccine*, 66 J. INFECTION 460 (2013) (Ex. 62)); Tr. 101-03 (discussing Alexandra H. Mandarano et al., *Myalgic Encephalomyelitis / Chronic Fatigue Syndrome Patients Exhibit Altered T Cell Metabolism and Cytokine Associations*, 130 J. CLINICAL INVESTIGATION 1491 (2020) (Ex. 78); Kenna M. Sleigh et al., *Double-Blind, Randomized Study of the Effects of Influenza Vaccination on the Specific Antibody Response and Clinical Course of Patients with Chronic Fatigue Syndrome*, 11 CANADIAN J. INFECTIOUS DISEASES 267 (2000) (Ex. 79)).) Dr. Neuenschwander explained that "the whole point of these papers was the immune system in somebody who has a history of chronic fatigue syndrome is different than somebody who doesn't have that history. And [petitioner] had that history." (Tr. 102.) He cited a study that observed an elevation in inflammatory cytokines – namely, an elevation in Interleukin-6, an inflammatory cytokine that is frequently elevated in patients with chronic fatigue syndrome – following flu vaccination. (Ex. 71, p. 3 (citing David A. G. Skibinski et al., *Induction of Human T-Cell and Cytokine Responses Following Vaccination with a Novel Influenza Vaccine*, SCI. REPS., Dec. 20, 2018, at 1 (Ex. 77)).) Given petitioner's "history of chronic immune activation (from prior Babesia, Epstein-Barr, or any number of other possible pathogens for which she was not tested)," Dr. Neuenschwander opined that petitioner "was already exhibiting immune system issues with a loss of immunotolerance and was at risk of having an adverse immune response to vaccination." (Ex. 69, p. 3.) He again pointed to Dr. Minkoff's note of "decreased CD57 (activated natural killer cells)" as indicative of the "alteration of the normal immune response" that "typically occurs when the immune system has been activated long enough to 'burn out' killer cell numbers." (*Id.*) As such, petitioner "was a prime target for an immune over-activation type response" to the flu vaccine. (Ex. 53, p. 3; Ex. 71, p. 3.)

Dr. Neuenschwander also described cell danger response ("CDR"), which was developed by Dr. Robert Naviaux to explain chronic disease and immune activation. (Ex. 53, p. 4 (citing Robert K. Naviaux, *Oxidative Shielding or Oxidative Stress?*, 342 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 608 (2012) (Ex. 64); Robert K. Naviaux, *Metabolic Features and Regulation of the Healing Cycle—A New Model for Chronic Disease Pathogenesis and Treatment*, 46 MITOCHONDRION 278 (2019) (Ex. 65); Robert K. Naviaux, Perspective: *Cell Danger Response Biology—The New Science that Connects Environmental Health with Mitochondria and the Rising Tide of Chronic Illness*, 51 MITOCHONDRION 40 (2020) (Ex. 66); Robert K. Naviaux et al., *Metabolic Features of Chronic Fatigue Syndrome*, PNAS, Aug. 29, 2016, at E5472 (Ex. 67)).) Under this process, the mitochondria inside a cell responds to external danger signals, such as Adenosine triphosphate ("ATP"), "by diverting energy production into the creation of a highly oxidative, hostile environment to prevent infection by a pathogen" and in an attempt to protect the cell. (Ex. 53, p. 4; Tr. 99-100.) He specifically identified chronic fatigue syndrome as resulting from "alterations in mitochondrial metabolism along with damage to membrane lipids" and "as being caused by chronic activation of

the CDR." (Ex. 53, p. 4 (citing Naviaux et al., *supra*, at Ex. 67); Tr. 99-100.) He stated that there is a "direct correlation" between the severity of the chronic fatigue and the mitochondrial dysfunction. (Tr. 100.) He also explained that the treatments administered to petitioner by Dr. Minkoff "were designed to alter mitochondrial function and the CDR," which explained why petitioner experienced improvement with Dr. Klass's treatments, and particularly with the IV ozone treatment. (Ex. 53, p. 4 (citing Catia Scassellati et al., *Molecular Mechanisms in Cognitive Frailty: Potential Therapeutic Targets for Oxygen-Ozone Treatment*, 186 MECHANISMS AGEING & DEV. 111210 (2020) (Ex. 68)); Tr. 50.) Dr. Neuenschwander opined that, as a result of the flu vaccine, petitioner's "chronic CDR activation was rekindled by re-exacerbating her chronic immune activation." (Ex. 53, p. 4.)

In sum, Dr. Neuenschwander opined that petitioner suffered from immune activation manifesting as chronic fatigue, which had resolved with treatment prior to vaccination but predisposed her to overreaction of the immune system. (Tr. 69.) Following receipt of the flu vaccine, petitioner's underlying immune activation "exploded." (*Id.*) Although petitioner continued to suffer from fatigue and cognitive issues post-vaccination, Dr. Neuenschwander opined that "the vaccine itself created a new condition," namely, post-vaccination myoclonus, which has persisted. (*Id.*)

Dr. Neuenschwander clarified that petitioner's movement disorder was distinct from her history of chronic fatigue. (Tr. 66.) Myoclonus is the random contractions of muscles, while opsoclonus is limited to random contractions of the muscles of the eyes. (Ex. 53, p. 3; Tr. 73.) Dr. Neuenschwander explained that myoclonus may affect any muscle, though "classically," it primarily affects the legs. (Tr. 116.) He explained that myoclonus-opsoclonus is usually part of a genetic syndrome or a manifestation of a paraneoplastic syndrome,[22] although he acknowledges that petitioner did not suffer from either condition. (Ex. 53, p. 3 (citing James P. Klaas et al., *Adult-Onset Opsoclonus-Myoclonus Syndrome*, 69 ARCHIVES NEUROLOGY 1598 (2012) (Ex. 59; Ex. A, Tab 6)).) He opined that petitioner's movement disorder was also caused by immune activation. (Tr. 66.) He explained that adult-onset myoclonus can be caused by toxin exposure and, in this case, the toxin was the flu vaccine. (Ex. 69, p. 4 (citing James P. Klaas et al., *Adult-Onset Opsoclonus-Myoclonus Syndrome*, 69 ARCHIVES NEUROLOGY 1598 (2012) (Ex. 59; Ex. A, Tab 6)).) He explained that "weird movements" are frequently observed in vaccine-injured patients and that flu infection is known to cause myoclonic jerking. (Tr. 49-50, 59, 108.) However, vaccine-caused movement disorders "are a little different" when compared to movement disorders seen in other syndromes. (*Id.* at 49-50, 74.) During the hearing, Dr. Neuenschwander reviewed three videos submitted by petitioner. (*Id.* at 114-16 (discussing Ex. 21).) While one of the videos showed "more of a classic myoclonic twitch" (*Id.* at 114), Dr. Neuenschwander suggested that petitioner's atypical presentation is to be expected in post-vaccination movement disorders, which "are just weird. They are not the traditional pattern that you see." (*Id.* at 74-75.) He

[22] A paraneoplastic syndrome is "a symptom complex arising in a cancer-bearing patient that cannot be explained by local or distant spread of the tumor." *Paraneoplastic syndrome*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=111154 (last visited Sept. 30, 2024).

explained, "I have seen all of those [symptoms] with other patients with vaccine injuries. This is not unique to [petitioner]." (*Id.* at 75.)

Dr. Neuenschwander explained that myoclonus and opsoclonus are also symptoms of a variant of Guillain-Barré syndrome ("GBS") known as Miller Fisher syndrome. (Ex. 53, p. 3.) Miller Fisher syndrome is known to occur "after both infection from and vaccination to many illnesses including influenza," and has been linked with the production of autoimmune antibodies to a number of targets, as well as acetylcholine receptors. (*Id.* (citing Shoamanesh et al., *supra*, at Ex. 60; Hara et al., *supra*, at Ex. 61; Krämer et al., *supra*, at Ex. 62); Ex. 69, p. 4 (citing Shoamanesh et al., *supra*, at Ex. 60; Jonathan R. Galli et al., *Adult-onset Opsoclonus-Myoclonus Syndrome Associated with Ganglionic Acetylcholine Receptor Autoantibody*, 21 NEUROLOGIST 99 (2016) (Ex. 63)).) Dr. Neuenschwander clarified that it is not his opinion that petitioner suffers from GBS or Miller Fisher syndrome as she does not meet the requisite diagnostic criteria. (Ex. 53, p. 3; Ex. 71, p. 4; Tr. 80.) However, he opined that petitioner likely suffered from a movement disorder that "is consistent with a neurological injury from her flu vaccine" and "similar to that seen with Miller Fisher." (Ex. 53, p. 4; Tr. 79-80.) He specifically noted that the opsoclonus that petitioner experienced can be seen in Miller Fisher syndrome. (Tr. 75-76.) He also noted that petitioner's muscle biopsy demonstrated an increase of internalized nuclei, which would be consistent with the myoclonic dystrophy that can be seen with Miller Fisher syndrome. (Ex. 53, p. 3-4.) He concluded, "At the end of the day and regardless of whose name you would like to apply to her symptoms, [petitioner] suffered a neurologic (likely brain) injury as a result of her Fluarix vaccine leaving her with myoclonic jerks and a mild myopathy creating chronic weakness." (*Id.* at 4.)

Although Dr. Neuenschwander acknowledged that he is not a neurologist, he opined that petitioner's post-vaccination symptoms, including myoclonus, tremors, and headache, were likely the result of inflammation of the central region of the brain, and more specifically in the basal ganglia, which can result in "all kinds of weird movement disorders." (Tr. 49, 67-68, 70, 73-74, 178-80.) He explained that inflammation of the basal ganglia has been linked to emotional responses, such as panic attacks, and that petitioner appeared to be having a panic attack during her initial emergency room visit that likely resulted from inflammation in the basal ganglia. (*Id.* at 70-71,125.) However, he later equivocated, opining that petitioner's initial response to vaccination was an inflammation-induced activation of the basal ganglia "or something like that." (*Id.* at 125.) He explained that there is objective testing, including MRI and bloodwork, that is used to determine whether there is inflammation in the brain. (*Id.* at 68-69.) He conceded that "nobody did a spinal tap. Nobody did any kind of scans . . . ." (*Id.* at 178.) He also indicated that involvement of the basal ganglia is "discounted" due to petitioner's normal EEG and EMG testing. (*Id.* at 74.)

Dr. Neuenschwander opined that petitioner's initial reaction to the vaccine was "an inflammatory response that subsequently developed into an autoimmune injury." (Tr. 77.) He later stated that the initial response "may have been" autoimmune in nature if petitioner had preexisting autoimmunity. (*Id.* at 78-79.) Dr. Neuenschwander's

opinion regarding the presence and relevance of autoimmune antibodies oscillated throughout his testimony during the hearing. At first, he testified that "Miller Fisher is demyelination. I'm not saying that [petitioner] had demyelination. I don't know." (*Id.* at 76.) He denied that he was relying on the pathophysiology of GBS or Miller Fisher syndrome, stating "I added that paper just to give an example of how a vaccine can cause these symptoms, but I'm not saying that's the mechanism in this case. I don't think that she had developed demyelinating antibodies to cause those symptoms." (*Id.* at 80.) He clarified that "what I'm saying is the inflammation created those symptoms because it affected the same thing that Miller Fisher would have affected." (*Id.* at 97.) He later stated that petitioner "probably had autoimmune antibodies at some point because most vaccine-injured patients that have neurologic symptoms do, but nobody checked it on her, so I don't know if that's true or not." (*Id.* at 105.) Then, he further equivocated, stating that whether the brain inflammation "was from preexisting antibodies or whether that was strictly a cytokine response, I don't know." (*Id.* at 178.)

Dr. Neuenschwander summarized his opinion of petitioner's clinical presentation as follows:

> The vaccine appeared to almost immediately reactivate her chronic CDR and resulted in the initial symptoms of fatigue (CDR induced lack of energy production), joint pain (immune activation targeted inflammation), and headache (brain inflammation and ultimately autoimmune targeted brain injury). The myoclonus and opsoclonus symptoms are consistent with an autoimmune driven brain injury similar to that seen in Miller-Fisher syndrome. Although the eye movements appear to have improved, the myoclonus persists. The persistent weakness is a result of a mild myopathy induced by the myoclonus syndrome. The chronic immune activation induced by the vaccine has resulted in a persistent cell danger response, which has robbed [petitioner] of the ATP needed to make adequate energy and left her chronically fatigued.

(Ex. 53, pp. 4-5.) He criticized Dr. Werdiger for dismissing petitioner's symptoms. (Ex. 71, p. 3.) He indicated that the persistence of petitioner's symptoms over the span of several years suggests that her condition "is some type of neurologic injury." (Tr. 107.) Ultimately, Dr. Neuenschwander testified that "whether this injury at this point is reversible, I don't know, because I don't really know exactly what kind of injury we are dealing with." (*Id.* at 79.)

Dr. Neuenschwander admitted that it is not typical for onset of a neurologic injury to occur within 48 hours. (Tr. 51, 103.) He suggested that the time frame for developing an allergic reaction to a vaccine typically takes around 10 days. (Ex. 71, p. 4; Tr. 51-52.) However, he explained that, "once the immune system is primed for that allergen, the next reaction can occur within minutes." (Ex. 71, p. 4; Tr. 51-52, 117-18.) Although it wasn't her first flu vaccination, Dr. Neuenschwander suggests that it was first flu vaccinations she received "since she was sick." (Tr. 118.) Dr. Neuenschwander suggested that the rapid immune response to vaccination "proved" that petitioner was

primed for overreaction. (*Id.* at 106.) He pointed to VAERS reports to support the biological plausibility of this time frame, noting that he uncovered 64 VAERS reports of myoclonus following flu vaccination, 21 reporting a 5-day onset and 12 reporting 1-day onset. (*Id.* at 51.) He further noted that a review of VAERS reports from 2019 revealed 506 cases of tremors within 24 hours of vaccination. (Ex. 71, p. 4.) Dr. Neuenschwander criticized Dr. Werdiger's reliance on Rowhani-Rahbar et al. study as it deals with the timing of febrile seizures and acute disseminated encephalomyelitis, neither of which petitioner suffers. (Tr. 103-06 (citing Ali Rowhani-Rahbar et al., *Biologically Plausible and Evidence-Based Risk Intervals in Immunization Safety Research*, 31 VACCINE 271 (2012) (Ex. 82; Ex. A, Tab 19)).) Although, Dr. Neuenschwander suggested that 48-hour time frame for onset of febrile seizures was at least somewhat relevant because febrile seizures result from inflammation, which aligns with his theory of causation. (*Id.* at 104-05.)

b. Respondent's Expert, Neurologist Norman S. Werdiger, M.D.[23]

Dr. Werdiger authored two reports on behalf of respondent in this case. (Exs. A, C.) He also provided expert testimony at the hearing. (Tr. 127.) Dr. Werdiger opined, to a reasonable degree of medical certainty, that petitioner's neurological complaints were not related to her flu vaccination. (Ex. A, p. 12; Tr. 138.) Dr. Werdiger addressed the petitioner's clinical presentation, noting that petitioner primarily complained of four symptoms: fasciculations, "Parkinsonian hand tremors," myoclonus, and muscle atrophy. (Ex. A, p. 9.)

Dr. Werdiger explained that fasciculations are spontaneous and intermittent contractions of muscle fibers, can have various causes, and are commonly observed in healthy individuals. (Ex. A, p. 9 (citing Marco Antonio Araujo Leite et al., *Another Perspective on Fasciculations: When Is It Not Caused by the Classic Form of Amyotrophic Lateral Sclerosis or Progressive Spinal Atrophy?*, 6 NEUROLOGY INT'L 5208 (2014) (Ex. A, Tab 12), *Muscle Cramps and Fasciculations*, 3 CONTINUUM LIFELONG LEARNING NEUROLOGY 116 (1997) (Ex. A, Tab 13)); Tr. 138-39.) An EMG is often helpful in objectively documenting fasciculations. (Ex. A, p. 9, Tr. 139.) Although petitioner underwent two EMGs during her clinical course, Dr. Werdiger opined that the results were unremarkable, showing no abnormal spontaneous movement in the muscles. (Tr.

[23] Dr. Werdiger received his medical degree from Weill Cornell Medical College (then called Cornell University Medical College) in 1977, before going on to complete a residency in internal medicine and adult neurology in 1982. (Ex. B, p. 1; Tr. 127-28.) He is board certified in neurology. (Ex. B, p. 1; Tr. 129.) Before retiring, Dr. Werdiger provided general adult neurologic care in a private practice setting. (Ex. B, p. 1; Tr. 128-29.) He also provided outpatient general neurological care as a member of the Yale Department of Neurology Group Practice, as well as in his position as an attending physician and Assistant Chief of Neurology at Yale New Haven Hospital. (Ex. B, p. 1.) He has held various academic teaching appointments at the Yale School of Medicine since 1982. (*Id.* at 2; Tr. 128.) Since retiring, Dr. Werdiger has stayed up to date on the current relevant medical literature in the field of neurology. (Tr. 131.) Dr. Werdiger was proffered as an expert in neurology at the hearing without objection. (*Id.* at 131-35.)

139-40; Ex. A, p. 11.) Additionally, no underlying pathological process that causes fasciculations was ever documented. (Ex. A, p. 11; Tr. 140.)

Dr. Werdiger described a tremor as "a rhythmic oscillation of a body part." (Ex. A, p. 9 (citing Mark J. Edwards & Guenther Deuschl, *Tremor Syndromes*, 19 CONTINUUM (MINNEAPOLIS, MINN.) 1213 (2013) (Ex. A, Tab 9), David R. Williams et al., *Parkinsonian Syndromes*, 19 CONTINUUM (MINNEAPOLIS, MINN.) 1189 (2013) (Ex. A, Tab 18)); Tr. 140.) Dr. Werdiger explained that are tremors are generally divided into Parkinsonian and non-Parkinsonian, depending on their characteristics, aggravating / mitigating features, and other accompanying symptoms. (Tr. 140.) Parkinsonian tremors are "rotational" and "hill-rolling." (*Id.* at 142.) They are most prominent at rest and dampen with distraction or activity. (*Id.*; Ex. A, p. 9.) Non-Parkinsonian tremors are "essentially linear" and more rapid than Parkinsonian tremors. (Tr. 142.) These tremors tend to dampen with rest and exacerbate with activity. (*Id.* at 142-43.) Dr. Werdiger explained that there can at times be some overlap with a combination of Parkinsonian and essential tremors in Parkinson's disease, but this phenomenon is thought to be a coincidence, rather than part of the Parkinson's disease.[24] (*Id.* at 143.) He notes that, because petitioner's tremors were "not well described in the medical reports," they cannot be accurately classified. (Ex. A, p. 11; Tr. 141.) However, he opined that petitioner did not display any other features associated with Parkinsonism. (Ex. A, p. 11; Tr. 142.) Moreover, "[t]here is no documentation in the medical reports of any known cause for or disorder associated with her tremor." (Ex. A, p. 11.) Although there are many different causes for Parkinsonian-like tremors, Dr. Werdiger opined that they have not been associated with vaccination. (Tr. 159-60.)

Regarding myoclonus, Dr. Werdiger explained it as a "sudden, brief, involuntary muscle jerk" caused by "abrupt muscle contraction (positive myoclonus) or by sudden cessation of ongoing muscular activity (negative myoclonus)." (Ex. A, p. 9.) Myoclonus can be classified based on the clinical presentation, anatomical localization, and etiology. (*Id.*; Tr. 145.) Dr. Werdiger described four broad classes of myoclonus:

- physiological myoclonus, which occurs in otherwise healthy individuals and is not indicative of any pathological process involving the nervous system;
- essential myoclonus, which can be either an inherited or a sporadic condition that typically manifests with multifocal myoclonic jerks that originate in the subcortical region of the central nervous system;
- epileptic myoclonus, which is primarily associated with a seizure disorder that includes myoclonic jerks as a concomitant clinical feature; and
- symptomatic myoclonus, which can be due to a large number of underlying causes, including "viral infections that cause encephalitis or post/para-infections encephalitis."

[24] Dr. Werdiger explained that Parkinsonian tremors can occur in "Parkinson-plus syndromes or atypical Parkinson's disease"; however, these conditions have different clinical features beyond the Parkinsonian tremors that distinguish them as unique disorders. (Tr. 143-44.)

(Ex. A, pp. 9-10 (citing Maja Kojovic et al., *Myoclonic Disorders: A Practical Approach for Diagnosis and Treatment*, 4 THERAPEUTIC ADVANCES NEUROLOGICAL DISORDERS 47 (2011) (Ex. A, Tab 1); Karen A. Blindauer, *Myoclonus*, 10 CONTINUUM LIFELONG LEARNING NEUROLOGY 174 (2004) (Ex. A, Tab 2); John N. Caviness, *Myoclonus*, 25 CONTINUUM (MINNEAPOLIS, MINN.) 1055 (2019) (Ex. A, Tab 3); K. Bhatia et al., *"Isolated" Postinfectious Myoclonus*, 55 J. NEUROLOGY NEUROSURGERY & PSYCHIATRY 1089 (1992) (Ex. A, Tab 4)); Tr. 145.) With regard to acute viral and post/para-infectious encephalitis, Dr. Werdiger explained that these syndromes are "characterized by seizures, alterations of consciousness, and focal neurological signs" and that myoclonus, when present, is often a minor clinical feature. (Ex. A, p. 10.) Dr. Werdiger explained that opsoclonus is "the ocular manifestation of myoclonus" and presents as involuntary, jerky eye movements. (*Id.*; Tr. 146.) He acknowledges that the combination of myoclonus and opsoclonus has been "reportedly associated with acute influenza infection or post/para-influenza infection." (Ex. A, p. 10 (citing Bhatia et al., *supra*, at Ex. A, Tab 4; Klaas et al., *supra*, at Ex. A, Tab 6; Akihiko Morita et al., *Opsoclonus-Myoclonus Syndrome Following Influenza A Infection*, 51 INTERNAL MED. 2429 (2012) (Ex. A, Tab 7); Amanda L. Piquet et al., *Opsoclonus-Myoclonus Syndrome Post-Vaccination and Viral Illness*, 3 INT'L J. CLINICAL MED. 304 (2012) (Ex. A, Tab 8)).) However, although post-vaccination myoclonus "is a well known entity," the medical literature does not support an association between myoclonus or myoclonus-opsoclonus and the flu vaccine. (Tr. 165; Ex. A, p. 12.) Although there is a single case report of myoclonus-opsoclonus following flu vaccination, any causal relation is confounded by an association flu infection following vaccination. (Ex. A, p. 12 (citing Piquet et al., *supra*, at Ex. A, Tab 8).) Dr. Werdiger explained that when post-vaccination myoclonus occurs, it is benign and self-limited. (Tr. 165.) It typically resolves within six months and is seldom disabling. (*Id.* at 165-66.) In the instant case, Dr. Werdiger opined that neither myoclonus nor opsoclonus was observed by examiners or documented by EMG study. (Ex. A, p. 11; Tr. 146.) He explained that he accepted Dr. Machado's observation of post-vaccination myoclonus until the myoclonus continued beyond six months, at which point a diagnosis of post-vaccination myoclonus would be "atypical." (Tr. 167-68 (citing Ex. 8, p. 4).)

Dr. Werdiger also described muscle atrophy as the wasting and thinning of muscles and noted that this symptom can have many causes that are unrelated to vaccination. (Ex. A, p. 10 (citing Robert W. Jackman & Susan C. Kandarian, *The Molecular Basis of Skeletal Muscle Atrophy*, 287 AM. J. PHYSIOLOGY. CELL PHYSIOLOGY C834 (2004) (Ex. A, Tab 14); Alessandro Fanzani et al., *Molecular and Cellular Mechanisms of Skeletal Muscle Atrophy: An Update*, 3 J. CACHEXIA SACROPENIA & MUSCLE 163 (2012) (Ex. A, Tab 15)); Tr. 146.) However, he opined that petitioner's muscle biopsy showed nonspecific findings not indicative of a neuropathic or myopathic process. (Ex. A, p. 11; Tr. 146-47.) He further opined that there was no evidence of myotonic dystrophy based on petitioner's muscle biopsy. (Tr. 148-49.)

At the hearing, Dr. Werdiger explained his understanding of the relevance of Miller Fisher syndrome in this instant case. (Tr. 158-59.) He explained his understanding of Dr. Neuenschwander's opinion as including that petitioner has a "Miller

Fisher syndrome-like disorder," meaning that petitioner's symptoms overlapped with the clinical features of Miller Fisher syndrome. (*Id.*) Dr. Werdiger explained that GBS "comprises a spectrum of related acute inflammatory peripheral nerve and nerve root disorders" and that it "is considered to be an autoimmune disorder characterized by aberrant activation of the adaptive immune response to peripheral nerves." (Ex. A, p. 10.) Dr. Werdiger acknowledged that the "precise mechanisms for the development of GBS remain incompletely understood." (*Id.*) However, there "is a general consensus that GBS is triggered by environmental agents in genetically susceptible hosts." (*Id.* (citing Kazim A. Sheikh, *Guillain-Barré Syndrome*, 26 CONTINUUM (MINNEAPOLIS, MINN.) 1184 (2020) (Ex. A, Tab 16)).) While not the most common type of GBS, the Miller Fisher variant of GBS "is characterized by the triad of ophthalmoplegia (weakness in muscles that move the eyes), ataxia (gait imbalance and unsteadiness), and areflexia (the depression or absence of muscle tendon reflexes)." (*Id.* at 10-11 (citing Sheikh, *supra*, at Ex. A, Tab 16; James J. Sejvar et al., *Guillain-Barré Syndrome and Fisher Syndrome: Case Definitions and Guidelines for Collection, Analysis, and Presentation of Immunization Safety Data*, 29 VACCINE 599 (2011) (Ex. A, Tab 17); Tr. 149.) Dr. Werdiger opined that there is no evidence that petitioner suffers from the Miller Fisher variant of GBS as myoclonus and/or opsoclonus are not considered to be features of the syndrome. (Ex. A, p. 12; Tr. 150.) He explained that he is not comfortable diagnosing GBS, even where a patient has some symptoms that overlap with GBS, if the patient's clinical presentation does not fit the diagnostic criteria for GBS. (Tr. 175.) The most he would say was that the patient's condition was "GBS-like." (*Id.*) In that context, the relevance of the underlying causes of GBS would need to be evaluated on a case-by-case basis. (*Id.*) Because Dr. Werdiger does not believe that petitioner suffers from Miller Fisher syndrome, he does not believe that the causes of the syndrome are helpful in understanding petitioner's condition. (*Id.*)

Dr. Werdiger further opined that there is no objective suggestion that petitioner suffered from a brain injury. (Tr. 151.) Specifically, he opined that petitioner's symptoms "do not reasonably fit with any neuroanatomical localization, or any medically accepted neurological disorder, neurological syndrome, or neuropathological process." (Ex. C, p. 2; Ex. A, p. 13; Tr. 151-52.) He explained that myoclonus, opsoclonus, and non-Parkinsonian tremors are not together symptoms or manifestations of an underlying neurological process. (Tr. 162-64.) "[A]s individual symptoms, they may or may not exist, but together they are not part of a particular process, disease process or syndrome that I'm aware of." (*Id.* at 163.) Moreover, Dr. Werdiger opined that petitioner's alleged myoclonus, fasciculations, tremors, and atrophy were not consistently observed at the bedside or on objective testing. (Ex. C, p. 1.) Dr. Werdiger criticized Dr. Neuenschwander's reliance on inflammation of the nervous system as the purported mechanism of vaccine injury "was not supported by findings of a normal EEG and blood tests (ESR or CRP)." (Ex. A, p. 12; Ex. C, p. 1; Tr. 150.)

Dr. Werdiger explained that VAERS is a "completely subjective reporting" system for purported vaccine-related reactions and injuries and represents a passive database that can include information that has not been medically validated. (Tr. 153-54; Ex. C, p. 2.) At the hearing, he clarified that VAERS is not reliable for diagnostic purposes and

is instead used "to monitor possible vaccine-related reactions. (Tr. 156.) As a result, Dr. Werdiger opined that information contained in VAERS reports does not support vaccine causation. (*Id.* at 154.)

Dr. Werdiger explained that petitioner reportedly began experiencing muscle twitching and tremors within one day of vaccination. (Ex. A, p. 12; Tr. 153.) He further explained that, following vaccination, "an interval of less than 48 hours between provision of the stimulus and the mounting of a subsequent immunologic response is biologically implausible." (Ex. A, p. 12 (Rowhani-Rahbar et al., *supra*, at Ex. 82); Tr. 152.) While a 48-hour time frame was possible in non-immune-mediated neurological reactions like febrile seizures, antigen-antibody-mediated reaction occurred in a time period that ranged from nine days to six weeks. (Tr. 170-72 (citing Rowhani-Rahbar et al., *supra*, at Ex. 82); Ex. C, pp. 2-3 (citing Matthew Z. Dudley et al., *The State of Vaccine Safety Science: Systematic Reviews of the Evidence*, 20 LANCET e80 (2020) (Ex. C, Tab 1)).) Although petitioner does not suffer from febrile seizures or ADEM, Dr. Werdiger explained that the study by Rowhani-Rahbar et al. is relevant because the pathophysiological mechanism that is believed to cause ADEM, *i.e.*, antigen-antibody-mediated reaction, aligns with Dr. Neuenschwander's proposed mechanism of vaccine-causation in this case. (Tr. 170.) He noted that a single case report of post-vaccination myoclonus-opsoclonus detailed an onset of 2 weeks following flu vaccination. (Ex. A, p. 12 (citing Piquet et al., *supra*, at Ex. A, Tab 8).) Thus, Dr. Werdiger opined that petitioner's 24-hour onset "does not accord" with her expert's "purported mechanism of neurological injury." (*Id.*; Tr. 169.)

Dr. Werdiger asserted that a search of peer-reviewed medical literature, as well as the most recent reports by the Institute of Medicine and the World Health Organization, did not uncover any association between petitioner's symptoms and medically accepted adverse effects of the flu vaccine. (Ex. A, p. 13.) He concluded that "[n]either the temporal onset of the petitioner's neurological systems (within 24 hours of vaccination), or her symptoms (myoclonus, tremors, fasciculations, muscle atrophy), can be reasonably attributed to adverse influenza vaccine related neurological events." (*Id.* at 12.)

V. Analysis

a. Dr. Neuenschwander's Opinion Is Neither Credible Nor Reliable

A special master's decision may be in part "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 v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). Indeed, 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 v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1325-26 (Fed. Cl. Spec. Mstr. Jan. 13, 2010) ("Assessments 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) ("[T]his 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."). Here, I agree with respondent that Dr. Neuenschwander's expertise does not extend to neurology, immunology, neuroimmunology, or metabolic medicine, all of which he attempts to touch upon in this case.

During the hearing, petitioner proffered Dr. Neuenschwander, who is board certified in emergency medicine as well as integrative and holistic medicine (Ex. 70), as an expert in integrative medicine.[25] (Tr. 43.) Importantly, however, Dr. Neuenschwander has not substantiated that his expertise in integrative medicine meaningfully expands his expertise beyond the scope of what he could otherwise present as a general medical practitioner based on his emergency medicine credentials. Dr. Neuenschwander explained that certification in integrative medicine, which is comparable to holistic or functional medicine, is relatively new (within the last five years) and so most practitioners of integrative medicine do not hold board certification in that field. (*Id.* at 45, 121-22.) Asked what, if any, other certification could be a natural segue into integrative medicine, Dr. Neuenschwander testified that "it tends to be people that are more generalized in medicine. So emergency room physicians, internists, pediatricians, family practice, those types of people tend to gravitate towards that versus somebody that's specialized . . . ." (*Id.* at 46.) In fact, in explaining what integrative medicine is, Dr. Neuenschwander stressed his own general medical training as an M.D. to distinguish his practice from that of an unlicensed naturopath. (*Id.* at 122.) In that regard, while respondent did not object to Dr. Neuenschwander's qualification and proffer as an expert in integrative medicine itself, he did stress his objection to any acceptance of Dr. Neuenschwander's credentials as supporting expertise in the specific areas of immunology, neurology, or neuroimmunology. (*Id.* at 46.)

Relevant to respondent's objection, Dr. Neuenschwander confirmed that his contention is that petitioner's alleged injury constitutes a neurologic injury with an underlying immune cause while also acknowledging that he is not board certified in either neurology or immunology. Nor did he complete any residency in neurology. (Tr. 120-21, 124.) Instead, he asserted that "I'm an expert at treating vaccine injuries. I'm not a neurologist. I'm not an immunologist, but I see and treat these patients. And most of it is self-education and education through meetings that I have been to with like-minded people, mainly in functional medicine." (*Id.* at 124-25.) However, although Dr. Neuenschwander represents that he has an ongoing role as an invited speaker, his curriculum vitae does not list any area of research interest leading to peer-reviewed publications on these (or indeed any) topics. (*Compare* Tr. 46, *with* Ex. 70.) As Dr. Neuenschwander explained it, he spent two and half years practicing in a general

[25] When asked to indicate for what area of expertise Dr. Neuenschwander was proffered, petitioner's counsel initially indicated that Dr. Neuenschwander was offered for his "expertise in immune activation syndrome for some type of vaccine-induced inflammation that was exacerbated by the vaccination." (Tr. 42.) Counsel was then asked to clarify if, based on her prior questions, she was proffering Dr. Neuenschwander as an expert in integrative medicine, which she agreed was correct. (Tr. 42-43.)

surgery residency before turning to integrative medicine, which he did exclusively in private practice. (Tr. 39-40; Ex. 70, p. 1.)

Dr. Neuenschwander describes his practice as involving a population of patients that are chronically ill. (Tr. 38.) He estimates that he has determined about 20-30% of his patients have been vaccine injured, though he indicates that is not a "clearcut" determination. (*Id.* at 38.) Dr. Neuenschwander describes himself as generally involved in patient care (*Id.* at 39); however, when asked specifically what diagnoses his vaccine-injured patients carry, he testified that they generally have "nonspecific conditions" (*Id.* at 44). When asked whether he is typically the diagnosing physician, he testified:

> Well, again, we are going to have to be careful about diagnosis. So somebody might come in with a diagnosis of chronic fatigue syndrome or fibromyalgia or a small fiber neuropathy or chronic pain syndrome. My diagnosis is going to be – and this is integrative medicine, my diagnosis is going to be more specific as to the cause. So my diagnosis would be, you know, a chronic encephalitis, an autoimmune encephalitis-type disorder. So they will come to me almost always with one of those other diagnoses because I'm almost never the primary person that sees them. I'm the 12th, 15th, 20th doctor that sees them. I am then going to do an integrative workup to look at root cause. And those root causes are part of what I'm going to talk about, I'm assuming, in my testimony today because these are things like inflammation, immune activation, chronic encephalitis. Those kind of things. And that's what I diagnose because I'm doing that type of testing.

(*Id.* at 44-45.) However, apart from this vague reference to additional testing, Dr. Neuenschwander did not explain why, or on what basis, he is better able to determine the root causes of a patient's symptoms, especially given that his testimony suggests that he favors the conclusion that his patients are suffering "nonspecific" conditions in lieu of any formal diagnosis that could at least begin to speak to a pathophysiologic explanation. In fact, while describing integrative medicine generally, Dr. Neuenschwander indicated that what distinguishes integrative medicine from general medical practice is "trying to expand the horizon of what we have" in terms of treatments, including lifestyle changes, nutrition, and non-medication supplements. (*Id.* at 121-22.) Especially in the absence of any research interest or peer-reviewed publications of any kind, Dr. Neuenschwander's clinical experience from private practice engaging in management of the symptoms of chronic illness is not strong evidence of expertise regarding the cause(s) of those conditions. While it is not impossible for experience in disease management to lead to insights regarding the cause of a disease, this has not been substantiated with respect to Dr. Neuenschwander's own experience. For example, during the hearing Dr. Neuenschwander conceded with respect to the chronic fatigue that forms the basis for his opinion in this case that "nobody really knows what causes chronic fatigue, as far as I know." (*Id.* at 54.)

Regardless of the expert's discipline, in order for petitioner to prevail on a cause-in-fact claim, she must present medical or scientific explanation that is "sound and reliable." *Boatmon*, 941 F.3d at 1359 (quoting *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994)). Even accepting that Dr. Neuenschwander's medical degree and board certification in emergency medicine renders him at least minimally qualified to *potentially* provide a reliable medical opinion in this case, his actual testimony was riddled with statements that demonstrate that his opinion falls below any reasonable threshold of credibility that could support sound and reliable medical explanation.

In particular, Dr. Neuenschwander was asked at the outset of his hearing testimony to simply explain his view that petitioner suffered a "classic vaccine injury resulting from overstimulation of her immune system." (Tr. 48.) His explanation includes the following, which is worth quoting at length:

> So the way vaccines are engineered, they are engineered for [a] certain immune response. I think she went off the deep end with her immune response. And because she had that predisposition, her reaction was very rapid and involved obvious signs of inflammation and immune activation. So if you look at the course of her symptoms, you know, she, within six hours, has problems tying a karate belt, you know, *because there's something wrong with her hands that has to do with inflammation*.
>
> Two days later she has the worst headache of her life. I mean, as an ER doctor, if you walk in and say I have the worst headache of my life, the first thing I'm going to do is a spinal tap to make sure you don't have encephalitis or myeloencephalitis or something like that. *So that is a sign of brain inflammation*.
>
> And then in addition, she gets these weird movements, which we see this frequently in vaccine-injured patients, and I don't think – you know, *again, I'm not a neurologist, but my understanding is if you start messing with the basal ganglia of the brain and you inflame them, then you can start getting some of these symptoms simply from that.* This is the coordination part of the brain that coordinates movement for the body. So when you inflame those basal ganglia, you can get tremors, you can get herky-jerky movements that we're seeing.
>
> And we can argue about the specific terms you are going to apply to that, because I think *the movement disorders we see in vaccine injuries are a little different than the movement disorders we see in aneurysms or brain bleeds or sort of the classic neurology stuff*. And that's what makes it difficult to even speak on this, because if I say myoclonus as a neurologist – or *if somebody says myoclonus as a neurologist, they might have a different definition than what I would say is myoclonus if I'm looking at somebody with a vaccine injury*.

> So once you get inflammation of the brain, you start getting all the symptoms that [petitioner] had early on. And the trouble is, if that inflammation doesn't resolve, if the body isn't able to take care of that, then you are going to end up with chronic symptoms. . . .

(*Id.* at 48-50 (emphasis added).) Without suggesting that the above quotation is the sum total of Dr. Neuenschwander's testimony, this passage is important because, as the overview explanation of Dr. Neuenschwander's opinion, it illustrates the types of deficits that permeate his reasoning.

First, Dr. Neuenschwander displays a clear willingness to opine beyond his knowledge base. As noted above, Dr. Neuenschwander confirmed that he believes petitioner's alleged injury is an immune-mediated neurologic condition. (Tr. 124.) Thus, he explains that he is purporting to opine that petitioner's immune response "went off the deep end," despite not having any demonstrated background in immunology. He further premises that discussion on the idea that petitioner had a predisposition to such a reaction based on her prior chronic fatigue even though, as separately noted above, he conceded that he does not know what causes chronic fatigue. (*Id.* at 54.) Further still, he proceeds to present neurologic concepts as underlying his opinion despite providing caveats, such as "again, I am not a neurologist, but my understanding is . . . " (*Id*. at 49; *see also* Tr. 67 ("that settled into what looks like probably a chronic autoimmune type injury to, I'm guessing, basal ganglia, I don't know . . .") While expert testimony offered at the entitlement hearing must be heard and considered, a special master may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See, e.g.*, *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (finding petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications).

Second, even narrowing focus to areas that are credibly within Dr. Neuenschwander's knowledge base, he still offers testimony that is unreliable. For example, there is an aspect of this extended explanation that Dr. Neuenschwander places within his board-certified specialty of emergency medicine, namely what emergency medicine may suspect as the potential cause of a severe headache. However, despite specifically acknowledging that objective testing is needed to determine whether a headache is evidence of encephalitis, he summarily accepts petitioner's own reported headache presentation as evidence of brain inflammation without any such test actually having been performed. (*See also* Tr. 67 (acknowledging this data is absent).) Similarly, Dr. Neuenschwander attributes petitioner's difficulty tying her son's karate belt to inflammation, despite being unable to characterize the issue as anything more specific than "something wrong with her hands." Thus, Dr. Neuenschwander purports to portray assertions as medical fact, despite betraying that these assertions are not supported by any actual medical assessment or knowledge. Nothing requires the acceptance of an expert's conclusion "connected to existing data

only by the *ipse dixit* of the expert." *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (Fed. Cl. Spec. Mstr. Aug. 11, 2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012) (noting that a special master "is entitled to require some indicia of reliability to support the assertion of the expert witness" (quoting *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 n.3 (Fed. Cir. 2010))), *mot. for rev. den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013).

And, third, Dr. Neuenschwander purports to distinguish neurologic symptoms from their ordinary understanding within the discipline of neurology by contending that there is a population of vaccine-injured people who demonstrate a proposed alternative understanding of the symptom, contributing to his overall view that there is such a thing as a "classic" vaccine injury for which any diagnosis would otherwise be "nonspecific." However, this is based on nothing more than Dr. Neuenschwander's anecdotal experience with individuals that he has himself diagnosed as vaccine-injured despite a lack of any other clear-cut diagnosis and despite lacking any expertise in any relevant medical specialty. Rather than being a medically or scientifically sound approach, this merely presents a circular and conclusory logic whereby Dr. Neuenschwander's own prior practice of disregarding the neurologic meaning of a term or symptom, such as myoclonus, serves as the justification for doing so again in the future. Thus, for example, especially in light of Dr. Neuenschwander's lack of any documented research effort leading to peer-reviewed publication, this overall approach of seeking to identify a "classic" vaccine injury as an entity unto itself does not readily comport with any of the *Daubert* factors that have been accepted as a method of weighing the reliability of expert testimony in this program. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594-96 (1993); *see Cedillo*, 617 F.3d at 1339 n.3 (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), which approved the special master's use of the Daubert factors "as a tool or framework for conducting the inquiry into the reliability of the evidence").[26]

Based on his educational background and decades of private practice, Dr. Neuenschwander is at least minimally qualified to opine on medical matters; however, he is not a neurologist, immunologist, or metabolic specialist, and is therefore not qualified to offer opinions with regard to the fields that are implicated by his causal theories. This significantly reduces the relative value of his testimony. *Accord Ruzicka*

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[26]

> 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). Special masters may, but are not required to, apply the Daubert factors in weighing expert evidence in this program. *Boatmon*, 941 F.3d at 1359.

v. Sec'y of Health & Human Servs., No. 17-109V, 2023 WL 8352496, at *17 (Fed. Cl. Spec. Mstr. Nov. 13, 2023) (finding Dr. Neuenschwander qualified to opine on medical matters, but unpersuasive as to neurology and immunology, given his qualifications).[27] Moreover, the quality of his opinion testimony falls below the threshold of what could be considered reliable or persuasive.

b. Even If Credited, the Substance of Dr. Neuenschwander's Opinion Does Not Satisfy Petitioner's Burden Under *Althen* Prong One

Under *Althen* prong one, a petitioner must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (quoting *Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006)). Scientific evidence offered to establish the first *Althen* prong is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1380 (Fed. Cir. 2009). To satisfy this prong, petitioner's theory need only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-499. Although petitioners may satisfy *Althen* prong one without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory, *Andreu*, 569 F.3d at 1378-79 (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)), a petitioner's theory must still be based on "sound and reliable medical or scientific explanation," *Knudsen*, 35 F.3d at 548.

In this case, Dr. Neuenschwander's theory of causation is predicated on the idea that, regardless of the fact that he cannot fully explain petitioner's post-vaccination presentation via any medically recognized diagnosis, petitioner's prior history demonstrates that she had a preexisting predisposition to an aberrant immune response, which can explain how she developed brain inflammation and ultimately neurologic symptoms in response to her vaccination that are akin to, but not diagnostic of, Miller Fisher syndrome. There are several issues with this. Ultimately, what Dr. Neuenschwander submitted in this case was several inchoate opinions that do not in whole or in part add up to a sound and reliable causal theory.

First, Dr. Neuenschwander's opinion is unpersuasive because it is premised on an assumption that petitioner suffered a susceptibility in the form of preexisting immune activation, which is not preponderantly evidenced. *See Burns v. Sec'y of Health & Human Servs.*, 3 F. 3d 415, 417 (Fed. Cir. 1993) (holding that "[t]he special master

[27] The *Ruzicka* special master further found Dr. Neuenschwander's credibility to be lacking at least in part because membership on the board of Informed Consent Action Network suggests that he maintains "anti-vaccine views." 2023 WL 8352496, at *17 n.9. Dr. Neuenschwander's CV filed in this case indicates that he maintains an association with this organization. (Ex. 70, p. 2.) However, because this case turns on other factors, I do not find it necessary to reach that issue. For all the reasons discussed throughout this decision, Dr. Neuenschwander's opinion is unpersuasive regardless of whether he harbors anti-vaccine biases.

concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner's medical expert."); *see also Rickett v. Sec'y of Health & Human Servs.*, 468 F. App'x 952, 958 (Fed. Cir. 2011) (holding that "it was not error for the Special Master to assign less weight to Dr. Bellanti's conclusion regarding challenge-rechallenge to the extent it hinged upon Mr. Rickett's testimony that was inconsistent with the medical records"); *Dobrydnev v. Sec'y of Health & Human Servs.*, 566 F. App'x 976, 982-83 (Fed. Cir. 2014) (holding that the special master was correct in noting that "[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion" (alteration in original) (quoting *Dobrydneva v. Sec'y of Health & Human Servs.*, No. 04-1593V, 2010 WL 8106881, at *9 n.12 (Fed. Cl. Spec. Mstr. Oct. 27, 2010), *rev'd sub nom. Dobrynev v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 190 (2011), *rev'd*, 566 F. App'x 976 (Fed. Cir. 2014))); *Bushnell v. Sec'y of Health & Human Servs.*, No. 02-1648V, 2015 WL 4099824, at *12 (Fed. Cl. Spec. Mstr. June 12, 2015) (finding that "because Dr. Marks' opinion is based on a false assumption regarding the onset of J.R.B.'s condition, and the incorrect assumption of a 'stepwise regression' after each vaccine administration, it should not be credited"). As explained above, Dr. Neuenschwander initially sought to rely on the premise that petitioner suffered immune dysfunction in the form of ongoing Lyme disease. (Ex. 53, p. 3.) However, after Dr. Neuenschwander was directed to substantiate that assertion, given that petitioner tested negative for Lyme disease multiple times, he instead opined that she was suffering chronic immune activation from "any number of other possible pathogens for which she was not tested." (Ex. 69, pp. 1, 3.) Yet, even granting that petitioner could suffer chronic fatigue syndrome initiated by an unknown infectious cause, there is not preponderant evidence that petitioner suffered chronic fatigue syndrome prior to vaccination.

Chronic fatigue syndrome was purportedly diagnosed by Dr. Klass. However, during the hearing Dr. Neuenschwander acknowledged that naturopaths like Dr. Klass "are not doctor, doctors." (Tr. 122.) Apart from Dr. Klass's opinion, Dr. Neuenschwander opined that chronic fatigue syndrome can be diagnosed when there is: (1) persistent fatigue (2) lasting for longer than three-to-six months (3) without another cause. (*Id.* at 55.) However, petitioner's sworn statements in this case aver that, prior to her vaccination, she had no medical conditions other than her alleged Lyme disease and that she was able to work as a health care worker at Yale New Haven Hospital and care for her family "without any problems, medical issues or disabilities." (Ex. 20, ¶¶ 2, 4-5, 7.) Petitioner's testimony during her workers' compensation deposition further confirms that there is not preponderant evidence supporting Dr. Neuenschwander's opinion in this regard. Petitioner deposition testimony indicates that, despite considering herself to have been diagnosed with chronic fatigue syndrome, she only experienced extreme fatigue in May of 2013, prior to her treatment of doxycycline. (Ex. 34, pp. 54, 62.) Although she testified that she had "low energy" at other times, she testified that she was fully functional prior to her alleged vaccine injury. (*Id.* at 54.) However, according to the literature filed by petitioner, diagnosis of chronic fatigue syndrome requires fatigue that results in "[a] substantial reduction or impairment in the ability to engage in preillness levels of occupational,

educational, social, or personal activities." (Naviaux et al., *supra*, at Ex. 67, p. 2.) Additionally, Dr. Neuenschwander's own stated diagnostic standard requires that there be no other cause for the fatigue. However, even without accepting the presence of Lyme disease as preponderantly established given her negative test results, the medical records do confirm that petitioner had symptoms of an infection in May of 2013 at the time of her extreme fatigue, which resolved with her subsequent doxycycline treatment. (Ex. 19, p. 6 (reporting that she developed malaise and a swollen lymph node in May of 2013 and improved with doxycycline); Ex. 31, p. 25.) Thus, petitioner's only significant fatigue correlated to a period of her more acute infection. Indeed, petitioner herself asserted that her alleged Lyme disease had resolved prior to the fall of 2016. (Ex. 20, ¶ 5.) Thus, there is not preponderant evidence supporting the pre-vaccination chronic immune activation underlying Dr. Neuenschwander's opinion.

Second, even granting his starting premise, Dr. Neuenschwander has not persuasively established that the "cell danger response" can explain how the flu vaccine would act in connection with preexisting chronic fatigue syndrome to result in a neurologic injury. He describes the cell danger response as a method by which the cell protects itself from infection "by diverting energy production into the creation of a highly oxidative, hostile environment." (Ex. 53, p. 4.) During the hearing, he explained,

> We are talking about the mitochondria when we talk about cell danger response. So the mitochondrial dysfunction is going to manifest as impaired ATP production. So you are not making enough energy. And also, it's going to create . . . oxidative stress, but in cell danger response they call it shielding. There's all these oxidative compounds, but they are there to protect the cell rather than damage it. The trouble is if you don't turn that response off, it will eventually damage the cell. . . .
>
> As a result of that, because the mitochondria aren't functioning and because we are dealing with the brain, you are going to have fatigue and cognitive dysfunction and neurologic dysfunction . . . .

(Tr. 99-100.) He stated that "there's evidence in chronic fatigue that you have this type of mitochondrial dysfunction and persistent elevation of these oxygen and nitrogen free radicals." (*Id.* at 100.) He cited a paper to show how "chronic-low grade inflammation" in chronic fatigue syndrome "will impact mitochondrial dysfunction" (*Id.* at 99 (citing Morris & Maes, *supra*, at Ex. 76), and a review study by Chaves-Filho et al. to support that there is a "relationship between microglial activation and neuro-inflammation with chronic fatigue syndrome" (Ex. 71, p. 2 (citing Chaves-Filho et al., *supra*, at Ex. 72)). He went on to state that "[w]e known that vaccines induce an inflammatory immune response, and that immune response varies amongst individuals." (Ex. 71, p. 5.)

However, the medical literature that Dr. Neuenschwander relies upon largely identifies chronic fatigue syndrome as a multifactorial condition of unknown cause for which metabolic and inflammatory factors are variously hypothesized. Although Dr. Neuenschwander separately submitted papers regarding the inflammatory effects of the

flu vaccine more broadly, none of the literature includes any hypothesis of vaccine causation comparable to what Dr. Neuenschwander proposes in this case.[28] Nor does Dr. Neuenschwander possess the expertise in immunology and metabolic medicine that would be necessary to credibly stitch these various papers together as circumstantial evidence of a coherent theory. By contrast, two of the papers cited by Dr. Neuenschwander, by Sleigh et al. and Prinsen et al., directly contradict his theory. Sleigh et al. found that flu vaccination was safe in chronic fatigue syndrome patients, "with no more untoward early side effects than a placebo injection," and that chronic fatigue syndrome patients experienced a normal immunizing response to the flu vaccine antigens studied. (Sleigh et al., *supra*, at Ex. 79, p. 5.) The authors explain that chronic fatigue syndrome is "a condition of immune unresponsiveness and dysregulation" and observed a "blunted humoral immune response to the influenza A antigens and less so to B/Panama." (*Id.* at 5-6.) Prinsen et al. found that humoral and cellular immune responses to the flu vaccine among chronic fatigue syndrome patients were comparable to health controls and that "aberrations in immune responses in [chronic fatigue syndrome] patients were not evident." (Hetty Prinsen et al., *Humoral and Cellular Immune Responses After Influenza Vaccination in Patients with Chronic Fatigue Syndrome*, 13 BMC IMMUNOLOGY 1 (2012) (Ex. 89, p. 1).) These papers directly contradict Dr. Neuenschwander's suggestion that preexisting chronic fatigue syndrome would help explain how petitioner's immune response could "explode" in response to vaccination. (Ex. 69, p. 3.) Ultimately, Dr. Neuenschwander acknowledges that "nobody really knows what causes chronic fatigue" (Tr. 54), which makes it difficult to offer any reliable assertion as to what other factors or triggers might interact with it. *Accord Skinner-Smith v. Sec'y of Health & Human Servs.*, No. 14-1212V, 2022 WL 4116896, at *31-35 (Fed. Cl. Spec. Mstr. Aug. 15, 2022), *mot. for recons. denied*, No. 14-1212V, 2022 WL 13461862 (Fed. Cl. Spec. Mstr. Sept. 9, 2022). *But see Bryan v. Sec'y of Health & Human Servs.*, No. 14-898V, 2020 WL 7089841 (Fed. Cl. Spec. Mstr. Oct. 9, 2020).

Finally, to explain how this could ultimately result in neurologic injury, Dr. Neuenschwander seems to further suggest that the causes of medically recognized syndromes – mainly the Miller Fisher variant of GBS – can be applied to an unidentified and as-of-yet unrecognized syndrome. (*See, e.g.*, Ex. 53, p. 1 (Dr. Neuenschwander opining that petitioner's condition "likely has the same mechanism" as Miller Fisher syndrome).) However, that analogy is not helpful. Miller Fisher syndrome is a clinical syndrome and, as such, it does not necessarily point clearly to a pathologic mechanism that would support a causal opinion by analogy. For example, Dr. Neuenschwander readily admits that Miller Fisher syndrome "has been linked with the production of autoimmune antibodies to a number of targets." (*Id.* at 4.) Moreover, Dr.

[28] Dr. Neuenschwander did file literature advancing the so called "ASIA" hypothesis (autoimmune syndrome induced by adjuvants). (Solange Murta Barros & Jozélio Freire de Carvalho, *Shoenfeld's Syndrome After Pandemic Influenza A/H1N1 Vaccination*, 36 ACTA RHEUMALOGICA PORTUGUESA 65 (2011) (Ex. 80); Isa Seida et al., *Vaccines and Autoimmunity—From Side Effects to ASIA Syndrome*, 59 MEDICINA 364 (2013) (Ex. 90).) ASIA does purport to encompass chronic fatigue syndrome. (Barros & Carvalho, *supra*, at Ex. 80, p. 3.) However, ASIA itself has been unequivocally rejected as a sound and reliable theory within this program. For a full discussion of ASIA, see *J.F. v. Secretary of Health & Human Services*, No. 13-799V, 2022 WL 5434214 (Fed. Cl. Spec. Mstr. Sept. 9, 2022).

Neuenschwander ultimately acknowledged that petitioner's presentation did not meet the diagnostic criteria for Miller Fisher syndrome. (*Id.* at 3-4; Tr. 79-80.) Thus, as Dr. Werdiger explained, there is little to no basis for invoking Miller Fisher syndrome as any explanation for petitioner's condition. Ultimately, Dr. Neuenschwander conceded during the hearing that "I don't really know exactly what kind of injury we are dealing with." (Tr. 79.) If Dr. Neuenschwander does not know what the injury is, then he necessarily cannot opine as to its causes. *Accord Broekelschen*, 618 F.3d at 1345 (explaining that "causation is relative to the injury"). Therefore, Dr. Neuenschwander's opinion in this regard amounts to mere speculation.

In sum, even setting aside the threshold concerns regarding Dr. Neuenschwander's credibility and reliability, review of the substance of Dr. Neuenschwander's opinion reveals that he has not articulated a theory of causation sufficient to meet petitioner's burden of proof under *Althen* prong one.

c. Petitioner Is Entitled to Compensation for a More Limited Injury of Myoclonus as Evidenced in Her Medical Records

Although petitioner failed to meet her burden of proof through the presentation of her expert's opinion, it is important to stress that a petitioner in this program can satisfy her evidentiary burden through either expert opinion or medical records. § 300aa-13(a). Although the diagnoses and medical judgments of the treating physicians are not binding, the special master must conduct a review of the complete record and "shall consider" any medical conclusion or judgment contained within the record. § 300aa-13(b). In that regard, the Federal Circuit has recognized that "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.'" *Capizzano*, 440 F.3d at 1326 (alteration in original) (quoting *Althen*, 418 F.3 at 1280).

Here, petitioner's overall clinical history is clouded by a prolonged and varied search for an overarching explanation for a variety of clinical symptoms, many of which remain to be reliably or definitively explained. It is precisely this overarching suspicion that Dr. Neuenschwander has failed to credibly present as a "classic" vaccine injury. However, in the course of her treatment history, petitioner was evaluated by a treating neurologist and movement disorder specialist, Dr. Machado, who diagnosed a more specific post-vaccination myoclonus. Dr. Machado first saw petitioner just over one week post vaccination. (Ex. 7, p. 1.) At that time, he reviewed petitioner's history of symptoms arising post-vaccination and reviewed video of petitioner's myoclonus symptoms. (*Id*. at 3-4.) Dr. Machado indicated that "post infectious and post vaccination myoclonus is a well described clinical entity where the myoclonus is the sole manifestation." (*Id*. at 4.) He further opined that the timeframe and description of the condition were appropriate for a post-vaccination myoclonus. (*Id*.) For the reasons discussed below, Dr. Machado's assessment, with respondent's expert's further partial endorsement, is sufficient to meet her burden of proof with respect to vaccine-caused myoclonus.

Under *Althen* prong one, petitioner must present a causal theory connecting her vaccination and injury. 418 F.3d at 1278. Of course, Dr. Machado's reasoning is quite limited in that he merely notes that post-vaccination myoclonus is a known clinical entity. (Ex. 7, p. 4.) In that regard, respondent has also filed literature explaining that, while there are instances of myoclonus that are accepted as representing a post-infectious process, the actual pathophysiology of the myoclonus otherwise remains unclear. (Bhatia et al., *supra*, at Ex. A, Tab 4.) Importantly, however, scientific evidence offered to establish the first *Althen* prong is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380. To satisfy this prong, petitioner's theory must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49. Petitioners need not demonstrate a specific biologic mechanism. *Andreu*, 569 F.3d at 1378-79. While the limits of Dr. Machado's explanation could present a stumbling block if the concept of post-vaccinal myoclonus were challenged, Dr. Werdiger conceded on respondent's behalf that "Post-vaccinal myoclonus is a well known entity." (Tr. 165.) Although Dr. Werdiger did question whether this entity could be linked to the flu vaccine specifically based on a lack of published literature (Ex. A, p. 12), he also accepted Dr. Machado's initial decision to attribute petitioner's own post-flu vaccine condition to a post-vaccinal myoclonus (Tr. 167).

Under *Althen* prong two, petitioner must also demonstrate a logical sequence of cause and effect showing that the vaccination was the reason for the injury. 418 F.3d at 1278. This showing is usually supported by facts derived from a petitioner's medical records. *Id.*; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians generally garner significant weight. *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326. Following review of petitioner's history and a physical exam, Dr. Machado was explicit in documenting five criteria he used during his initial encounter with petitioner to assess petitioner as having post-vaccination myoclonus. (Ex. 7, p. 4.) Specifically: (1) sudden onset of generalized multifocal or segmental mild clonus; (2) history of recent preceding infectious illness or vaccination; (3) no features of encephalitis or the opsoclonus myoclonus syndrome; (4) a nonprogressive course without seizures, ataxia, or dementia; and (5) recovery in a short but variable period of time. (*Id*.) These considerations by Dr. Machado are reasonably reflective of reasoning that can support a logical sequence of cause-and-effect implicating petitioner's vaccination as a cause of her condition. Additionally, although petitioner's records also include competing assessments disagreeing as to the presence of myoclonus (Ex. 33, pp. 9-10), during the hearing Dr. Werdiger indicated on respondent's behalf that he had no disagreement with this assessment, at least as of the time it was rendered (Tr. 167).

Over time, however, petitioner's condition did not resolve in a short period and she continued to see Dr. Machado. Despite the failure of her condition to resolve, Dr. Machado repeatedly maintained his assessment of post-vaccination myoclonus. (Ex. 7, p. 8 (January 24, 2017); Ex. 41, p. 12 (March 7, 2017); Ex. 41, p. 21 (May 17, 2017); Ex. 41, p. 30 (October 3, 2017).) As of June of 2018, notwithstanding his prolonged

treatment history with petitioner, Dr. Machado noted that "[t]he timeframe and description of her condition thus far again points to this being a post-vaccination induced myoclonus and muscle atrophy." (Ex. 35, p. 5; Ex. 36.) Dr. Werdiger disagreed with this longer-term assessment by Dr. Machado. He opined that once the myoclonus persisted for more than six months, "it would take it into the less likely than not category or unusually category, atypical." (Tr. 168.) However, in describing post-vaccination myoclonus as a known entity, Dr. Werdiger stated that it "usually" or "typically" resolves in six months. (*Id.* at 165.) He further indicated that post-vaccination myoclonus can be disabling, albeit "seldom." (*Id.*) Although Dr. Werdiger's competing clinical judgment as to the likelihood of an atypical presentation carries some weight, it is not sufficient to outweigh the clinical judgment of the actual treating physician that personally saw and treated petitioner, especially given that Dr. Werdiger otherwise agreed with the initial assessment and acknowledged that post-vaccination myoclonus may rarely persist and can be disabling. Dr. Machado's opinion is also at least partly buttressed by another treating neurologist, Dr. J. Hasbani. As of April 26, 2017, about five months post-vaccination, Dr. J. Hasbani assessed a post-vaccination movement disorder, which he later characterized as myoclonic jerks, and which he expressed he merely "hope[d]" would resolve, strongly suggesting a view that a worse prognosis remained possible. (Ex. 39, p. 11; Ex. 11, p. 6.)

Under *Althen* prong three, petitioner must demonstrate a proximate temporal relationship between her vaccination and her injury. 418 F.3d at 1278. Here, as with her showing under *Althen* prong one, petitioner's showing is very limited insofar as Dr. Machado simply recorded his impression that the timing of onset is appropriate to infer causation without any explanation. (Ex. 7, p. 4; Ex. 35, p. 5.) However, this potential shortcoming is overcome by Dr. Werdiger's explicit agreement on respondent's behalf that he agreed with Dr. Machado's initial assessment of a post-vaccination myoclonus in petitioner's own case. (Tr. 167.) Although respondent has challenged that an immune-mediated neurologic injury can occur within 24 hours of vaccination, when asked about this during the hearing, Dr. Werdiger limited his response to antibody-mediated immune responses, acknowledging that other systemic reactions can occur sooner. (*Id.* at 152-53.) But in any event, myoclonus was not among the initial symptoms that petitioner reported as occurring within 24 hours of her vaccination. (Ex. 5, p. 1.)

Once petitioner has met her *prima facie* burden of proof, respondent may still demonstrate that her injury is nonetheless due to factor(s) unrelated to the vaccination. *Althen*, 418 F.3d at 1278. In this case, however, Dr. Werdiger opined that no other potential causes are present to explain petitioner's condition. (Ex. A, p. 12; Ex. C, p. 2.) The Federal Circuit has also stressed that the vaccine program was designed so that "close calls regarding causation are resolved in favor or injured claimants." *Althen*, 418 F.3d at 1280. Here, while this demonstration of causation-in-fact is not robust, it is based on medical record evidence, including reputable treating physician opinion by a qualified neurology specialist. In fact, during the hearing, Dr. Werdiger revealed that he trained Dr. Machado. (Tr. 166-67.) Importantly, the totality of Dr. Werdiger's opinion has been accounted for in reaching this determination. However, Dr. Werdiger's overall opinion regarding the enigmatic nature of petitioner's complete clinical picture does not

negate Dr. Machado's opinion that a portion of petitioner's clinical picture is properly diagnosed as a post-vaccination myoclonus. That a person suffers imperfect health does not mean they cannot also suffer a distinct vaccine-caused injury.

It must be stressed, however, that given petitioner's failure to present any credible expert opinion, this finding of entitlement is limited to Dr. Machado's assessment of post-vaccinal myoclonus, in particular. Based on petitioner's muscle biopsy, Dr. Machado also felt that petitioner's later muscle wasting was secondary to her myoclonus as part of an autoimmune process. (Ex. 35, p. 5; Ex. 36.) Importantly, though, Dr. Machado expressed the view that petitioner's muscle biopsy was evidence of a separate neuropathic or myopathic process occurring as a result of a post-vaccination autoimmune process. (Ex. 35, p. 5.) Nothing in Dr. Machado's records explains petitioner's muscle wasting as a sequela of the myoclonus itself. Moreover, Dr. Machado's opinion with respect to post-vaccination myoclonus was otherwise predicated on the understanding that in post-vaccination myoclonus the myoclonus is the "sole manifestation" of the condition. (Ex. 7, p. 4.)

Ultimately, both Dr. Machado and Dr. Werdiger explained that the finding of internalized nuclei, cited by Dr. Machado upon review of the biopsy result, is a non-specific finding. (Ex. 35, p. 5; Tr. 147-49.) In that regard, Dr. Werdiger explained that petitioner's biopsy result is consistent with what can be found in healthy individuals or individuals with prior minor muscle trauma. (Tr. 147.) Although Dr. Werdiger agreed that internalized nuclei can be seen in myoclonic dystrophy, that is an inherited chronic condition that petitioner does not have. (Tr. 148-49.) He specifically explained that, without more, these biopsy results are not diagnostic of a neuropathological or myopathic process. (Tr. 147.) Additionally, petitioner's other treating neurologist, Dr. J. Hasbani, who otherwise similarly identified the presence of post-vaccination myoclonic jerking, did not agree that petitioner's biopsy evidenced a neuropathological or myopathic process. (Ex. 39, p. 19.) Given that Dr. Machado himself noted the biopsy findings to be nonspecific, his medical record lacks sufficient explanation to outweigh Dr. J. Hasbani's contrary treating physician opinion coupled with Dr. Werdiger's more robust explanation of the issue.

This ruling does not entitle petitioner to recover damages for aspects of her medical history that go beyond the specific condition of post-vaccinal myoclonus as discussed by the neurologists. As explained above, petitioner did not meet her burden of proof with respect to any aspect of her broader constellation of symptoms via Dr. Neuenschwander's opinion, which was found to be unpersuasive. Note, in particular, that Dr. Neuenschwander himself distinguished petitioner's movement disorder from her complaints of chronic fatigue (Tr. 66, 69) and that Dr. Machado's assessment of post-vaccinal myoclonus was specifically predicated on the absence of any features of an encephalitis (Ex. 7, p. 4), which is incompatible with Dr. Neuenschwander's opinion relying on inflammation of the basal ganglia.

VI. Conclusion

Petitioner's complete medical history eludes easy explanation, and she does have the undersigned's sympathy for everything she has endured regardless of the underlying cause. Clearly, petitioner herself has identified her flu vaccination as a key turning point in her health. However, based on a review of the record, including the expert medical opinion that has been provided, there is not preponderant evidence that petitioner's vaccine explains the entirety of her presentation. In light of all of the above, petitioner has preponderantly shown that she suffered a course of post-vaccinal myoclonus caused in fact by her flu vaccination. She has not preponderantly shown that any other symptom or condition was vaccine caused. Accordingly, petitioner is entitled to compensation for her myoclonus injury only. A separate damages order will issue.[29]

IT IS SO ORDERED.

s/ Daniel T. Horner
Daniel T. Horner
Special Master

[29] Because petitioner has not prevailed in all regards, she does have the right to ultimately seek review of the determinations made within this ruling notwithstanding that she has been found entitled to at least some compensation. Petitioner is cautioned, however, that under the Vaccine Rules petitioner's right to review does not accrue until after the damages phase of litigation and the issuance of a decision awarding damages consistent with this ruling. Any motion for review filed at this juncture would be premature and procedurally defective. *See Gaiter ex rel. D.S.G. v. Sec'y of Health & Human Servs.*, 142 Fed. Cl. 666, 675 (2019) (noting that the Court of Federal Claims "does not have jurisdiction over a motion for review involving a Special Master's Order that does not determine whether compensation is to be provided and, if compensation is to be provided, the amount of such compensation"), *aff'd per curiam*, 784 F. App'x 759 (Fed. Cir. 2019); *J.T. v. Sec'y of Health & Human Servs.*, 125 Fed. Cl. 164, 166-67 (2016) (concluding that petitioner's motion for review of a ruling on how damages should be calculated was premature because, although entitlement had been granted, compensation had not yet been awarded); *Shaw v. Sec'y of Health & Human Servs.*, 609 F.3d 1372, 1376 (Fed. Cir. 2010) (concluding that a decision on interim attorneys' fees and costs is reviewable as it amounts to a decision on entitlement to such fees).