In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
Filed: August 31, 2022

J.D.,	*	No. 14-742V
	*	
Petitioner,	*	Special Master Sanders
	*	
v.	*	
	*	Influenza ("Flu") Vaccine; Small
SECRETARY OF HEALTH	*	Fiber Neuropathy ("SFN");
AND HUMAN SERVICES,	*	Connective Tissue Disease;
	*	Raynaud's Phenomenon
Respondent.	*	

Renee J. Gentry, Vaccine Injury Clinic, George Washington Univ. Law School, Washington, DC, for Petitioner.
Jennifer L. Reynaud, United States Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On August 15, 2014, J.D.[2] ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 to -34 (2012).[3] ("Vaccine Act" or "Program"). Petitioner alleged that she suffered from "a plethora of unprecedented symptoms and illnesses, including unspecified diffuse connective tissue disease ("UCTD"),[4] and

[1] This Decision shall be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be withheld from public access.

[2] Following a Fact Ruling issued on September 14, 2018, Petitioner filed a motion to redact. ECF No. 107. I granted Petitioner's motion and ordered the Clerk of Court to amend the case caption to refer to Petitioner by her initials. Order at 3–4, ECF No. 118.

[3] National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99–660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[4] Connective tissue is "the tissue that binds together and is the support of the various structures of the body." *Dorland's Illustrated Medical Dictionary* 1901 (33rd ed. 2020) [hereinafter "*Dorland's*"]. Mixed connective tissue disease is "a disorder combining features of scleroderma, myositis, systemic lupus erythematosus, and rheumatoid arthritis, and marked serologically by the presence of antibody against extractable nuclear antigen." *Id.* at 532.

other severe autoimmune illnesses, such as Raynaud's phenomenon"[5] ("Raynaud's") as a result of an influenza ("flu") vaccine she received on October 29, 2013. Pet. at 1, ECF No. 1. Petitioner did not file an amended petition. However, she filed a motion for a ruling on the record on November 10, 2021, wherein she asserts that she "has established by a preponderance of the evidence that she suffers from small fiber neuropathy [("SFN")]," [6] and requests "a ruling on the record in favor of entitlement." Pet'r's Mot. at 1, 14, ECF No. 144.

After carefully analyzing and weighing the evidence presented in this case, in accordance with the applicable legal standards, I find that Petitioner has failed to provide preponderant evidence that her flu vaccination caused her to develop any of the injuries alleged in her petition. Further, I find that Petitioner has failed to provide preponderant evidence that her flu vaccination caused her to develop small fiber neuropathy, as alleged in her motion for a ruling on the record. Therefore, this case must be dismissed.

I. Procedural History

Following her petition, Petitioner submitted two affidavits, medical records, and two letters from her treating rheumatologist, Prashanth Palwai, M.D., between August of 2014 and December of 2015. *See* Pet'r's Exs. 1–45, ECF Nos. 7–48. On February 8, 2016, the presiding special master ordered Petitioner to submit an expert report or a status report by April 6, 2016. Order at 1, ECF No. 54. On March 28, 2016, however, Petitioner's counsel submitted a motion to withdraw. ECF No. 55. Following a month of Petitioner appearing *pro se*, Mr. Clifford Shoemaker entered as Petitioner's counsel on April 27, 2016. ECF No. 59. Petitioner supplemented her medical record over the ensuing months. *See* Pet'r's Exs. 46–74, ECF Nos. 70–78. On January 11, 2017, the case was transferred to me.[7] ECF No. 80.

Respondent filed his Rule 4(c) report on January 31, 2017, and argued that this case should be dismissed. *See* Resp't's Report, ECF No. 81. I held a Rule 5 status conference on February 17, 2017, and directed Petitioner to file an expert report. Order at 1, ECF No. 84. During an additional status conference on June 20, 2017, Petitioner disputed factual assertions made by Respondent in his report. Order at 1, ECF No. 88. Petitioner requested an opportunity to respond to Respondent's report and to submit updated medical records, an amended affidavit, and a fact timeline. *Id.* Petitioner filed these documents, as well as an affidavit from her mother, Ms. Beverly Dark, on August 21, 2017. *See* Pet'r's Exs. 75–103, ECF Nos. 91–95. On September 22, 2017, Respondent filed a status report requesting a fact hearing. *See* ECF No. 97 at 1.

Petitioner filed additional medical records on January 11 and January 23, 2018. Pet'r's Exs. 104–08, ECF Nos. 100, 103. I held a fact hearing on January 24, 2018. ECF No. 99; Min. Entry, docketed Jan. 24, 2018. On September 14, 2018, I issued a Fact Ruling and held that Petitioner

[5] Raynaud's phenomenon is an "intermittent bilateral ischemia [deficiency of blood] of the fingers, toes, and sometimes ears and nose, with severe pallor and often paresthesias and pain . . . ." *Dorland's* at 1409. "It is usually due to an underlying disease or anatomical abnormality." *Id.*

[6] Small fiber neuropathy is "a type of neuropathy in which only the small sensory cutaneous nerves are affected." *Dorland's* at 1252.

[7] The case was originally assigned to Special Master Hamilton-Fieldman. ECF No. 4.

presented to her treating physician with wrist pain and bruising on October 22, 2013, prior to her flu vaccination. Fact Ruling at 1, ECF No. 106. Following my Ruling, Petitioner filed additional medical records on December 6 and December 7, 2018, along with an affidavit. Pet'r's Exs. 109–125, ECF Nos. 115–17.

Petitioner filed Dr. Carl Tornatore's first expert report with accompanying medical literature on June 24, 2019. Pet'r's Exs. 127–138. ECF Nos. 126–28. Petitioner also filed an expert report by Dr. Holly Varner, Petitioner's treating neurologist, on September 16, 2019. Pet'r's Ex. 139, ECF No. 130-2. Ms. Renee Gentry substituted in as counsel for Mr. Shoemaker, and Petitioner filed her last batch of medical records on October 28, 2019. Pet'r's Exs. 140–144, ECF Nos. 131–32.

Respondent filed Dr. Vinay Chaudhry's expert report on March 6, 2020. Resp't's Ex. A, ECF No. 136-1. Accompanying medical literature followed on August 28, 2020. Resp't's Ex. A, Tabs 1–12, ECF No. 137. Petitioner filed Dr. Tornatore's second report with medical literature on February 8, 2021. Pet'r's Exs. 145–150, ECF No. 140. Petitioner filed additional medical literature on November 10, 2021. Pet'r's Ex. 151, ECF No. 143-2.

Petitioner also filed a motion for a ruling on the record on November 10, 2021. ECF No. 144. Respondent responded to Petitioner's motion on February 10, 2022, and Petitioner filed a reply on March 19, 2022. Resp't's Resp., ECF No. 150; Pet'r's Reply, ECF No. 151. This matter is now ripe for consideration.

II. Medical Records

A detailed account of Petitioner's relevant medical history can be found in my September 14, 2018 Fact Ruling. It is incorporated below with additional information, as needed, that has been provided in medical records filed post fact hearing. All medical records have been considered, although they may not all be discussed herein.

A. Pre-Vaccination

From 2009 through 2012, Petitioner's medical records primarily chronicle Petitioner's treatment for ADHD and gynecological care. *See generally* Pet'r's Ex. 21, ECF No. 14-2. On September 14, 2012, Petitioner initiated care with gynecologist Dr. Diane Hughes. Pet'r's Ex. 36 at 38, ECF No. 31-5. She was seen by her primary care practice on March 14, 2012, with general complaints of muscle cramps and aches, back pain, and arthritis. Pet'r's Ex. 35 at 13–14, ECF No. 31-4. Petitioner was treated for a rash in her underarms on May 9, 2012. *Id.* at 5. On October 11, 2012, Petitioner received a flu vaccine at her workplace, the San Jacinto Hospital. Pet'r's Ex. 25 at 4–5, ECF No. 21-1. On December 21, 2012, Dr. Hughes performed a colposcopy on Petitioner and diagnosed her with mild cervical dysplasia. Pet'r's Ex. 36 at 29. Petitioner was seen by Dr. Hughes for treatment of this condition through 2014. *See id.* at 2.

On August 6, 2013, Petitioner called Dr. Hughes' office to state that her birth control, Loestrin, was causing her to have nausea and diarrhea. *Id.* at 15. Petitioner requested to change her

birth control, and Dr. Hughes advised Petitioner to stop taking the current cycle of Loestrin and wait until the next cycle to start a new pack. *Id.* On August 12, 2013, Petitioner visited Dr. Hughes to discuss her birth control options. *Id.* at 13. Dr. Hughes wrote that Petitioner was "willing to try Loestrin again, as I believe diarrhea is coincidental." *Id.* at 14. Dr. Hughes told Petitioner that it was fine to use a different birth control medication if her problems with Loestrin did not improve. *Id.*

Petitioner called Dr. Hughes' office again on September 4, 2013, complaining of continued nausea and diarrhea from Loestrin. *Id.* at 12. Ms. Vanessa Ramirez, a medical professional in Dr. Hughes' office, informed Petitioner that diarrhea is "not a cause of the pill." *Id.* Ms. Ramirez advised Petitioner to see her primary care physician for her gastrointestinal symptoms. *Id.* Dr. Hughes subsequently ordered a prescription for NuvaRing, an alternative method of birth control, for Petitioner. *Id.*

On October 22, 2013, Petitioner presented to rheumatologist Dr. Prashanth Palwai following one week of pain "located in [her] bilateral wrists and hands [with] bruising . . . ." Pet'r's Ex. 6 at 13, ECF No. 7-6. Dr. Palwai noted in Petitioner's medical history that her mother is also a patient of his, and her mother suffers from systemic lupus erythematosus ("SLE").[8] *Id.* Dr. Palwai wrote that Petitioner's pain was "achy," with morning stiffness, and Petitioner's hands had been swelling for ten days. *Id.* at 13–14. Dr. Palwai ordered labs and x-rays of Petitioner's hands and wrists. *Id.* Dr. Palwai ultimately diagnosed Petitioner with unspecified inflammatory polyarthropathy[9] during the visit. *Id.* Petitioner's labs later returned as normal, except for a high glucose level and low vitamin D. *Id.* at 8–10; Pet'r's Ex. 77, ECF No. 91-4. Petitioner's x-rays were normal. Pet'r's Ex. 71 at 446–48, ECF No. 74-4.

B. Vaccination

On October 29, 2013, Petitioner received the flu vaccine at issue in this case in her right arm during her shift as a nurse at the San Jacinto Hospital. Pet'r's Ex. 25 at 1–3.

C. Post-Vaccination

On November 4, 2013, Petitioner saw Dr. Palwai to follow up on her diagnosis of polyarthropathy. Pet'r's Ex. 6 at 6. Dr. Palwai's notes show that Petitioner complained of left knee swelling for one day. *Id.* Dr. Palwai wrote that Petitioner's labs and x-rays were negative, and that a Medrol pack[10] had helped Petitioner's symptoms. *Id.* An examination of Petitioner's hands

[8] SLE is a "chronic, inflammatory, often febrile multisystemic disorder of connective tissue that proceeds through remissions and relapses . . . ." *Dorland's* at 1066. It is "characterized principally by involvement of the skin[], joints, kidneys, and serosal membranes." *Id.* The cause of this condition is unknown "but it may be a failure of regulatory mechanisms of the autoimmune system, since there are high levels of numerous autoantibodies against nuclear and cytoplasmic cellular components." *Id.*

[9] Inflammatory arthropathy is a "disease of a joint of inflammatory origin." *Dorland's* at 155.

[10] Medrol is a glucocorticoid steroid used to treat several types of disorders, including endocrine, rheumatological, dermatological, and ophthalmic. Upjohn Co., *Medrol Medicine Label* (1993),

"show[ed] no active synovitis[11] . . . ." *Id.* at 7. Dr. Palwai told Petitioner to monitor her symptoms, to start a vitamin D supplement, and to follow up as needed. *Id.* Petitioner called Dr. Palwai's office on November 16, 2013 "stating that her hands are red," and she was "hav[ing] a flare up." *Id.* Petitioner could not identify any reason why she would be experiencing these symptoms. *Id.* Dr. Palwai advised her to go to the emergency room if her symptoms became any worse and prescribed another Medrol pack. *Id.*

Petitioner returned to Dr. Palwai on December 9, 2013. *Id.* at 5. Petitioner chiefly complained of bilateral achy pain in her wrists and hands with bruising. *Id.* She further complained of a burning pain and that her hands and feet would turn red and her knuckles blue. *Id.* Dr. Palwai considered a differential diagnosis of Raynaud's versus acrocyanosis.[12] *Id.* Petitioner told Dr. Palwai that these symptoms were happening on a daily basis. *Id.* Dr. Palwai wrote that Petitioner had a negative SLE panel and normal labs in October of 2013, and that Petitioner's "symptoms started back then." *Id.* Dr. Palwai wrote that Medrol packs helped Petitioner's bruising. *Id.* Dr. Palwai reaffirmed Petitioner's diagnosis of unspecified inflammatory polyarthropathy and added unspecified diffuse connective tissue disease. *Id.* Dr. Palwai prescribed Petitioner another Medrol pack for six weeks and told her to follow up in three months. *Id.*

On December 17, 2013, Petitioner returned to Dr. Hughes. Pet'r's Ex. 36 at 6–7. Petitioner reported burning, swelling, and pain in her wrists "and other joint[s]." *Id.* at 7. Petitioner said that she was on steroids for her joint pain and swelling but thought her NuvaRing may be causing her symptoms. *Id.* Dr. Hughes asked Petitioner to stop using the NuvaRing to see how she felt. *Id.* at 8. Dr. Hughes also wrote that she "suspect[ed] [Petitioner is] taking after her mom[,] who also has SLE." *Id.* at 9.

On December 30, 2013, Petitioner visited Dr. Chandra Higginbotham at the Women's Health Solution for "a consultation regarding her immune system." Pet'r's Ex. 27 at 2, ECF No. 24-1. Petitioner presented "with malaise and [f]atigue" and generalized weakness. *Id.* Dr. Higginbotham wrote that Petitioner was experiencing extreme fatigue and that she began "having problems with weakness [starting in] 8/2013 [sic]." *Id.* Petitioner further described "burning in both hands [and feet] and redness." *Id.* Dr. Higginbotham recorded that "[Petitioner] did not start to feel bad until 8/2013 [sic]." *Id.* Dr. Higginbotham ordered lab tests, including tests for antibodies to the Epstein-Barr virus[13] and Lyme disease.[14] *Id.* at 3–5.

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https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=011153. It is unclear from Dr. Palwai's medical records if, or when, he prescribed Petitioner a Medrol pack from October 22, 2013 to November 4, 2013. Pet'r's Ex. 6 at 6–13.

[11] Synovitis is the inflammation of the synovium, a fluid-filled membrane surrounding joints. *Dorland's* at 1826.

[12] Acrocyanosis is the "symmetrical cyanosis [bluish discoloration] of the extremities, with persistent, uneven blue or red discoloration of the skin of the digits, wrists, and ankles accompanied by profuse sweating and coldness of the digits." *Dorland's* at 19.

[13] Epstein-Barr virus causes infectious mononucleosis. *Dorland's* at 843.

[14] Lyme disease is "a recurrent, multisystemic disorder caused by the spirochete *Borrelia burgdorferi*[.]" *Dorland's* at 531.

Prior to receiving her lab test results from Dr. Higginbotham, Petitioner returned to Dr. Palwai on December 31, 2013. Pet'r's Ex. 6 at 3. Dr. Palwai wrote that Petitioner had "persistent joint symptoms" and felt frustrated. *Id.* Petitioner complained of increased, "burning" pain as she tapered her Medrol. *Id.* A neurologic exam revealed no localized findings. *Id.* Dr. Palwai repeated the diagnoses of unspecified inflammatory polyarthropathy and unspecified diffuse connective tissue disease. *Id.* He decreased Petitioner's Medrol dose and started her on Plaquenil[15] and gabapentin[16] for pain. *Id.* at 4.

On January 10, 2014, Ms. May Kassm from Dr. Hughes' office called Petitioner to confirm a medical record release. Pet'r's Ex. 36 at 3. Petitioner assented and explained that she "ha[d] not been feeling well since August." *Id.* Petitioner returned to Dr. Higginbotham on January 16, 2014, to review her test results. Pet'r's Ex. 27 at 7. Petitioner's insulin was "very elevated," as were her platelets and lymphocytes. *Id.* Dr. Higginbotham also noted that Petitioner had abnormal results on her thyroid tests, consistent with a "nonspecific abnormality." *Id.* Petitioner explained that she was "under a lot of stress" and continued to suffer from fatigue. *Id.* Dr. Higginbotham wrote that Petitioner had seen "minimal improved status of the erythema of the hands," and presented with a rash. *Id.* Dr. Higginbotham wrote that "[Petitioner] states after receiving the flu shot [two] years ago she developed a rash on her cheek area, [which] flares up from time to time and is now darker and pruritic."[17] *Id.* Dr. Higginbotham prescribed a cream for Petitioner's rash and wellness pills for her abnormal thyroid results and advised Petitioner to minimize stress. *Id.* at 9–10.

On January 27, 2014, Petitioner saw Dr. Srinivas Panja on referral from Dr. Palwai for an evaluation of her abnormal thyroid tests and hyperglycemia. Pet'r's Ex. 32 at 15, ECF No. 31-1. Dr. Panja wrote that Petitioner was in good health until recently. *Id.* Dr. Panja indicated that four months ago, Petitioner "started with painful red lesions on her leg," which "[were] associated with joint pain and fatigue, muscle ache[,] and weight loss." *Id.* Upon review, Dr. Panja did not see any redness in Petitioner's extremities. *Id.* at 16. Dr. Panja diagnosed Petitioner with an abnormal thyroid function test, "[o]ther malaise and fatigue," and "[d]ysmetabolic syndrome X."[18] *Id.* He

[15] Plaquenil is the brand name for hydroxychloroquine sulfate. Concordia Pharm., Inc., *Plaquenil Medicine Label* (2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/009768s037s045s047lbl.pdf. It is approved to treat malaria, rheumatoid arthritis, and SLE, although the mechanisms by which it treats these symptoms is unknown. *Id.* at 2.

[16] Gabapentin is the generic version of Neurontin and is "structurally related to the neurotransmitter gamma-aminobutyric acid (GABA) but has no effect on GABA binding, uptake, or degradation." Pfizer, Inc., *Neurontin Medication Guide* 18 (2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020235s064_020882s047_021129s046lbl.pdf. Neurontin is indicated for the treatment of post-herpetic neuralgia in adults and as adjunctive therapy for partial onset seizures. *Id.* at 1.

[17] Pruritus is defined as any condition that causes "an unpleasant cutaneous sensation that provokes the desire to rub or scratch the skin to obtain relief." *Dorland's* at 1516.

[18] Dysmetabolic syndrome X, otherwise known as a metabolic syndrome or metabolic syndrome X, consists of "a combination including at least three of the following: abdominal obesity, hypertriglyceridemia, low level of the high-density lipoproteins, hypertension, and high fasting plasma glucose levels." *Dorland's* at 1809. This syndrome "is associated with an increased risk for development of diabetes mellitus and cardiovascular disease." *Id.*

did not recommend any treatment then but ordered more labs. *Id.* The lab results showed abnormally low levels of immune cell function and parathyroid hormone. Pet'r's Ex. 50, ECF No. 70-6.

On that same day, January 27, 2014, Petitioner visited Dr. Michelle E. Legall-Johnson to initiate care at Integrity Family Healthcare. Pet'r's Ex. 73 at 13, ECF No. 78-3. Dr. Legall-Johnson wrote that Petitioner had symptoms of an upper respiratory infection for the past month; worsening joint pain, mostly in her wrists; unexplained bruising; and daily swelling and warmth of both hands and feet. *Id.* Dr. Legall-Johnson wrote that Petitioner "began bruising in 08/2014 [sic] and it worsened until 10/2014 [sic]."[19] *Id.* Petitioner stated that she feels "hot and tired all [of] the time." *Id.* Dr. Legall-Johnson listed "[d]iagnoses attached to this encounter[]" as endometriosis, ADHD, Raynaud's disease, multiple join pain, and limb swelling. *Id.*

On February 3, 2014, Petitioner returned to Dr. Palwai. Pet'r's Ex. 19 at 131, ECF No. 10-2.[20] Dr. Palwai observed an ulcer on Petitioner's left ear but noted no other complaints. *Id.* He recorded that Medrol was helping Petitioner's symptoms. *Id.* Dr. Palwai's assessment included bruising, rash, pain, Raynaud's, and ADD. *Id.* at 132. On the same day, Petitioner visited Dr. Legall-Johnson. Pet'r's Ex. 73 at 11. Dr. Legall-Johnson recorded that Petitioner felt "generally the same[, s]till tired [and] achy." *Id.* Dr. Legall-Johnson's assessment included a skin ulcer on the left ear, hypoparathyroidism,[21] "[d]isorder of adrenal gland," and major depressive disorder. *Id.*

On February 20, 2014, Petitioner visited Dr. Higginbotham. Pet'r's Ex. 27 at 11. Petitioner complained of generalized weakness, malaise, and fatigue. *Id.* Dr. Higginbotham reviewed Petitioner's lab results, noting that Petitioner tested positive for Epstein-Barr virus antibodies and that her results were consistent with insulin resistance syndrome. *Id.* Dr. Higginbotham wrote that "[she] is concerned about [Petitioner's] overall immune status" and "can[not] see how [Petitioner] can go back to work and function at her normal capacity with her level of physical compromise [sic]." *Id.* at 14. Dr. Higginbotham recommended that Petitioner should continue her disability "until further notice" because she "could be more susceptible to illness if exposed in the hospital setting." *Id.*

On February 25, 2014, Petitioner established care with the rheumatologist Dr. Sabeen Najam. Pet'r's Ex. 8 at 10, ECF No. 7-8. Petitioner complained of "pain on [her] legs." *Id.* Dr. Najam wrote that Petitioner's labs were positive for antinuclear antibodies[22] ("ANA"), "but specific antibodies are negative." *Id.* Dr. Najam ordered additional labs and diagnosed Petitioner

[19] Respondent wrote in his Rule 4(c) Report that this timeline from Dr. Legall-Johnson was "a typographical error" given the date of Petitioner's appointment. ECF No. 81 at 6 n.5. I agree.

[20] Petitioner filed Exhibit 19 in five parts. *See* ECF Nos. 10-1–10-5.

[21] Hypoparathyroidism is "the condition produced by greatly reduced function of the parathyroid glands[,]" which are "small bodies apposed to the posterior or interior surfaces of the thyroid gland[] . . . ." *Dorland's* at 892.

[22] ANAs are antibodies "directed against nuclear antigens" and are "frequently found in rheumatoid arthritis, scleroderma (systemic sclerosis), Sjögren's syndrome, and mixed connective tissue disease." *Dorland's* at 99.

with unspecified diffuse connective tissue disease and joint pain. *Id.* Petitioner's labs, taken the same day, were negative for ANA. *Id.* at 13. Petitioner visited allergist Dr. Kenneth Kray that day for a complete evaluation. Pet'r's Ex. 19 at 331, ECF No. 10-5. Dr. Kray recorded that Petitioner had been experiencing immune system dysfunction since October of 2013 and was being treated with Medrol and Plaquenil. *Id.* Dr. Kray diagnosed Petitioner with pruritus and perennial rhinitis[23] and ordered a spirometry test.[24] *Id.* at 333.

On March 4, 2014, Petitioner returned to Dr. Higginbotham. Pet'r's Ex. 27 at 15. Petitioner complained that "some days she has severe fatigue and [becomes] very hot in her extremities." *Id.* Petitioner told Dr. Higginbotham that she had foot pain "that all started with bruising of her hands." *Id.* Dr. Higginbotham also recorded that Petitioner had been "texting [Dr. Higginbotham] pictures of her extremities for the past few weeks." *Id.* These texts included photographs of the bruising in Petitioner's hands. *Id.* Dr. Higginbotham wrote that "as [Petitioner] is looking through her phone[,] the date the bruises began was 10/20/2013 [sic]." *Id.* Dr. Higginbotham recorded that Petitioner was denied short-term disability, "which [Dr. Higginbotham] can[not] understand even with [her] doctor's note." *Id.* Dr. Higginbotham wrote that she would send a letter to help Petitioner obtain short-term disability. *Id.*

Dr. Higginbotham authored a letter for Petitioner's short-term disability claim on the same day. Pet'r's Ex. 3 at 26, ECF No. 7-3. Dr. Higginbotham summarized Petitioner's diagnoses[25] and wrote that Petitioner "is not able to perform her job duties as a nurse due to her immunodeficiency[,] as she will be a risk to her health and the patients." *Id.* at 26–27, 29. Dr. Higginbotham also ordered labs, which were positive for blastocystis hominis.[26] *Id.* at 17.

On March 6, 2014, Petitioner visited Dr. Kray. Pet'r's Ex. 4 at 2, ECF No. 7-4. Dr. Kray observed "localized erythema without itching" that was not severe and advised Petitioner to continue her medications. *Id.* at 3. Dr. Kray also wrote a letter for Petitioner advising her employer that Petitioner is to perform "no patient care until [a] complete rheumatological evaluation is complete." *Id.* at 1. On this date, Petitioner also had an MRI of her right wrist performed. Pet'r's Ex. 8 at 18. The study showed "no evidence of [an] active inflammatory arthropathy." *Id.*

On March 17, 2014, Petitioner had an MRI performed of her left wrist, which showed "no active marginal erosions." *Id.* at 17. On March 25, 2014, Petitioner visited Dr. Najam to follow up

[23] Perennial rhinitis is an "inflammation of the mucous membrane of the nose" that "may occur continuously or intermittently all year round; it is caused by an allergen to which the individual is more or less always exposed . . . ." *Dorland's* at 1613.

[24] Spirometry is "the measurement of the breathing capacity of the lungs, such as in pulmonary function tests." *Dorland's* at 1722.

[25] Dr. Higginbotham listed Petitioner's diagnoses and the dates on which they were given. Pet'r's Ex. 3 at 26. They included: unspecified inflammatory polyarthropathy (October 22, 2013); unspecified diffuse connective tissue disease (December 9, 2013); Raynaud's phenomenon, rash, pain and bruising (February 3, 2014); allergic reaction (February 13, 2014). *Id.*

[26] Blastocystis hominis is "a species of yeast frequently found in human feces" that can cause blastocystosis, a fungal infection resulting in diarrhea and other gastrointestinal discomfort. *Dorland's* at 219.

on her MRI results. *Id.* at 8. Dr. Najam counseled that Petitioner's MRI and lab results showed no evidence of rheumatoid arthritis, systemic lupus, Sjögren's Syndrome, mixed connective tissue disease, "or any other connective tissue disease at this time." *Id.* Dr. Najam diagnosed Petitioner with unspecified diffuse connective tissue disorder and ordered blood tests. *Id.* Petitioner's blood tests were normal and Dr. Najam prescribed Imuran.[27] *Id.* at 15.

On April 15, 2014, Dr. Najam authored a note to Petitioner's employer. Pet'r's Ex. 47 at 12, ECF No. 70-3. Dr. Najam wrote that Petitioner was under her care "for [the] diagnosis of [u]ndifferentiated connective disease" and should avoid "close contact with actively sick patients" due to her immunocompromised state. *Id.* Petitioner visited Dr. Najam on April 22, 2014, when Petitioner noted a "[R]aynaud['s-]like change of her feet." Pet'r's Ex. 14 at 49, ECF No. 9-2.[28]

On May 3, 2014, Petitioner presented to the San Jacinto Methodist Hospital with abdominal pain and rectal bleeding. *See generally* Pet'r's Ex. 5, ECF No. 7-5. A sigmoidoscopy[29] was performed and revealed internal hemorrhoids and "mild colonic spasm consistent with irritable bowel syndrome." *Id.* at 14. An abdominal ultrasound was normal, and an abdominal x-ray showed no obstruction or abnormalities. *Id.* at 16–17. A CT scan was also performed on Petitioner, but it showed normal results. *Id.* at 18. Petitioner was diagnosed with "lower [gastro-intestinal tract] bleeding" and discharged the same day. *Id.* at 1, 9.

The next day, Petitioner saw Dr. Legall-Johnson with continuing abdominal pain and was admitted to the Kingwood Medical Center. Pet'r's Ex. 71 at 213. Dr. Legall-Johnson noted that Petitioner's fecal studies from her hospitalization "were significant for leukocytes and tested positive for [cytomegalovirus ("CMV") antigens]."[30] *Id.* Petitioner told Dr. Legall-Johnson that her rectal bleeding "had subsided[,] but [she] still feels like she has [a] subjective fever [with] chills and feels exhausted all of the time." *Id.* Dr. Legall-Johnson diagnosed Petitioner with CMV gastritis and hematochezia[31] and referred Petitioner to gastroenterologist Dr. George Nunez, Jr. *Id.* at 214.

On the same day, Dr. Nunez recorded Petitioner's complaints as "[b]ilateral lower quadrant abdominal pain[,] [r]ectal bleed[ing, and] [n]ausea." *Id.* at 210. Dr. Nunez wrote that "[t]he patient [presents] with a history of onset of an undetermined autoimmune disorder[] that apparently was initiated after [a] flu vaccine." *Id.* Dr. Nunez recorded that after Petitioner was discharged from her hospital stay, "[she] continued to have bilateral lower quadrant abdominal cramping pain and [was] no longer was having diarrhea . . . ." *Id.* Petitioner also complained of constipation to Dr.

[27] Imuran is an immunosuppressive antimetabolic indicated to treat rheumatoid arthritis. Prometheus Labs., Inc., *Imuran Medication Label* 1, 3 (2014), https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/016324s037,017391s016lbl.pdf.

[28] The page number for this exhibit refers to the pagination generated by CM/ECF.

[29] A sigmoidoscopy is "inspection of the sigmoid colon through a sigmoidoscope."

[30] These studies are found in Petitioner's Exhibit 5, pages 19–30. The results from these tests do not corroborate Dr. Legall-Johnson's assertions. Petitioner, in fact, tested negative for fecal leukocytes and cytomegalovirus. Pet'r's Ex. 5 at 27; Pet'r's Ex. 19 at 38.

[31] Hematochezia is the presence of blood in the feces. *Dorland's* at 822.

Nunez. *Id.* Upon examination, Dr. Nunez noted Petitioner's complaints of chronic nausea, "thought to be due to her medication[,]" and joint pain. *Id.* at 211. Dr. Nunez wrote that he "doubts we are dealing with [an] inflammatory or infectious process[;] it is likely functional." *Id.* Dr. Nunez added Bentyl[32] and a laxative to Petitioner's medications to address her constipation and wrote, "[w]e will monitor and treat her with antiemetics as well." *Id.* Dr. Legall-Johnson ordered a CT with contrast of Petitioner's colon, which showed no obstruction. *Id.* at 338. Dr. Legall-Johnson also ordered an esophageal endoscopy. *Id.* at 283. The endoscopy revealed candida esophagitis,[33] a "small hiatus hernia" in the stomach, and erosive gastritis in the antrum and body of the stomach. *Id.* Petitioner also began complaining of "generalized itching" while in the Kingwood Medical Center. *Id.* at 217. On May 8, 2014, Petitioner was given hydroxyzine for her itching and was discharged. *Id.* at 215.

Petitioner was referred for psychological assessment and met with licensed psychologist Richard Krummel on July 23, 2014. Pet'r's Ex. 48 at 1–3, ECF No. 70-4. Dr. Krummel assessed Petitioner with depression. *Id.* at 3. Using a "self-report personality assessment," called the Minnesota Multiphasic Personality Inventory-2, Dr. Krummel noted "the clinical profile is significant for the presence of three scales which strongly suggest the conversion of psychological or situational stress into vague physical symptoms for which there may not be a medical etiology." *Id.* at 2–3. He continued that Petitioner "may have some functional medical dynamics[,] but it seems likely these are exacerbated by the conversion process." *Id.* He further opined that "[f]or individuals with this type of profile, the physical symptoms they complain of are real from their point of view and their psychological framework." *Id.* at 3.

On August 18, 2014, Petitioner established care with neurologist Dr. Holly Varner of the University of Texas Physicians Group. Pet'r's Ex. 19 at 142, ECF No. 10-2. Dr. Varner found that Petitioner "has myelopathic[34] symptoms and a history of post[-]vaccine reaction" and ordered an EMG. *Id.* at 145. On September 2, 2014, Dr. Najam examined Petitioner and found her clinically and objectively stable. Pet'r's Ex. 62 at 4, ECF No. 71-9. Dr. Najam did not see any sign of active connective tissue disease at the time and advised Petitioner to continue with Imuran and Plaquenil. *Id.* The next day, Petitioner had MRIs performed on her brain and spine. Pet'r's Ex. 19 at 138–39. Both showed normal results. *Id.*

On September 4, 2014, Dr. Varner performed an EMG and nerve conduction study on Petitioner. Pet'r's Ex. 18 at 3, ECF No. 9-6. This study revealed a "very mild, demyelinating, [] median mononeuropathy at the wrist (carpal tunnel syndrome)."[35] *Id.* at 6. There were "scattered myopathic appearing units" in the study "without evidence . . . of a diffuse myopathy." *Id.* The

[32] Bentyl is "an antispasmodic and anticholinergic (antimuscarinic) agent indicated for the treatment of functional bowel/irritable bowel syndrome." Aptalis Pharma US, Inc., *Bentyl Medicine Label* 1 (2013), https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/007409s042,008370s033lbl.pdf.
[33] Candidal esophagitis is an inflammation of the esophagitis caused by a fungal infection of the Candida species. *Dorland's* at 640.
[34] Myelopathy is "any of various functional disturbances or pathological changes in the spinal cord, often referring to nonspecific lesions in contrast to the inflammatory lesions of myelitis." *Dorland's* at 1203.
[35] Petitioner's records contain a large black streak obscuring the omitted word in this sentence. *See* Pet'r's Ex. 18 at 6.

study also noted "changes consistent with degenerative disc disease in the cervical and lumbosacral spines to a mild-moderate degree . . . ." *Id.* However, the study did not find any evidence of "a clear specific cervical or lumbosacral radiculopathy . . . ." *Id.* After the study, Dr. Varner saw Petitioner to follow up on her lower extremity pain. Pet'r's Ex. 19 at 31. Petitioner complained of pain and weakness in her legs, tingling in her fingertips, and intermittent bowel incontinence. *Id.* Dr. Varner called for more labs and an MRI of Petitioner's abdomen. *Id.* at 33. "Based upon these findings," Dr. Varner wrote, "we may need to refer [Petitioner] for a muscle biopsy." *Id.*

Petitioner visited Dr. Palwai on November 4 and December 2, 2014. Pet'r's Ex. 67 at 50, 47, ECF No. 72-5. On December 2, 2014, Petitioner complained that the Imuran was causing nausea and gastritis, but she otherwise had "no[]other complaints." *Id.* at 47. On January 22, 2015, Petitioner returned to Dr. Varner. Pet'r's Ex. 40 at 21, ECF No. 38-1. Dr. Varner noted that Petitioner had a recent muscle biopsy. *Id.* Petitioner's "main complaint[s] continue[d] to be burning in her legs [and] arms and weakness." *Id.* Dr. Varner wrote that she was "still in the process of establishing a clear etiology for [Petitioner's] condition." *Id.* at 24. Dr. Varner stated that she would "consider requesting a small fiber biopsy to help determine the cause of [Petitioner's] neuropathic symptoms[]" once Dr. Varner received Petitioner's muscle biopsy results. *Id.* The next day, January 23, 2015, Dr. Varner received the report from Petitioner's muscle biopsy, which was normal. *Id.* at 16–17. Petitioner continued to receive treatment for her condition over the following year. In a subsequent visit, Dr. Varner observed that Petitioner "ha[d] some allodynia[36][,] but [Dr. Varner] [did not] see any sign of peripheral neuropathy." Pet'r's Ex. 64 at 84, ECF No. 72-2. On April 22, 2015, Dr. Varner assessed Petitioner with muscle cramps, paresthesias, muscle weakness, mixed connective tissue disease, and vitamin D deficiency. *Id.* at 113.

On May 18, 2015, Dr. Palwai wrote a letter to clarify Petitioner's symptoms that she reported on October 22, 2013. Pet'r's Ex. 37 at 2, ECF No. 32-1. Dr. Palwai wrote that Petitioner first presented to him with "complaints of swelling, joint pain, and stiffness, along with [Raynaud's]." *Id.* Dr. Palwai noted that his "original diagnosis was an unspecific inflammatory polyarthropathy." *Id.* Dr. Palwai "added the diagnosis of unspecified diffuse connective tissue disease" after Petitioner's complaints persisted "and additional complaints . . . manifested." *Id.* He explained that unspecified diffuse connective tissue disease "is a diagnosis when there is evidence of an existing autoimmune condition which does not meet the criteria for any specific autoimmune disease." *Id.* Dr. Palwai concluded that he cannot opine on the cause of her condition, but "there is no question that [Petitioner's] diagnosis is [unspecified connective tissue disease], first manifesting in October of 2013." *Id.*

On October 23, 2015, Petitioner returned to Dr. Palwai. Pet'r's Ex. 53 at 21, ECF No. 70-9. Dr. Palwai diagnosed Petitioner with discoid SLE and ordered Benlysta[37] "as [Petitioner] has new onset discoid lesions[,] confirming [SLE]." *Id.* at 22. Petitioner was advised to continue her

[36] Allodynia consists of "pain resulting from a non-noxious stimulus to normal skin." *Dorland's* at 51.
[37] Benlysta is "a B-lymphocyte stimulator-specific inhibitor indicated for the treatment of adult patients with active, autoantibody-positive [SLE] who are receiving standard therapy." GlaxoSmithKline, Inc., *Benlysta Medicine Label* 1 (2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761043lbl.pdf.

medications. *Id.* On November 22, 2015, Dr. Palwai wrote a second letter clarifying Petitioner's symptoms during her initial visit in October of 2013. Pet'r's Ex. 45, ECF No. 48-2. Dr. Palwai stated that Petitioner "did not show signs or symptoms of [Raynaud's] on her initial visit on [October 22, 2013]." *Id.* On November 24, 2015, Petitioner received her first infusion of Benlysta to treat her SLE. Pet'r's Ex. 53 at 15. Petitioner visited Dr. Palwai for additional Benlysta infusions on December 8 and 18, 2015. *Id.* at 8, 11.

On February 11, 2016, Dr. Palwai wrote a case review in a third attempt to accurately describe Petitioner's symptoms during her initial visit on October 22, 2013, and her subsequent treatment. Pet'r's Ex. 67 at 13; *see also* Pet'r's Ex. 95, ECF No. 94-8. Dr. Palwai wrote that Petitioner presented with "pain in [her] hands and wrists[,] and bruising." Pet'r's Ex. 67 at 13. Dr. Palwai continued that during Petitioner's second visit on November 4, 2013, Petitioner "had new onset of left knee swelling." *Id.* Dr. Palwai wrote that Petitioner complained that "her hands were turning red and knuckles blue" on November 16, 2013, and Dr. Palwai first suspected Raynaud's on December 9, 2013. *Id.* "[S]ubsequent visits" established a diagnosis of Raynaud's. *Id.* Petitioner "had persistent joint symptoms[,] and her symptoms worsened when steroids were tapered[,] which led to the diagnosis of undifferentiated connective tissue disease on [December 31, 2013]." *Id.* Dr. Palwai then summarized Petitioner's medical history before concluding that, considering Petitioner's history and her mother's diagnosis with SLE, Petitioner "has an autoimmune disease which appears to be [l]upus." *Id.*

Furthermore, a letter from Dr. Palwai, also dated February 11, 2016, provides a symptom chronology and treatment timeline. *See* Pet'r's Ex. 95 at 1. In this letter, Dr. Palwai stated that Petitioner first complained of pain in her hands and wrists with bruising on October 22, 2013. *Id.* He indicated that those symptoms continued, and Petitioner later complained of left knee swelling, red hands, blue knuckles, and persistent joint symptoms. *Id.* Petitioner was diagnosed with Raynaud's and then UCTD. *Id.* Dr. Palwai repeated that Petitioner "has an autoimmune disease which appears to be lupus." *Id.* Dr. Palwai noted Petitioner was diagnosed with lupus in October of 2015. *Id.*

During 2016, Petitioner continued treatment related to her conditions. On March 2, 2016, Petitioner's treating rheumatologist, Dr. Kiran Farheen, diagnosed Petitioner with possible "myositis[38] [] which [may have] improved on Imuran." Pet'r's Ex. 56 at 9, ECF No. 71-3. Dr. Farheen referred Petitioner to the Mayo Clinic for a complete neurological workup. *Id.* at 14. Dr. Farheen additionally counseled Petitioner to stop Benlysta due to its ineffectiveness in treating her symptoms. *Id.* at 9.

Petitioner underwent a comprehensive single specialty neurologic examination on April 29, 2016, at the Mayo Clinic. Pet'r's Ex. 65 at 12–13, ECF No. 72-3. Her review of symptoms was broadly positive and neurologist Dr. Benn Smith wrote, "[w]hile this may reflect what has been thought to be an autoimmune process (considered to be mixed connective tissue disease) for which

[38] Myositis is an "inflammation of a voluntary muscle; called also inflammatory myopathy." *Dorland's* at 1208 (emphasis omitted).

she is receiving [a] corticosteroid, hydroxychloroquine[,] and azathioprine[39] treatment[,] currently there may be an element of a strong 'mind-body' interaction as well." *Id.* at 13. Dr. Smith noted that Petitioner's muscle strength and biopsy were normal, and her "EMG was close to normal with no evidence of active denervation." *Id.* He stated that evidence of "clinically significant myopathy [was] sparse at best." *Id.* Dr. Smith did report that Petitioner exhibited "subject sensory deficits in a length-dependent pattern despite the sensory nerve responses being normal in [her] upper and lower limbs by nerve conduction studies (09/04/2014) [sic]." *Id.* Additionally, he noted that "localization remains uncertain." *Id.*

Petitioner's medical record also includes a May 24, 2016 letter from Dr. Farheen, wherein she wrote, "[Petitioner] had 2 flu shots, the first one in 2012[,] and [she] developed a rash after that then again in 2013[. A]nd this time [her r]ash got worse followed by pain, fatigue, [and] joint pain/arthralgias." Pet'r's Ex. 72 at 239, ECF No. 78-2. Dr Farheen included a brief history of Petitioner's medical symptoms and conditions in her letter and ultimately concluded, "[a]t this time, I do[not] have any further diagnostic tests or evaluation to diagnose her . . . ." *Id.*

Petitioner saw Dr. Varner on May 27, 2016. Pet'r's Ex. 64 at 201. Dr. Varner recorded that Petitioner exhibited a decreased response to stimulation by vibration at the toes of both feet and decreased response to pain and temperature on the right and left sides. *Id.* at 204. Petitioner's assessment included dysphasia, leg weakness, muscle cramps, Raynaud's phenomenon, and paresthesias. *Id.* Petitioner had an EMG and nerve conduction studies performed on June 23, 2016. *Id.* at 216. Dr. Varner noted the NCS/EMG showed mild myopathic changes and evidence of mild degenerative changes. *Id.* at 219. Dr. Varner noted that Petitioner "has an improved EMG with normal nerve conduction studies. She does[not] have burning in her feet so I do[not] want to get a small fiber biopsy at this time that might be negative." *Id.* at 228.

On July 18, 2016, Petitioner presented to dermatologist Dr. Sarah Pinney after being referred by Dr. Farheen. Pet'r's Ex. 72 at 120. Petitioner presented for "darkening of the skin that started slowly after she started [] Plaquenil in" December of 2013, as well as ulcers on her ears that had also been present since December of 2013. *Id.* Dr. Pinney noted that Petitioner "began having systemic [symptoms] in 2013 after her flu shot." *Id.* In a note to Dr. Pinney dated July 19, 2016, Dr. Farheen stated that he had completed "a thorough workup" that "has not revealed a diagnosis." *Id.* at 115. He continued that there was "nothing [] really remarkable in labs on her." *Id.* Also in July of 2016, Petitioner requested a letter from Dr. Pinney stating that she had been diagnosed with a dermatological condition secondary to vaccination. *Id.* at 98. Dr. Pinney was unable to identify the cause of Petitioner's condition and could not attribute it to a vaccine administered several years prior. *Id.* at 99. Dr. Pinney also noted that she had "never s[een] [Petitioner's] original rash." *Id.*

Petitioner was examined at the Mann Eye Institute on September 16, 2016, and diagnosed with chronic bilateral giant papillary conjunctivitis. Pet'r's Ex. 94 at 4, ECF No. 94-7. She continued to seek treatment for her rheumatological, ophthalmological, dermatological, and psychiatric conditions throughout 2016.

[39] Azathioprine is used to treat rheumatoid arthritis and other autoimmune disorders. *Dorland's* at 184.

Petitioner had a rheumatology visit with Dr. Beth Scholz on April 19, 2017. Pet'r's Ex. 79 at 1, ECF No. 91-6. Dr. Scholz noted that Petitioner's "[d]isease seems to behave a lot like lupus but lacks appropriate serologies." *Id.* at 5. She believed "[t]he best label for [Petitioner's condition] is UCTD." *Id.* In July of 2017, Dr. Varner became "concerned about a peripheral neuropathy." Pet'r's Ex. 123 at 88, ECF No. 116-9. During a July 27, 2017 exam, Dr. Varner noted decreased light touch in Petitioner's right hand and decreased response to pain and temperature on her left side. *Id.* at 85, 88. During a rheumatology visit on August 3, 2017, Petitioner complained of right upper arm swelling and weakness, neuropathy, and bilateral arm pain. Pet'r's Ex. 110 at 1, ECF No. 115-3. A skin biopsy performed on November 14, 2017, revealed evidence of a mild small fiber neuropathy. Pet'r's Ex. 107 at 1–2, ECF No. 100-5. Specifically, on biopsy, Petitioner's epidermal nerve fiber density on her left distal leg was 7.7/mm, which the evaluating neurologist noted was "below the 5th percentile for sex and age matched controls (20-29 yrs. 8.4/mm[).]" *Id.* at 1. The skin biopsy also showed "[p]redegenerative changes includ[ing] attenuated caliber, minor axonal bleedings, and frequent fragmented appearing fibers[]" on Petitioner's left distal leg. *Id.* The samples from Petitioner's left distal thigh and left proximal thigh showed normal epidermal nerve fiber density, but "[m]ild predegenerative changes [were also] present[]" on Petitioner's left distal thigh. *Id.*

Dr. Varner's complete assessment of Petitioner as of December 7, 2017, was small fiber neuropathy, UCTD, myositis of the right forearm, scleritis, paresthesias, muscle weakness, and discoid lupus erythematous. Pet'r's Ex. 117 at 8, ECF No. 116-3. Dr. Varner noted that Petitioner's small fiber neuropathy was "most likely related to a connective tissue disease process." *Id.* Throughout 2018, Petitioner continued to complain of worsening bilateral hand, wrist, elbow, knee, ankle, and foot pain with stiffness. *Id.*

III. Other Fact Evidence

Petitioner submitted several personal affidavits[40] and testified at the fact hearing. *See* Pet'r's Exs. 1, 44, 89, 90. A detailed account of Petitioner's statements can be found in my September 14, 2018 Fact Ruling. Her statements are incorporated and summarized below as needed.

A. Petitioner's First Affidavit, Petitioner's Exhibit 1

Petitioner submitted her first affidavit on August 29, 2014. ECF No. 7-1. Petitioner wrote that she had never received a flu vaccine prior to October 29, 2013, "and the symptoms [relevant to her claim] did not occur until after [she] receiv[ed] the flu vaccine . . . ." *Id.* Petitioner attested that the symptoms of "swelling, pain, and burning sensation worsened and extended even deeper in [her] lower extremities" in December of 2013. *Id.* at 2.

Petitioner wrote that her symptoms worsened in her lower extremities again in February of 2014. *Id.* On March 25, 2014, Dr. Sabeen Najam "confirmed that [Petitioner] had unspecified diffuse connective tissue disease . . . ." *Id.* Petitioner wrote that she was hospitalized on May 5,

[40] Petitioner's fourth affidavit was related solely to her motion for redaction of my Fact Ruling.

2014, and informed "that [she] was allergic to the influenza vaccine."[41] *Id.* Petitioner stated that she was also told "[d]uring [this] hospital visit" that the flu vaccine "caused [her] autoimmune illness [and] Raynaud's phenomenon[] and triggered the autoimmune responses in [her] body."[42] *Id.* Upon discharge from her hospitalization, Petitioner saw Dr. George Nunez with "severe bilateral lower quadrant abdominal pain," and Dr. Nunez stated that her disease was "apparently initiated after receiving the flu vaccine." *Id.* at 3. She noted that her symptoms have not remitted, and therapies to ease her symptoms have failed. *Id.*

B. Petitioner's Second Affidavit, Petitioner's Exhibit 44

Petitioner filed her second affidavit on December 4, 2015, after "[her] attorney asked [her] to prepare a statement addressing the onset of [her UCTD] symptoms." ECF No. 48-1 at 2. Petitioner confirmed that she took her mother to her rheumatology appointment with Dr. Palwai on October 22, 2013. *Id.* Petitioner explained that "[b]ecause [she] knew Dr. Palwai through [her] mother," Petitioner discussed her wrist pain with him, and described "feeling numbness and tingling in [her] hands and wrists." *Id.* at 1. Petitioner stated that she was "concerned that [she] might have a repetitive trauma like carpal tunnel syndrome," and Dr. Palwai ordered an x-ray and blood work. *Id.* Petitioner wrote that by November 4, 2013, she was experiencing "new symptoms [she] had never had before." *Id.*

Petitioner repeated the summary of her medical records from her previous affidavit. *Id.* at 1–2. Petitioner wrote that her carpal tunnel diagnoses "was ultimately confirmed . . . [on] September 4, 2014[,] by [] Dr. [] Varner . . . ." *Id.* at 2. Petitioner attested that her symptoms prior to vaccination resulted from her carpal tunnel syndrome, and "ha[ve] nothing to do with [her UCTD]." *Id.*

C. Petitioner's Third Affidavit, Petitioner's Exhibit 89

Petitioner submitted her third affidavit on August 21, 2017. ECF No. 94-2. Petitioner admitted that on October 11, 2012, she received a flu vaccine at her workplace. *Id.* at 1. But she maintained that she had never received a flu vaccine prior to this date. *Id.* Petitioner wrote that shortly after the administration of her 2012 vaccine, she developed a rash at the site of her injection and on the right side of her face. *Id.* She purchased and took a Zyrtec to treat her symptoms, which quickly improved. *Id.*

Approximately one year later, on October 22, 2013, Petitioner visited Dr. Palwai "because [she] had no other treating physicians that [she] could go see for something as simple as a little wrist pain." *Id.* Petitioner attested that she had no other symptoms besides wrist pain when she saw Dr. Palwai in October of 2013. *Id.* Petitioner visited Dr. Palwai because her mother was a patient

[41] Neither Dr. Nunez, nor any other medical professional that treated Petitioner during her May 2015 hospitalization, noted that Petitioner had an allergy to the flu vaccine in any medical record. *See* Pet'r's Ex. 71 at 210–11.

[42] The records for Petitioner's hospital stay do not include evidence of any physician indicating that the flu vaccine caused Petitioner's condition. *See generally* Pet'r's Ex. 5.

of his for SLE. *Id.* at 2. Petitioner stated that she believed that Dr. Palwai incorrectly charted her mother's records as Petitioner's. *Id.* at 3. Petitioner wrote that it was her mother who was experiencing morning stiffness, bruising, fatigue, and swelling. *Id.*

On October 29, 2013, Petitioner received the flu vaccination at issue in this case, and stated that "[w]ithin minutes[, she] developed a rash and itching on the arm of the injection site and on [her] face." *Id.* at 4. By November 4, 2013, "[Petitioner] began to experience new symptoms that [she] never had before, such as bruising, severe joint pain, and swelling of the extremities." *Id.* at 5.

Petitioner wrote that she first visited Dr. Sabeen Najam on February 25, 2014. *Id.* at 9. Petitioner noted that Dr. Najam confirmed Petitioner's diagnosis of unspecified diffuse connective tissue disease on March 25, 2014. *Id.* Petitioner was hospitalized for a "massive gastrointestinal bleed" on May 3, 2014, and she reiterated in this affidavit that during her hospitalization she was told that she "was allergic to the [flu] vaccine and that the [flu] vaccine caused [her] autoimmune illness." *Id.*

D. Testimony

Petitioner testified at a fact hearing held on January 24, 2018. *See* Tr. 12–59, ECF No. 105. Petitioner's testimony primarily consisted of describing dates and incidences from her third affidavit. *See* Pet'r's Ex. 89.

Petitioner testified that she received her first flu vaccine on October 11, 2012, as a requirement of the San Jacinto Houston Methodist Hospital. *Id.* at 17. She attested that she started itching "[i]mmediately after the vaccination . . . ." *Id.* Petitioner developed a rash on her face and at the site of injection. *Id.* at 19–20. Petitioner's rash and itching resolved after she took a dose of Zyrtec. *Id.* at 19. She "did[not] think anything about [her reaction]." *Id.* Petitioner said that her only health issues in 2013 were gynecological and related to her treatment for ADHD. *Id.* at 20.

Petitioner then recounted her October 22, 2013 visit with Dr. Palwai. *Id.* at 25. At the time, Petitioner "was in good health." *Id.* Petitioner said that she complained of wrist pain "that[was] worse when typing at work" that had been bothering her for one week. *Id.* at 25–26, 34. Petitioner stated that Dr. Palwai "wanted to do labs [and] x-rays" and prescribed a Medrol pack. *Id.* at 26. Petitioner stated that Dr. Palwai's response "was [that] he did not know what was going on[,] and he just wanted to prescribe Medrol to see if it helped." *Id.* Petitioner testified that she did not have any fatigue or morning stiffness at this visit and only approached Dr. Palwai because "it was more convenient." *Id.* Petitioner testified that her mother complained of bruising due to her lupus, but Petitioner had no bruising "anywhere." *Id.* Petitioner stated that Dr. Palwai misdiagnosed her with unspecified inflammatory polyarthropathy. *Id.* at 27. Petitioner explained that she was suffering from carpal tunnel syndrome at that time, and that diagnosis was later confirmed by Dr. Varner "maybe [ten] months later." *Id.* at 27–28.

Petitioner testified that she had no other health problems until October 29, 2013. *Id.* at 27. On that date, Petitioner received the flu vaccine at work. *Id.* at 28. Once she returned to her station, "[she] began itching and . . . getting hot." *Id.* Petitioner stated that she developed a rash on her arm and right side of her face. *Id.* Petitioner took a dose of Zyrtec, which stopped the itching. *Id.* "Three to four days later," Petitioner stated, her hands "began getting red and puffy and [began] burning[,]" and she developed "knee swelling." *Id.* at 29. Petitioner testified that she "never had any swelling or knee pain in [her] life" prior to this experience. *Id.* Petitioner also began feeling "very fatigued" and waking to "morning stiffness." *Id.* Petitioner testified that Dr. Palwai faxed a note to Petitioner's workplace for her to wear a brace to help with what was ultimately diagnosed as carpal tunnel syndrome. *Id.*

Petitioner noted that Dr. Hughes' records from January 16, 2014, indicate that Petitioner told the physician that she "had not felt well since August [of] 2013." *Id.* at 37. Petitioner denied that she said this to Dr. Hughes. *Id.* Instead, Petitioner testified that she spoke with Dr. Hughes' "receptionist," May Kassm, who was aware of the side effects Petitioner experienced in August of 2013 from her birth control pills. *Id.*

I asked Petitioner about her carpal tunnel syndrome diagnosis. *Id.* at 56. Petitioner stated that she was first diagnosed with carpal tunnel syndrome around September of 2014. *Id.* She stated "[t]hat[is] when [] Dr. Varner did her first . . . nerve conduction [tests] . . . ." *Id.* I asked Petitioner if her carpal tunnel syndrome symptoms were "separate and apart from the numbness and the tingling[] . . . that [she] had[.]" *Id.* Petitioner stated, "[y]es[]" and testified that she is now only receiving treatment for small fiber neuropathy. *Id.*

IV. Experts

A. Petitioner's Expert, Dr. Carl Tornatore

1. A Logical Sequence of Cause and Effect: *Althen* Prong Two

Dr. Tornatore ultimately opined that Petitioner's October 29, 2013 flu vaccine, "resulted in the development of a small fiber sensory neuropathy [("SFSN")]." Pet'r's Ex. 127 at 8, ECF No. 126-2. The results from Petitioner's November 14, 2017 biopsy, specifically that Petitioner's "epidermal nerve fiber density was below the 5th percentile for sex and age matched controls," were the basis for Dr. Tornatore's conclusion that Petitioner had developed SFN. *See id.* at 2. He then cited the description of SFN in an article by Oaklander[43] to compare to Petitioner's clinical progression. *Id.* (citing Pet'r's Ex. 129, ECF No. 127-2). Dr. Tornatore noted that red hands and feet, burning dysesthesias, swelling and warmth of hands and feet, leg pain, and erythema are all symptoms of SFN that Petitioner experienced post vaccination up to her biopsy. *See generally id.* Dr. Tornatore discussed Petitioner's first report of red hands during a November 16, 2013 phone call to Dr. Palwai. *Id.* at 3. Dr. Tornatore wrote, "[t]his is the first time that [Petitioner] describe[d] color changes in her hands, which [] can be a symptom of small fiber sensory neuropathy." *Id.* Dr. Tornatore conceded that Petitioner "had a constellation of non-neurologic symptoms[.]" *Id.* at 2.

[43] Anne Louise Oaklander, *Immunotherapy Prospects for Painful Small-fiber Sensory Neuropathies and Ganglionopathies*, 13 NEUROTHERAPEUTICS 108 (2016).

However, he only discussed those "neurologic symptoms to make [her] progression of [] symptoms easier to ascertain." *Id.*

Dr. Tornatore included the following chart in his report:

November 16, 2013	Red hands
December 9, 2013	Red hands and feet
December 30, 2013	Red hands and feet as well burning dysesthesias
December 31, 2013	Burning dysesthesias, started Plaquenil and gabapentin
January 27, 2014	Swelling and warmth of hands and feet
February 25, 2014	Pain on legs
March 4th, 2014	Hot extremities
March 6th, 2014	Erythema with/without itching
August 18, 2014	Exam consistent with a sensory neuropathy
January 22, 2015	Small fiber biopsy considered

Id. at 5–6. This progression, according to Dr. Tornatore, shows "the sequence of symptoms" and indicates "the onset of small fiber sensory neuropathy symptoms starting on November 16, 2013[,] (18 days following the vaccination)[,] which then progressed over the subsequent year." *Id.* at 6.

In his supplemental expert report, Dr. Tornatore further argued that Petitioner's "abrupt onset of symptoms" supports his theory of causation. *See* Pet'r's Ex. 145 at 6, ECF No. 140-2. He conceded that there are other conditions that share these same symptoms but argued that "they would have resulted in more indolent and progressive symptoms, a pattern which is not evident in [Petitioner's case]." *Id.*

2. A Biological Mechanism: *Althen* Prong One

Dr. Tornatore asked the question, "[i]s it biologically plausible for small fiber neuropathy to be a post-vaccinal autoimmune event?" Pet'r's Ex. 127 at 6. Continuing to rely on the Oaklander article, he wrote, "[p]reliminary evidence suggests that dysimmunity causes some cases of small-fiber neuropathy." *Id.* (quoting Pet'r's Ex. 129 at 1). Oaklander also stated that there is "rudimentary evidence [that]," according to Dr. Tornatore, "suggests humoral rather than cellular mechanisms and complement consumption." Pet'r's Ex. 129 at 1; Pet'r's Ex. 127 at 6. Dr. Tornatore noted that "the time course and etiology of small fiber sensory neuropathy is strikingly similar to Guillain-Barr[é syndrome ("GBS")][44] as noted by Koike et al.[45] . . . ." Pet'r's Ex. 127 at 6–7 (citing Pet'r's Ex. 130 at 4, ECF No. 127-3). Dr Tornatore quoted the authors' assertion that "[a]cute autonomic and sensory neuropathy is characterized by autonomic and sensory impairment without motor dysfunction that reaches its nadir within a short period of time mimicking the progression of [GBS]. The monophasic clinical course and frequent presence of a history of

[44] GBS is "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face[.]" *Dorland's* at 1802.

[45] Haruki Koike and Gen Sobue, *Autoimmune autonomic ganglionopathy and acute autonomic and sensory neuropathy*, 53 CLIN. NEUROL. 1326 (2013).

antecedent infections suggests a participation of immune mechanisms." *Id.* at 7 (quoting Pet'r's Ex. 130 at 4). Dr. Tornatore argued that Koike concludes that "small fiber sensory neuropathy can occur subacutely with evidence of autonomic involvement (in [Petitioner's] case bowel incontinence)." *Id.* He next argued that the involvement of the immune system in the pathogenesis of small fiber sensory neuropathy creates a biological plausibility for vaccine-caused injury via molecular mimicry. *See id.* at 7–8.

Molecular mimicry is described by Dr. Tornatore as a process by which there are "antigens present on [a] vaccine [that] share [] homology with host antigens, [causing an] immune response [to] be directed at both the injected antigens and host antigens, leading to an autoimmune response." *Id.* at 7. He asserted that "vaccines have been recognized to trigger autoimmune responses [] that lead to autoimmune responses directed against antigens on peripheral nerves, resulting in inflammatory polyneuropathies." *Id.* Dr. Tornatore named swine flu and tetanus as "two such vaccines." *Id.* He also noted articles[46] that describe "the onset of [SFN] following vaccination for rabies, varicella, Lyme, and human papillomavirus." *Id.* (citing Pet'r's Exs. 136–137, ECF Nos. 128-3–128-4). Dr. Tornatore stated that "influenza vaccines, rarely may lead to an autoimmune response targeted at peripheral nerves based on the principal [sic] of molecular mimicry." *Id.* He then described a molecular mimicry process that, unlike the more commonly described molecular mimicry process, is not based on amino acid homology. "Receptors on B and T cells that were once thought to have a high level of specificity for individual foreign antigens are now known to recognize peptide sequences that share no homology." *Id.* Dr. Tornatore ultimately concluded that either of these processes constitute "a plausible biological mechanism to account for a small fiber sensory neuropathy by [Petitioner]." *Id.* at 8.

In Dr. Tornatore's supplemental report, he highlighted that Respondent's expert agreed on the viability of molecular mimicry as a mechanism for flu vaccine induced GBS. Pet'r's Ex. 145 at 2 (citing Resp't's Ex. A at 82, ECF No. 136-1). Dr. Tornatore acknowledged that Petitioner "was not diagnosed with GBS." *Id.* at 2. However, he argued that Dr. Chaudhry has essentially conceded that "there are mechanisms to explain how exposure to microbiological antigens (in this case the influenza virus antigens in the form of a vaccine) could result in immune activation and injury to the peripheral nervous system." *Id.*

Dr. Tornatore noted "GBS and small fiber sensory neuropathy share many common immunopathogenic features[] . . . ." *Id.* He argued that "[s]mall fiber sensory neuropathy, has been postulated to be a variant of [GBS]." *Id.* He continued, quoting an article by Uncini and Yuki titled *Sensory Guillain-Barré Syndrome and Related Disorders: An Attempt at Systematization*:[47] "[p]atients with clinically pure acute sensory neuropathy and electrophysiological evidence of demyelination in motor and sensory fibers, or more rarely only in sensory fibers, have been classified as having 'sensory GBS.'" *Id.* at 4 (quoting Pet'r's Ex. 147 at 1, ECF No. 140-4). The authors also proposed "[o]n the basis of the size of fibers involved and the possible site of primary damage, [to] tentatively classify[] sensory GBS and related disorders into three subtypes: acute

[46] Nizar Souayah et al., *Small fiber neuropathy following vaccination for rabies, varicella or Lyme disease*, 27 VACCINE 7322 (2009); S. Blitshteyn, *Postural tachycardia syndrome following human papillomavirus vaccination*, 21 EUROPEAN J. NEUROLOGY 135 (2014).

[47] Antonio Uncini and Nobuhiro Yuki, *Sensory Guillain-Barré Syndrome and Related Disorders: An Attempt at Systemization*, 45 MUSCLE NERVE 464 (2012).

sensory demyelinating polyneuropathy; acute sensory large-fiber axonopathy–ganglionopathy; and acute sensory small-fiber neuropathy–ganglionopathy." *Id.* (quoting Pet'r's Ex. 147 at 1). A second Yuki et al. paper titled *Acute Painful Autoimmune Neuropathy: A Variant of Guillain-Barré Syndrome*[48] noted that "[s]ome authors have used the term acute small fiber sensory neuropathy to describe [] patients [with antibodies confirming that their SFSN had an autoimmune etiology] and have proposed this as another variant of [GBS]." *Id.* at 4–5 (quoting Pet'r's Ex. 149 at 4, ECF No. 140-6). The article acknowledged that "[t]raditionally, [GBS] is a neuropathy restricted to the large motor-sensory fibers . . . ." *Id.* (quoting Pet'r's Ex. 149 at 4). However, the authors maintained that "case series and the cases identified in the literature suggest that an acute immune response can be directed against small fibers and exhibit similarities to [GBS]." *Id.* (quoting Pet'r's Ex. 149 at 4).

3. Timing: *Althen* Prong Three

Dr. Tornatore relied on the established causal relationship between the flu vaccine and GBS as a reference for his asserted appropriate timeframe for injury onset in this case. *See* Pet'r's Ex. 127 at 8. He wrote that "GBS and small fiber sensory neuropathy share many similarities with regard to the tempo of onset." *Id.* Citing an article by Schonberger et al.,[49] Dr. Tornatore also wrote that "the onset of inflammatory neuropathies following swine flu vaccination" revealed "that the period of increased risk was concentrated primarily within the 5-week period after vaccination, although it lasted for approximately 9 or 10 weeks." *Id.* (citing Pet'r's Ex. 132, ECF No. 127-5). Petitioner's symptoms, Dr. Tornatore asserted, "occurred within 3 weeks of vaccination, a plausible period for the initiation of an immune response following vaccination." *Id.*

In his supplemental report, Dr. Tornatore wrote that he vehemently disagreed with Dr. Chaudhry's "conflat[ion of] non-neurologic and neurologic symptoms." Pet'r's Ex. 145 at 8. Dr. Tornatore wrote that Petitioner's "unexplained bruising, tenderness to touch, pain[,] and [bilateral erythema from bruises near her wrists]" are "clearly [] not" neurological symptoms. *Id.* Dr. Tornatore reiterated that "the earliest mention [he] could find in the medical records of symptoms referable to small fiber neuropathy was 11/16/2013 [sic]." *Id.* These symptoms were mentioned in a phone call "to Dr. Palwai [who] noted that [Petitioner] stated that 'her hands are red, having a flare up.'" *Id.*; Pet'r's Ex. 127 at 3. Dr. Tornatore concluded that this onset, approximately three weeks post vaccination, marks the beginning of "a straight line [that] can be drawn from the influenza vaccination that [Petitioner] received on 10/29/2013[, sic to] the subacute onset of a small fiber sensory neuropathy." Pet'r's Ex. 145 at 8.

B. Petitioner's Expert, Dr. Holly Varner

Dr. Varner wrote a letter to express her agreement with Dr. Tornatore's conclusion that Petitioner developed small fiber neuropathy as a result of her flu vaccination. Pet'r's Ex. 139. Dr. Varner noted that she first saw Petitioner on August 18, 2014, approximately ten months post vaccination. *Id.* at 2. Petitioner indicated to Dr. Varner that she was experiencing "weakness and

[48] Nobuhiro Yuki et al., *Acute Painful Autoimmune Neuropathy: A Variant of Guillain-Barré Syndrome*, 57 MUSCLE NERVE 320 (2018).

[49] Lawrence B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976–1977*, 110(2) AM. J. EPIDEMIOLOGY 105 (1979).

burning in her hands and feet, all having developed following a flu vaccination in October of the previous year." *Id.* Petitioner further indicated that she had "an allergic reaction to a prior flu vaccination." *Id.* Dr. Varner concurred with Dr. Tornatore's opinion that "[a]utoimmune acute neuropathies such as AIDP [and GBS] have been documented to be associated with vaccinations, including the flu vaccination, and [Petitioner's] presentation is similar in pathophysiology to such a situation." *Id.* Dr. Varner added that she has "had several patients who have developed a neuropathy [in response] to a vaccine and then subsequently went on to have a longstanding sensorimotor peripheral polyneuropathy, with large and/or small fiber involvement as well as autoimmune and more systemic symptoms." *Id.* at 3.

C. Respondent's Expert, Dr. Vinay Chaudhry

Respondent's expert, Dr. Chaudhry, began his eighty-eight-page report with a seventy-three-page chronology of Petitioner's medical history from her first HPV vaccination on April 7, 2009, through rheumatology and ophthalmology assessments conducted on September 14, 2019. *See generally,* Resp't's Ex. A. He noted that during that period, Petitioner "ha[d] seen at least 38 physicians of 13 different specialties (8 rheumatologists, 7 ophthalmologists, 7 family medicine/internal medicine, 2 dermatologists, 2 psychiatrists, 1 each allergy physician, pulmonologist, gastroenterologist, cardiologist, endocrinologist, infectious disease, foot physician, and oncologist-hematologist) with the total number of visits approximating to 150." *Id.* at 74. He further noted that Petitioner "has carried over 90 different diagnoses," including rheumatic, neurologic, dermatologic, ophthalmologic, and psychiatric conditions. *Id.* Dr. Chaudhry identified mixed connective tissue disease, inflammatory polyarthropathy, Raynaud's phenomenon, alopecia, uveitis, SFN, and GERD, along with many other symptoms and diseases, within Petitioner's medical records. *Id.* at 74–76. He then noted that despite all of these diagnoses, many of Petitioner's treaters continued to express uncertainty about the cause of all her symptoms more than 2.5 years post vaccination. *See id.* at 76. Dr. Chaudhry highlighted the following assessments in the medical record:

Date	Specialty	Comments	Pet'r's Ex.
3/25/14	Rheumatology	Labs all negative for any serological evidence of any connective tissue disease.	8 at 8
4/13/14	Hematology	No evidence of hematological disorder.	17 at 4
5/6/14	Gastroenterology	It is not clear what [Petitioner] has.	11 at 3
7/23/14	Psychology	The clinical profile is significant for the presence of three scales which strongly suggest the conversion of psychological or situational stress into vague symptoms for which there may not be a medical etiology.	48 at 2–3
4/22/15	Neurology	Have not been able to find a separate neurologic diagnosis to explain the cause of her symptoms.	64 at 111
7/26/16	Rheumatology	Nothing is really remarkable in labs on her. A thorough workup at this time has not revealed a diagnosis.	72 at 115

Id. After asserting that it is difficult, in this case, to "dissect out a single neurologic symptom and a single neurologic diagnosis[,]" Dr. Chaudhry stated that he would focus "on neurological symptoms and signs and her visits and assessment by the neurologists[]" to assess Petitioner's diagnosis. *Id.*

Neurological diagnosis, Dr. Chaudhry explained, "is based on anatomical localization that is dependent on symptoms and signs. The localization diagnosis is followed by finding the etiology based on further laboratory testing." *Id.* Dr. Chaudhry noted Petitioner first saw a neurologist, Dr. Varner, post vaccination on August 18, 2014, with complaints of "joint pain, bruising, fatigue, redness/blueness knuckles, malaise, urticaria, abdominal pain, diarrhea, [and a] non-healing ear wound[,] among others." *Id.* at 77. Dr. Varner also recorded "patchy decreased prick in the legs." *Id.* Dr. Chaudhry noted that Dr. Varner diagnosed Petitioner with myelopathy on that date. *Id.* Dr. Chaudhry then detailed the chronology of Petitioner's subsequent neurological testing and diagnoses:

Date	New Symptoms	Testing	Added Diagnoses
9/4/14	—	EMG	Carpal tunnel syndrome, scattered myopathies, and neuropathic changes
12/19/14	Muscle weakness, lower extremity pain and upper extremity paresthesias		Muscle weakness
1/9/15	—	Biopsy	Normal results
1/22/15	Pain and weakness in arms & legs	Neuro exam	Paresthesias, muscle cramps, dysphagia
8/24/15	Follow up	Sensory exam	Allodynia (no signs of peripheral neuropathy)
2/24/16	Muscle aches	Sensory exam	(No clear signs of peripheral neuropathy or muscle problem)
4/29/16	—	Comprehensive single specialty neuro exam	Strong mind-body interaction, testing normal (no evidence of active denervation, sparse evidence of significant myopathy, location uncertain)
5/27/16	Follow up		Decreased response to vibration, pain and temperature on the toes of both feet
6/23/16	Follow up (denied burning in feet)	EMG	Normal EMG
7/27/17	Numbness in several digits in right hand	Sensory exam	Decreased pinprick in fingers on left hand, brachial plexopathy, myositis
11/14/17	—	Skin biopsy	Mild small fiber neuropathy
12/7/17	—	Complete neuro exam	Small fiber neuropathy most likely related to a connective tissue

			disease process; myositis of right forearm, paresthesias, and muscle weakness
10/19/18	—		Optic neuritis
2/27/19	—		Systemic lupus erythematous

See id. at 77–79.

Dr. Chaudhry opined that Petitioner's "diffuse symptoms with normal examination are difficult to put together in one diagnosis." *Id.* at 79. He argued that Petitioner's consistent testing did not reveal evidence of small fiber neuropathy until four years post vaccination. *Id.* He then noted that "[t]he criteria used for defining her abnormality is based on [the] age group of 20-29[]" but asserted that Petitioner, who was 29 years, 9 months, and 11 days at the time of testing, was "over 29 at the time . . . ." *Id.* Petitioner's epidermal nerve fiber density, at 7.7/mm, was below the 5th percentile for women aged 20–29. But, citing guidelines from the European Federation of Neurological Societies and Peripheral Nerve Society,[50] Dr. Chaudhry suggested that Petitioner's left distal leg measurement was within the proper normative value for women 30 to 39 years old. *Id.* (citing Resp't's Ex. A, Tab 4, ECF No. 137-4). Dr. Chaudhry then offered several alternative explanations for "the mild reduction in skin biopsy [ ]." These include insulin resistance syndrome, which Petitioner had been diagnosed with based on her "elevated glucose, high insulin, and elevated HbAlc values." *Id.* He further noted her high levels of vitamin B6 and connective tissue disease, which he stated are each associated with small fiber neuropathy. *Id.*

Dr. Chaudhry argued that there were several points in Petitioner's medical history when new and significant symptoms manifested pre vaccination. *See id.* at 80–81. He noted that Petitioner reported during a December 30, 2013 doctor's appointment that she had indicated symptoms of generalized weakness since August of 2013. *Id.* at 80. During a subsequent rheumatological referral, she further noted knee aches and joint warmness, burning and redness in her hands, and burning feet. *Id.* During a January 27, 2014 appointment, Petitioner described joint pain, fatigue, and red lesions on her leg that started four months prior in September of 2013. *Id.* Dr. Chaudhry also noted an assessment in Petitioner's medical records from an October 22, 2013 medical record, listing bilateral wrist and hand pain with swelling, bruising, and morning stiffness. *Id.*

Dr. Chaudhry strongly disputed the accuracy and relevance of Petitioner's SFN diagnosis. *See id.* at 81. He argued that Petitioner's symptoms, "muscle pain, joint pains, weakness and fatigue[, are] symptoms that are not part of small fiber neuropathy." *Id.* Small fiber neuropathy patients, Dr. Chaudhry explained, "present with burning pain," and "show clinical signs of small fiber impairment – loss of pinprick and thermal sensory loss." *Id.* He continued that Petitioner's test results from the Mayo Clinic did not reveal localized reduced sensation but instead showed reduced sensation to all modalities. *Id.* He asserted that "[r]eduction of sensation to all modalities is note [sic] seen with SFN." *Id.* Dr. Chaudhry concluded that Petitioner's "skin biopsy findings

[50] G. Lauria et al., *European Federation of Neurological Societies/Peripheral Nerve Society Guideline on the use of skin biopsy in the diagnosis of small fiber neuropathy. Report of a joint task force of the European Federation of Neurological Societies and Peripheral Nerve Society*, 17 EUROPEAN J. NEUROLOGY 903 (2010).

are normal by one criteri[on] and close to normal on another criteri[on.]" *Id.* He opined that "[t]hese mild findings of small fiber neuropathy findings [sic] limited to [the] distal left leg do[] not explain the multitude of symptoms noted by [Petitioner]." *Id.*

Dr. Chaudhry was skeptical of molecular mimicry and wrote, "molecular mimicry has never been established for any vaccine." *Id.* He noted the lack of "epidemiological and mechanistic evidence for [the] influenza vaccine and small fiber neuropathy." *Id.* at 85. He continued that the IOM[51] "did not identify literature reporting clinical, diagnostic, or experimental evidence of small fiber neuropathy developing after administration of an influenza vaccine." *Id.* (citing Resp't's Ex. A, Tab 10 at 29). Dr. Chaudhry pointed out that "Dr. Tornatore draws on Guillain-Barre [sic] syndrome as a cause of acute autonomic and sensory neuropathy." *Id.* at 84. However, Dr. Chaudhry argued, "[Petitioner] did not have GBS – was not monophonic [sic], acute onset, reflexes were not absent[,] and [she] did[not] have any clinical features to support this diagnosis." *Id.* Even in the case of GBS, Dr. Chaudhry argued that Petitioner's identified biological mechanism, molecular mimicry, "has only been proved for C. jejuni related to the atonal form of GBS and is not associated with any infection or vaccine-related immune neuropathy." *Id.* at 85. Dr. Chaudhry conceded that "[i]mmune-mediated mechanisms have been advocated for SFN associated with connective tissues disorders . . . based on the response to immunoglobulin or immunosuppressive treatments in single patients or small case series." *Id.* at 84. In general, however, "[t]he immune hypothesis mechanism of small fiber neuropathies has neither been proven yet nor been replicated by serum transfection experiments in animal models []." *Id.* at 85.

Finally, Dr. Chaudhry discussed Dr. Varner's report. *See id.* at 86. He noted that when Dr. Varner first saw Petitioner on August 18, 2014, Dr. Varner "did not even mention peripheral neuropathy or small fiber neuropathy . . . ." *Id.* Furthermore, Petitioner's symptoms at that time, weakness and soreness in her legs and bowel incontinence, "are not symptoms of small fiber neuropathy." *Id.* Dr. Chaudhry also commented on Dr. Varner's note from "her own clinic visit on 7/5/19 [sic], [which] states, '[Petitioner] does not have signs of a clear autonomic neuropathy at this point.'" *Id.*

V. Medical Literature

Petitioner and Respondent provided medical literature that identifies symptoms commonly associated with small fiber neuropathy. The Oaklander article filed by Petitioner explains that "[s]mall-fiber polyneuropathy [("SFPN")] typically presents with chronic widespread pain starting in the feet, and /or dysautonomic symptoms, most often cardiovascular or gastrointestinal." Pet'r's Ex. 129 at 5. Oaklander continues that "[t]he cardiovascular symptoms include not only orthostatic hypotension and tachy-cardia, but also impaired cognitive function, headache, and exercise intolerance due to circulatory insufficiency []." *Id.* Respondent filed an article by Devigili et al.,[52] which identifies the "[p]resence and distribution (e.g. length or non-length dependent) of sensory loss and pain, gait impairment[,] and dysautonomic symptoms (e.g. pupil abnormalities, impotence, impaired bladder function, constipation or diarrhea, early satiety and gastric fullness,

[51] K. Stratton et al., eds. *Adverse Effects of Vaccines: Evidence and Causality* (2011).
[52] Grazia Devigili et al., *The diagnostic criteria for small fibre neuropathy: from symptoms to neuropathology*, 131 BRAIN 1912 (2008).

abnormal sweating, flushing, skin decolouration [sic], xerostomia and xerophthalmia, [and] orthostatic hypotension)." Resp't's Ex. A, Tab 2 at 2, ECF No. 137-2.

Because Petitioner developed her biological mechanism and appropriate timeframe for symptom onset based on GBS, she provided articles that provide background information on GBS. The Uncini and Yuki article, which Dr. Tornatore relied on to establish that SFSN could be a variant of GBS, "operatively defined sensory GBS as an acute, monophasic, widespread neuropathy characterized clinically by exclusive sensory symptoms and signs that reach their nadir in a maximum of 6 weeks without related systemic disorders and other diseases or conditions." Pet'r's Ex. 147 at 1. A second article, by Seneviratne and Gunasekera,[53] also characterized acute sensory neuropathy as a type of sensory GBS. Pet'r's Ex. 148 at 2, ECF No. 140-5. The authors identified "the following diagnostic criteria[:] acute onset symmetric sensory loss, progression up to 4 weeks, diminished or absent reflexes, normal muscle power, electrophysiological evidence of demyelination in at least two nerves, monophasic course, no alternative cause for neuropathy, no family history of neuropathy, and increased CSF protein (in some)." *Id.*

The Souayah et al.[54] article filed by Petitioner includes case studies of patients who developed symptoms consistent with small fiber neuropathy and who had abnormal skin biopsies following several different vaccines. *See* Pet'r's Ex. 136 at 1–2, ECF No. 128-3. Patient one developed burning paresthesias across his chest and leg several hours post vaccination (rabies). *Id.* at 1. Patient two developed burning and itching sensations in extremities one day post vaccination (Lyme disease). *Id.* at 1–2. Patient three developed severe, sharp stabbing pains in her chest, face and arms approximately one week post vaccination (Lyme disease). *Id.* at 2. Patient four developed headaches, neck stiffness and dry mouth a few days post vaccination (combination of Lyme disease and hepatitis A). *Id.* Patient five developed a diffuse buzzing sensation with numbness and hyperesthesias in all extremities two months post vaccination (varicella zoster). *Id.* Patients one and two experienced a recurrence of some symptoms following initial improvement, and patient 4's symptoms persistent for up to six years post onset. *Id.* at 1–2. The authors stated that they "describe[d] five cases of small fiber neuropathy following vaccination without significant large fiber involvement." *Id.* at 2. They concluded that "[a]n acute or subacute small fiber neuropathy may occur following vaccination for rabies, Lyme disease or varicella zoster, and may have a chronic course." *Id.* at 3.

VI. Motion for Ruling on the Record

A. Petitioner's Argument

In her motion, Petitioner asserts that to prevail, "she must show[] a medical theory causally connecting the influenza vaccine with [] small fiber neuropathy[. T]hat theory must be reputable and based on reliable science." Pet'r's Mot. at 13. Petitioner concedes that her treater, Dr. Palwai, diagnosed her with unspecific inflammatory polyarthropaphy prior to vaccination. *Id.* at 14. She argues that this diagnosis was based on her wrist pain and bruising, which were the only symptoms

[53] U. Seneviratne and S. Gunasekera, *Acute small fibre sensory neuropathy: another variant of Guillain-Barré syndrome?*, 72 J. NEUROL. NEUROSURG. PSYCHIATRY 540 (2002).
[54] *See* Souayah et al., *supra* note 46.

she had at that time. *See id.* at 13–14. Petitioner continues that it was not until post vaccination that she developed the additional injuries that developed into her small fiber neuropathy. *See id.* at 14. Petitioner specifically notes that "in a visit on November 16, 2013, eighteen days after the vaccination, [Petitioner] first described color changes in her hands." *Id.* The ensuing "sequence of symptoms details the onset of small fiber sensory neuropathy symptoms starting [on] November 16, 2013, (18 days following the vaccination)[,] which then progressed over the subsequent years." *Id.*

Petitioner asserts that she "could satisfy the first *Althen* prong by simply demonstrating a 'biologically plausible theory' that the vaccine can cause the injury." *Id.* at 16 (quoting *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1369 (Fed. Cir. 2009)). To this end, Petitioner reiterates Dr. Tornatore's position "that it has been well-established that a vaccine can lead to an autoimmune response." *Id.* at 15. Petitioner continues that these responses "result[] in inflammatory polyneuropathies." *Id.* She references molecular mimicry as a biologically plausible theory and asserts that "the autoimmune response may accumulatively target mimic antigens on peripheral nerves." *Id.* at 16. She also notes that there are two potential "sources of the reaction – homological antigens from [the] vaccine, and non-specific recognition of host T cell receptors." *Id.* (citing Pet'r's Ex. 138 at 2, ECF No. 128-5).[55]

To meet her burden with respect to *Althen* prong two, Petitioner argues that her "clinical picture is consistent with her proposed medical theory." *Id.* at 20. Noting Dr. Tornatore's contention that "small fiber sensory neuropathy can occur subacutely and be 'strikingly similar' to [an] autoimmune disorder[,]" Petitioner contends that her symptoms, including cardiovascular and gastrointestinal symptoms, were evidence of her SFN that went undiagnosed. *Id.* Petitioner notes that Dr. Tornatore opined that "due to the complexity in her clinical presentation, it is not surprising that [Petitioner's] diagnosis was not confirmed until much later." *Id.* at 21. Dr. Tornatore also identified Petitioner's color changes in her hands and feet as an early and identifiable symptom of her SFN. *Id.* at 18 (citing Pet'r's Ex. 127 at 2). He argued in his second expert report that her "response to steroids clearly implicates an inflammatory process and would not be of value in the treatment of Raynaud's . . . , further evidence to support an inflammatory neuropathic process." Pet'r's Ex. 145 at 8.

Petitioner places her initial SFN symptom onset at three weeks post vaccination, "which is an appropriate and medically acceptable temporal relationship between the influenza vaccine and her reaction[,]" as required by *Althen* prong three. Pet'r's Mot. at 21–22. This onset date is based on Petitioner's complaint of color changes in her hands and feet during a November 16, 2013 tele-health visit, eighteen days after the vaccination. *Id.* at 22. This time frame is appropriate, Petitioner argues, based on the timeframe for inflammatory neuropathies, such as GBS, following receipt of the swine flu vaccination. *Id.* The Vaccine Injury Table also recognizes a 3–42-day[56] onset as appropriate for GBS, an inflammatory neuropathy, following flu vaccination. *Id.* (citing 42 C.F.R. § 100.3(a)).

[55] Don Mason, *A very high level of crossreactivity is an essential feature of the T-cell receptor*, 19(9) IMMUNOLOGY TODAY 395 (1998).

[56] Petitioner erroneously lists the Table's acceptable onset range as 2–42 days post vaccination.

B. Respondent's Argument

Respondent disputes that Petitioner suffered from SFN at all. Resp't's Resp. at 19. He notes that "[a]t the time[of her SFN diagnosis more than four years post vaccination], [P]etitioner was also carrying diagnoses of UCTD, myositis of the right forearm, scleritis, paresthesias, muscle weakness, and discoid lupus erythematosus." *Id.* at 20. He reiterates Dr. Chaudhry's assertion that despite Petitioner's "myriad of symptoms [beginning] before her October 29, 2013 flu vaccine, her physical exams have been, with rare exceptions, essentially normal, and her lab test results unremarkable, making it difficult for her various providers to arrive at a unifying diagnosis." *Id.* Respondent contends that Petitioner's expert "cherry-pick[ed] isolated symptoms to support the diagnosis, while failing to address all the others." *Id.*

Specifically, Dr. Chaudhry pointed to Dr. Tornatore's description of Petitioner's November 16, 2013 complaint of red hands, as "a symptom of small fiber sensory neuropathy." Pet'r's Ex. 127 at 3; Resp't's Ex. A at 82. Dr. Chaudry further noted in his expert report that Petitioner's rheumatologists thought she may have had Raynaud's. Resp't's Ex. A at 82. He asserted that "[r]ed hands . . . are not part of small fiber neuropathy." *Id.* He further asserted that "Medrol, which helped [Petitioner], is not a known treatment of small fiber neuropathy and w[ould] not be expected to reverse a neuropathy rapidly." *Id.*

Respondent notes that Petitioner's primary complaints as of December 30, 2013, included, "malaise, extreme fatigue, and generalized weakness, as well as burning and redness in her hands[]" with additional complaints of bruising and joint pain. Resp't's Resp. at 21. Respondent argues that these symptoms manifested prior to Petitioner's vaccination and are not indicative of SFN. *Id.* at 21–22. Respondent also notes that Dr. Chaudhry disagreed with Dr. Tornatore that Petitioner's painful, red lesions on her legs, joint pain, and muscle aches are symptoms of SFN. *Id.* at 22; *see also* Resp't's Ex. A at 82. Dr. Chaudhry "observed that the patchy sensory loss to pinprick sensation in the legs [noted during Petitioner's August 18, 2014 physical exam with Dr. Varner] was not reproduced in subsequent exams." Resp't's Resp. at 23 (citing Resp't's Ex. A at 83). Respondent highlights Petitioner's lack of "decreased sensation to pain or temperature" during a January 22, 2015 exam, also with Dr. Varner. *Id.* He notes that "Dr. Tornatore did not comment on [Petitioner's] Mayo Clinic neurologic work-up at all." *Id.* at 24.

Respondent further notes that "Petitioner relies heavily on the results of the skin biopsy to support her alleged diagnosis of SFSN." *Id.* However, Respondent argues that due to Petitioner's age, "had [P]etitioner undergone this test just three months later, her results would have been interpreted as completely normal." *Id.* This, Respondent asserts, when taken with Petitioner's complete medical record, is not sufficient to establish that she suffered from SFN. *See id.*

Respondent next argues that Petitioner's characterization of Dr. Tornatore's "biologically plausible" molecular mimicry theory as sufficient to satisfy her burden for entitlement is inaccurate. *Id.* at 25. He notes that the Federal Circuit has determined that a merely plausible theory does not satisfy a petitioner's burden. *Id.* (citing *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019)). Furthermore, Respondent notes that Dr. Tornatore "failed to identify any homology or cross-reactivity between any component of the flu vaccine and proteins

in the peripheral nervous system specific to SFN." *Id.* at 25–26. Petitioner's theory, without more, "is so overbroad that it basically amounts to a declaration that all vaccinations and pathogens cause all autoimmune diseases." *Id.* at 26.

Because Respondent disputes Petitioner's diagnosis and argues that her asserted mechanism is overbroad, he argues that "it necessarily follows that she cannot demonstrate that the vaccine did cause her alleged SFSN." *Id.* at 27. Respondent quotes Dr. Tornatore, who stated, "I believe the clinical history as well as the biologically plausibility [] all speak to a logical sequence of cause and effect with regards to the probability that the small fiber sensory neuropathy [Petitioner] suffers from was vaccine-mediated." *Id.* (quoting Pet'r's Ex. 127 at 8). Respondent argues that this assertion "does not satisfy [P]etitioner's burden." *Id.* Respondent's assertion that Petitioner has not presented a viable causation theory is also the basis for his argument that Petitioner cannot satisfy *Althen* prong three. *See id.* at 28–29. He states that "[b]ecause [P]etitioner has not demonstrated that the flu vaccine can cause SFSN, or that the vaccine did cause [P]etitioner's SFSN, [P]etitioner cannot demonstrate an appropriate temporal association between the vaccination and the onset of her alleged SFSN." *Id.* at 28. Respondent argues that GBS is not analogous to SFSN, and, therefore, there is no basis to apply the timeframe associated with vaccine-caused GBS to SFSN. *See id.* at 28–29. He writes in his response, "Dr. Tornatore's choice of eighteen days as the onset of [P]etitioner's alleged vaccine injury was completely arbitrary." *Id.* at 29. He continues that if Petitioner's November 16, 2013 complaints of red hands were resolved with Medrol, that symptom is not properly characterized as Petitioner's onset of SFSN. *Id.*

VII. Applicable Law

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, she must prove that her injury was caused-in-fact by a Table vaccine.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. 42 U.S.C. § 300aa-13(a)(1)(A); *see also Moberly*, 592 F.3d at 1322 n.2 (stating that the preponderance standard "requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence[]") (citations omitted). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the

vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *Id.* "[C]lose calls regarding causation are resolved in favor of injured claimants." *Id.* at 1280. Further, evidence used to satisfy one prong of the test may overlap to satisfy another prong. *Capizzano*, 440 F.3d at 1326.

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994). In such a case, the government must not merely prove the existence of an alternative cause, but that such an alternative actually caused the injury. *Knudsen*, 35 F.3d at 549. Consequently, when and if Petitioner establishes a prima facie case, the burden then shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008); *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" 42 U.S.C. § 300aa-13(a)(2).

To satisfy prong one, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the

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

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

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories."

Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert[,]" especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony based on a particular expert's credibility is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("Assessments as to the reliability of expert testimony often turn on credibility determinations[.]"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("[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.").

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I refer only to those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x. 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of a hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearings and those decisions were upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that the special master acted within his discretion in denying an evidentiary hearing); *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

VIII. Discussion

In this case, Petitioner's and Respondent's experts agree on virtually nothing. There is no dispute that Petitioner received a flu vaccine. However, her pre-vaccination medical history, symptoms, symptom onset, diagnoses, and even the evidentiary standard, are all points of

contention. Both experts presented summaries of Petitioner's disease development that focused on what each determined were relevant notations in Petitioner's record. I have reviewed the record itself along with both medical summaries and will discuss specific notes where appropriate. Due to the extensive medical history and prior Fact Ruling in this case, I will begin my analysis with Petitioner's clinical presentation**.** This discussion is necessary to determine whether there is a causal relationship between Petitioner's vaccine and her alleged injury pursuant to *Althen* prong two.

A. *Althen* Prong Two: Logical Sequence of Cause and Effect and Clinical Presentation

I previously found preponderant evidence that Petitioner presented to Dr. Palwai's office on October 22, 2013 (pre vaccination), with symptoms of wrist pain and bruising. Fact Ruling at 1. There is preponderant evidence that Petitioner's symptoms continued to worsen in the following months (post vaccination), and new symptoms appeared that gradually progressed to include Raynaud's, swelling, joint pain, and burning pain. The material question is which, if any, of Petitioner's symptoms are related to her eventual SFSN diagnosis.

In Petitioner's own motion, she notes that she was diagnosed with unspecified inflammatory polyarthropathy during her October 22, 2013 visit with Dr. Palwai. Pet'r's Mot. at 13. She then notes the emergence of additional symptoms "over the more than two years" and "nine doctors' visits," wherein "the treating physicians all noted progressive inflammatory symptoms" in her arms, legs, hands and feet. *Id.* at 14. Petitioner asserts that her November 16, 2013 complaint of red hands marked the acute onset of her SFN. *Id.* Respondent, on the other hand, argues Petitioner's red hands were successfully treated with steroids and were not a symptom of SFSN. Resp't's Resp. at 29. Petitioner also stated that the burning sensations that first appeared in December of 2013 are early evidence of her small fiber neuropathy. Pet'r's Mot. at 18. However, there is no indication from the medical record that this conclusion is shared by any of her treating professionals. Following Petitioner's complaints in November and December, Dr. Palwai began treatment for Raynaud's/acrocynosis. *See* Pet'r's Ex. 6 at 5. Notes from a December 31, 2013 visit reveal no localized findings during a neurological exam, and a working diagnosis of UCTD. *Id.* at 3.

Dr. Tornatore cited the Oaklander article, which states that presenting symptoms of SFN include "chronic[,] widespread pain starting in the feet, and/or dysautonomic symptoms, most often cardiovascular or gastrointestinal." Pet'r's Ex. 129 at 5. Dr. Chaudhry relied on the Devigili et al. article, which contends that SFN is indicated by "the presence and distribution (e.g. length or non-length dependent) of sensory loss and pain, gait impairment[,] and dysautonomic symptoms . . . ." Resp't's Ex. A, Tab 2 at 2. Petitioner's symptom onset does not follow either of these clinical progressions.

During November and December 2013, Petitioner's initial complaints of wrist pain and bruising expanded to include redness and joint pain, and then a burning pain in her hands and feet. Despite her assertions, Petitioner's medical records do not show an acute change of symptoms, beginning in November of 2013. On the contrary, her medical records document a progression of symptoms affecting the same or similar parts of the body, specifically the joints and limbs,

beginning with her pre-vaccination polyarthropathy diagnosis. Petitioner's expert, Dr. Tornatore, engaged in a very specific parsing of Petitioner's symptoms, despite Petitioner's comprehensive complaints, to find evidence of SFSN in 2013. For example, he noted that the November 16, 2013 phone call, is "the first time that [Petitioner] describes color changes in her hands, which . . . can be a symptom of small fiber sensory neuropathy." Pet'r's Ex. 127 at 3. He noted this symptom again with the addition of blue knuckles and the Raynaud's versus acrocyanosis differential diagnosis. *Id.* However, he did not explain why Petitioner's accompanying and worsening symptoms of bilateral wrist and hand pain are unrelated. Unlike Dr. Tornatore, Petitioner's treaters considered all of Petitioner's symptoms at the time, and her differential diagnoses presumably reflect both her pain and discoloration. During a December 31, 2013 visit, Dr. Palwai noted that Petitioner had "persistent joint symptoms and [was] frustrated." Pet'r's Ex. 6 at 3. The note continued that her symptoms began in October but were now occurring daily. *Id.* Dr. Palwai also listed bruising and discoloration in this record. *Id.* Dr. Tornatore repeatedly asserted that he was separating non-neurologic and neurologic symptoms, but these symptoms can be accurately described as potentially neurological and non-neurological. He did not explain how he sorted these cross-over symptoms. Dr. Tornatore also did not meaningfully address why Petitioner's testing does not support a pathological immune process. During the December 31, 2013 visit, Dr. Palwai noted that Petitioner's rheumatological labs from when her symptoms started in October of that year came back negative. *Id.* A December 31, 2013 physical and neurological exam showed "no localized findings." *Id.* Dr. Tornatore also did not explain why the psychological explanations for Petitioner's symptoms from her treaters are inaccurate or whether he considered them.

Petitioner was regularly seen by an array of specialists in the months and years between her vaccination and SFN diagnosis. As Dr. Chaudhry pointed out, Petitioner saw at least 38 physicians and "carried over 90 different diagnoses . . . ." Resp't's Ex. A at 74. Her treaters, including Dr. Varner, did not diagnose her with a vaccine injury or a neuropathy, despite over three years of extensive testing and treatment. Furthermore, Petitioner underwent a complete neurologic examination at the Mayo Clinic in 2016 that did not reveal neuropathy. *See* Pet'r's Ex. 65 at 12–13. Petitioner's sensory deficits were subjective "despite the sensory nerve responses being normal in [her] upper and lower limbs by nerve conduction studies (09/04/2014) [sic]." *Id.* at 12. This record indicates a possible "strong mind-body interaction," but "no evidence of active denervation." *Id.* at 13. Petitioner has therefore not presented preponderant evidence that she developed acute SFN symptoms in November or December of 2013.

Respondent contends that Petitioner's small fiber neuropathy diagnosis was inaccurate based on her complete clinical presentation and the results from her skin biopsy. Respondent's assertions notwithstanding, Petitioner's treating neurologist diagnosed her with mild SFN following Petitioner's November 14, 2017 skin biopsy. I find that a diagnosis from a treater, supported by testing, is preponderant evidence of a medical condition. Therefore, Petitioner has presented preponderant evidence that she had developed small fiber neuropathy at the time of her diagnosis in November of 2017, four years post vaccination. The results of Petitioner's continuous testing and the notes in her medical record, including by rheumatologists and neurologists, do not, however, provide preponderant support that her neuropathy developed at any point prior to her Mayo Clinic evaluation in 2016. There is evidence that some of her treaters believed that she may have suffered from a condition with a rheumatological etiology, but her medical records note negative labs for any connective tissue disease in March of 2014 and unremarkable labs in July of

2016. Pet'r's Ex. 8 at 8, Pet'r's Ex. 72 at 115. Furthermore, Petitioner's treaters repeatedly noted the lack of evidence of any neurological condition. An April 22, 2015 neurology exam with Dr. Varner did not reveal "a separate neurologic diagnosis to explain the cause of her symptoms." Pet'r's Ex. 64 at 111. Dr. Varner instead assessed Petitioner with muscle cramps, paresthesias, muscle weakness, UCTD, and vitamin D deficiency. *Id.* at 113.

I have carefully reviewed Petitioner's extensive and detailed medical history. I have considered her treater's notes, the opinions of all experts, and the fact testimony. Given the thoroughness of Petitioner's medical evidence, it is impractical to discuss every potential symptom that Petitioner or Respondent asserts may be indicative of her many co-morbidities. The lack of discussion of a specific record should not serve as a basis to presume said record was not considered. As the fact finder, I have focused on the records most determinative in my decision on the clinical progression of Petitioner's small fiber neuropathy, because this is the alleged vaccine-caused injury in her most recent request for relief. Based on the totality of the record, Petitioner has not presented a logical sequence of cause and effect that links her October 29, 2013 vaccination to her SFN diagnosis four years later.

B. *Althen* Prong One: Vaccine-Causation Theory

1. Evidentiary Standard

Petitioner notes that she "must provide a scientific or medical theory demonstrating that the vaccine [she received] can cause [her] injury." Pet'r's Mot. at 15. She immediately cites to *Knudsen* and states her "theory need only be legally probable, not medically or scientifically certain." *Id.* (citing *Knudsen,* 35 F.3d at 548–49). Petitioner argues that she has met her burden because her expert's theory is "a biological plausibility causally connecting the influenza vaccination with the onset of [her] symptom [sic] and the progression of her small fiber sensory neuropathy." *Id.*

Petitioner's reliance on a "biologically plausible" theory appears to be an argument for a more relaxed standard. She states that her expert "noted in his report that it has been well-established that a vaccine can lead to an autoimmune response." *Id.* Her expert in his report did generally describe molecular mimicry and note it occurs in GBS cases following the flu vaccine. The fact that "vaccines have been recognized to trigger autoimmune responses that result in inflammatory neuropathies," is all, according to Petitioner, that is necessary to meet her burden under *Althen* prong one. *See id.* Petitioner's argument is not a "more-likely-than-not" explanation of how the flu vaccine can cause small fiber neuropathy.

Petitioner's insistence that she not be held to a certainty standard is correct. However, for the causal requirement for off-Table injuries, the applicable level of proof is not certainty, but the traditional tort standard of "preponderant evidence." *Moberly*, 592 F.3d at 1322. The Federal Circuit has consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard. *Boatmon,* 941 F.3d at 1359; *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014); *see also Moberly,* 592 F.3d at 1322. Rather, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen,* 35 F.3d at 548.The Act specifically states

that petitioners must demonstrate "by a preponderance of the evidence the matters required by the petition." 42 U.S.C. 300aa § 13(a)(1)(A). There is no logical reason to read it as requiring a preponderance when establishing that the vaccine "did cause" the injury pursuant to *Althen* prong two, but not when a petitioner must demonstrate his satisfaction of the "can cause" element pursuant to prong one.

2. General Causation Theory

In presenting a "biologically plausible" mechanism, Petitioner's causation theory is overly simplistic and vague. She argues that because we know that molecular mimicry occurs and can cause GBS, it could have caused SFSN. *See* Pet'r's Mot. at 15. Dr. Tornatore's assertion that some authors have proposed that acute SFSN is another variant of GBS is undercut by his acknowledgment that GBS, or any variant thereof, is not the relevant injury in this case. The articles that define GBS as a sensory neuropathy note that the condition is acute, monophasic, and peaks at four to six weeks with no alternative cause of neuropathy. *See* Pet'r's Ex. 146, ECF No. 140-3;[57] Pet'r's Exs. 147–48. One article, by Hughes and Cornblath, clarified that those "patients who deteriorated more than 9 weeks after the onset of their neuropathy[,] or who had more than two treatment-related fluctuations[,] were more likely to develop [chronic inflammatory demyelinating polyneuropathy [("CIDP")]." Pet'r's' Ex. 146 at 3. These articles do not contemplate a clinical progression that is prolonged for months and years and continually progressing with multiple comorbidities, and additional, unaccounted for symptoms. Petitioner has not provided preponderant evidence that the proposed biological mechanism that explains flu vaccine-caused GBS is applicable here.

Furthermore, Dr. Tornatore did not offer any potential homology between the flu vaccine and locations in the nerve structure where an autoimmune attack on small fibers could occur. He did not provide any evidence to show that a cross-reaction triggered by the flu vaccine is more likely than not. He did not explain if his causation theory requires homology. He appeared to argue that a molecular mimicry process based on homology was just as plausible as one that is not. Petitioner's explanation of molecular mimicry is not tailored to the development of small fiber neuropathy following a flu vaccination. I, and other special masters, have repeatedly warned petitioners that the mere mention of molecular mimicry is not a "get out of jail free card" in the Program, entitling claimants to compensation, merely because it has scientific reliability as a general matter. *Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018) ("Petitioners cannot simply invoke the concept of molecular mimicry and call it a day . . . Rather, they need to offer *reliable* and persuasive medical or scientific evidence of some kind . . . that suggests the vaccine components could interact with self structures as maintained."); *see also Haubner v. Sec'y of Health & Hum. Servs.*, No. 16-1426V, 2021 WL 5614942, at *32 (Fed. Cl. Spec. Mstr. Oct. 22, 2021); *Sheets v. Sec'y of Health & Hum. Servs.*, No. 16-1173V, 2019 WL 2296212, at *17 (Fed. Cl. Spec. Mstr. Apr. 30, 2019). Petitioner has not provided preponderant evidence that the flu vaccine can cause small fiber sensory neuropathy.

[57] Richard A. C. Hughes and David R. Cornblath, *Guillain-Barré syndrome*, 366 THE LANCET 1653 (2005).

C. *Althen* Prong Three: Timing

As I stated during my prong one analysis, Petitioner has not presented preponderant evidence to explain why GBS arising from a molecular mimicry process following a flu vaccine should be applied to an alleged small fiber sensory neuropathy. Dr. Tornatore's conclusory statement that the two complex and varying conditions are similar is not persuasive without probative, supporting evidence. As I previously stated, Petitioner's onset was not similar to a typical GBS onset, or even an atypical acute sensory GBS. Her symptoms progressed for years with several other diagnoses that explain many of her symptoms. Therefore, Petitioner's reliance on the timing presumption for GBS Table claims is misplaced. This case is not a Table claim, and Petitioner does not have GBS.

Furthermore, Petitioner did not present preponderant evidence that the onset of her SFN occurred three weeks post vaccination, as alleged. Petitioner was routinely tested for neuropathy in the months and years following her November 16, 2013 complaints. Her treaters did not diagnose SFN, any neurological condition, or any condition they claimed may be associated with her vaccination, until well over three years later. Lastly, even assuming Petitioner's November 16, 2013 complaints had a neurological etiology, Petitioner has not presented preponderant evidence that explains the extended manifestation period from her initial symptom onset in November of 2013, to a biopsy-based diagnosis in November of 2017. The case studies presented by Petitioner had onset periods that ranged from several hours to two months post vaccination. Pet'r's Ex. 136 at 1–2. Additionally, none of these cases involved the flu vaccine that Petitioner received. *See id.* Petitioner has not presented preponderant evidence that her SFN has a temporal relationship with her vaccination to support causation.

IX. Conclusion

Petitioner has not established it more-likely-than-not that she suffered from small fiber sensory neuropathy, or any other previously alleged condition, as the result of her flu vaccine. Therefore, Petitioner's claim must be dismissed.

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

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master