

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Originally Filed: July 18, 2024

Reissued for Public Availability: September 12, 2024

M.M.,	*	PUBLISHED
	*	
Petitioner,	*	No. 18-583V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH	*	Dismissal; Influenza (“Flu”) Vaccine;
AND HUMAN SERVICES,	*	Guillain-Barré Syndrome (“GBS”);
	*	Neuroinflammation; Asthma; Significant
Respondent.	*	Aggravation.

M.M., *pro se*, Yonkers, NY, for Petitioner.
Nina Ren, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On April 24, 2018, M.M. (“Petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program (“Vaccine Act” or “the Program”), 42 U.S.C. § 300aa-10 *et seq.* (2018),² alleging that she suffered an “exacerbation of asthma[] and an unspecified neurological injury/complication” as a result of receiving an influenza (“flu”) vaccination on September 19, 2015. Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating the case was “not appropriate for compensation under the terms of the Vaccine Act.” Respondent’s Report (“Resp. Rept.”) at 1 (ECF No. 21).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards, the undersigned finds Petitioner failed to provide preponderant evidence that the flu vaccination caused her to develop a neurological condition or an exacerbation of asthma. Thus, Petitioner has failed to satisfy her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005) and Loving v.

¹ Pursuant to Vaccine Rule 18(b), this Decision was initially filed on July 18, 2024, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly, this Decision is reissued in its original form for posting on the Court’s website.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) (“Vaccine Act” or “the Act”). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

Secretary of Health & Human Services, 86 Fed. Cl. 135, 142-44 (2009). Accordingly, the petition must be dismissed.

I. ISSUES TO BE DECIDED

The parties stipulate Petitioner received a flu vaccine on September 19, 2015 when she was 53 years old. Joint Submission, filed July 3, 2023, at 1 (ECF No. 126). The parties also stipulate that at the time of vaccination, Petitioner “already had an approximately [20-year] history of asthma, which included hospitalization in 2011 and an [emergency department (“ED”)] visit in 2012.” Id. Thus, the parties do not dispute that Petitioner had pre-existing asthma.

The parties dispute Petitioner’s neurological diagnosis, including whether she “developed any definable neuroinflammatory autoimmune disease” or “suffered a neurological injury.” Joint Submission at 1-2. Although the parties do not define “neuroinflammatory autoimmune disease” or “neurological injury,” Petitioner’s primary care physician (“PCP”), Dr. Gary Rogg, referenced Petitioner’s neurological condition as “neuropathic changes related to [Guillain-Barré Syndrome (“GBS”).]” Petitioner’s Exhibit (“Pet. Ex.”) 2 at 102. And Petitioner’s expert immunologist, Dr. Omid Akbari, referenced her injuries as “neuroinflammation^[3] in the . . . nervous system” and “neuropathic changes related to GBS.” Pet. Ex. 13 at 1, 10. Therefore, the undersigned will use these definitions, “neuroinflammation” and “neuropathic changes related to GBS,” for the purposes of analyzing Petitioner’s diagnosis.

Also, the parties dispute causation, particularly (1) whether Petitioner has preponderantly established that the flu vaccine caused her neurological injury, and (2) whether Petitioner preponderantly established that the flu vaccine significantly aggravated her preexisting asthma. Joint Submission at 2. Lastly, if Petitioner did establish that the flu vaccination “caused a neurological injury or significantly aggravated her preexisting asthma,” the parties dispute whether there is “preponderant evidence that those conditions were due to an unrelated factor, i.e., an intervening upper respiratory infection [(“URI”).]” Id. at 2.

II. MEDICAL TERMINOLOGY

GBS is an acute demyelinating polyneuropathy characterized by symmetrical limb weakness and decreased or absent reflexes, and it reaches its peak severity at approximately four weeks. Resp. Ex. B.1 at 1.⁴ Sensory symptoms, like numbness and tingling, begin distally and usually are symmetrical. Id. Diagnosis is based on the clinical course and diagnostic studies.

³ Neuroinflammation is “inflammation of a nerve or of the nervous system.” Neuroinflammation, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=33741> (last visited July 3, 2024).

⁴ Bianca van den Berg et al., Guillain-Barré Syndrome: Pathogenesis, Diagnosis, Treatment and Prognosis, 10 Nature Revs. Neurology 469 (2014).

Resp. Ex. B.2 at 1.⁵ While GBS includes a “spectrum of neuropathic disorders that may differ in the underlying pathogenesis and clinical manifestations,” there is consensus as to the clinical course of the majority of patients although there is considerable variability. Id. at 2, 7. Most patients have symmetrical limb weakness and decreased or absent deep tendon reflexes, a monophasic disease course, and cerebrospinal fluid (“CSF”) with increased protein cell count. Id. at 7-10. Additionally, electromyography (“EMG”)/nerve conduction study (“NCS”) findings show demyelinating polyneuropathy. Id. GBS is “of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated.” Guillain-Barré Syndrome, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=110689> (last visited June 27, 2024).

Asthma is defined as “recurrent attacks of paroxysmal [sudden and intense] dyspnea,^[6] with airway inflammation and wheezing due to spasmodic contraction of the bronchi.” Asthma, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=4552> (last visited July 3, 2024). Some cases of asthma are “allergic manifestations in sensitized persons [described as allergic or atopic]; others are provoked by factors such as vigorous exercise, irritant particles, psychologic stresses, and others.” Id.

III. BACKGROUND

A. Procedural History

Petitioner filed her petition on April 24, 2018. Petition. Petitioner filed an affidavit and medical records throughout 2018.⁷ Pet. Exs. 1-12. Respondent filed his Rule 4(c) report, arguing against compensation, on February 4, 2019. Resp. Rept. at 1.

On June 27, 2019, Petitioner filed an expert report from Dr. Akbari. Pet. Ex. 13. On November 4, 2019, Respondent filed an expert report from Dr. Arnold Levinson. Resp. Ex. B.

The undersigned held a Rule 5 conference on January 16, 2020. Order Staying Case dated Jan. 17, 2020 (ECF No. 41). The undersigned briefly gave her preliminary findings then stayed the proceedings for six months to allow Petitioner the opportunity to investigate a diagnosis, including a complete workup and additional testing. Id. at 1-2. By December 2021, Petitioner had still not undergone the necessary testing. Order dated May 4, 2021 (ECF No. 58); Order dated Dec. 2, 2021 (ECF No. 75).

At a status conference on February 3, 2022, the undersigned emphasized Petitioner’s need for further evidence and expert opinion from a medical doctor. Order dated Feb. 3, 2022

⁵ Christiaan Fokke et al., Diagnosis of Guillain Barré Syndrome and Validation of Brighton Criteria, 137 Brain 33 (2014).

⁶ Dyspnea is “breathlessness or shortness of breath; difficult or labored respiration.” Dyspnea, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=15277> (last visited July 3, 2024).

⁷ Petitioner continued to file medical records throughout the course of litigation.

(ECF No. 87). On April 22, 2022, Petitioner submitted an affidavit indicating she had appointments scheduled but because she was exposed to Covid-19, they had been rescheduled for a later date. Pet. Ex. 66 at 1. On May 12, 2022, Petitioner’s counsel moved to withdraw because she could not secure another expert to support Petitioner’s claim “and d[id] not believe [Petitioner] ha[d] reasonable basis to continue with this claim.” Motion to Withdraw, filed May 12, 2022, at 1 (ECF No. 100).

Thereafter, the undersigned granted Petitioner, who opted to proceed pro se, additional time to submit supporting evidence. See Order dated July 19, 2022 (ECF No. 112); Order dated Sept. 20, 2022 (ECF No. 114); Order dated Oct. 26, 2022 (ECF No. 116).

By May 2023, the undersigned noted Petitioner still had not submitted any new records or medical opinion. Order dated May 5, 2023 (ECF No. 123). Accordingly, the undersigned ordered the parties to propose a plan for resolving the case. Id. at 3-4.

The parties agreed to proceed with a ruling on the record. Joint Status Rept., filed June 5, 2023 (ECF No. 124). Petitioner filed a motion for a ruling on the record on September 5, 2023. Pet. Motion for Ruling on the Record (“Pet. Mot.”), filed Sept. 5, 2023 (ECF No. 129). Respondent filed his response on October 31, 2023. Resp. Response to Pet. Mot. (“Resp. Response”), filed Oct. 31, 2023 (ECF No. 130). Petitioner did not file a reply.

This matter is now ripe for adjudication.

B. Factual History

1. Summary of Medical Records⁸

a. Prior to Vaccination (2012 to 2015)

Prior to the vaccination at issue, medical records dating back to 2012 show that Petitioner had multiple medical problems, including a history of “gastroesophageal reflux disease, mitral valve prolapse, asthma, irritable bowel syndrome, kidney stones, melanoma resection, 25 and 10 years ago, Lyme disease treated in the past with [intravenous (“IV”)] antibiotics, hypercholesterolemia,” and headaches and was diagnosed with “chronic paroxysmal hemicrania” which was treated with Indocin. Pet. Ex. 3 at 5. She also had prior head trauma, and computerized tomography (“CT”) scan of the brain in 2004 showed lipoma and nonspecific findings “likely representing benign bony lesion[s].” Id. Petitioner also had a history of ventricular tachycardia treated with Verapamil, atypical chest pain, and mitral valve prolapse. Id. In addition to these conditions, Petitioner also had “intermittent pruritus” of the “left shoulder blade area,” a “history of left rotator cuff injury,” and a history of “benign [] left breast biopsies.” Id. She had significant eye conditions, including diminished vision in her right eye,

⁸ Due to Petitioner’s significant visual problems, she frequently saw her ophthalmologist. Except for early visits, information about these visits are not included in these summaries, as they do not appear to be relevant to the issues herein. Further, there are many visits to other physicians and health care providers in the medical records that are not included for the sake of brevity, however, the undersigned has reviewed all of the Petitioner’s medical records.

diagnosed as endophthalmitis, and she also had conjunctivitis, exudative senile macular degeneration of the retina, bilateral dry eyes, and progressive degenerative myopia. Id. at 11, 13, 16-17, 19, 23. In September 2012, she had “[c]ellulitis and abscess of [the] face.” Id. at 34. In October 2012, Petitioner was diagnosed with pharyngitis and chronic rhinitis. Id. at 55, 58. She had lumbar radiculitis in October, and two falls in November 2012, sustaining a coccyx fracture and left knee and ankle injuries. Id. at 63-64, 69, 80-83. After these falls, she developed bilateral numbness of the anterior thighs, pain in her left shoulder, and “pain and numbness radiating to the left 4th and 5th fingers.” Id. at 90. On physical examination in December 2012, Petitioner had slightly decreased sensation in the distribution of the left C7 nerve root and a number of other abnormal findings. Id. X-rays revealed degenerative changes of cervical intervertebral disc, rotator cuff sprain, and closed fracture of metacarpal bones. Id. at 92-94. Magnetic resonance imaging (“MRI”) showed degenerative changes and medial meniscal tear of the left knee. Id. at 104.

Regarding Petitioner’s history of asthma, her records show that in October 2012, she had mild to moderate persistent asthma, for which she was prescribed Singular, Asmanex, Flonase and ProAir HFA Aerosol inhaler. Pet. Ex. 3 at 41-42. She also took Proventil⁹ when needed. Id. In 2013, Petitioner had lost weight, resulting in significant improvement in her asthma. Id. at 156. Her medication was adjusted due to improvement in her condition and lack of insurance. Id.

In a letter authored by her physician in 2013,¹⁰ Petitioner was noted to also have a history of cancer in 1987 and a history of Epstein-Barr virus. Pet. Ex. 3 at 107. She was noted to suffer from asthma, irritable bowel syndrome, nephrolithiasis, kidney infections, thyroid nodule, lipoma, and “multiple lesions in her brain which have caused debilitating headaches.” Id. She had also suffered a “major bleed in her right eye” resulting in partial blindness. Id. In November 2013, Petitioner had a fall onto her right knee causing swelling and pain and was subsequently diagnosed with a right knee meniscus tear, Baker’s cyst, degenerative arthritis, and neuroforaminal stenosis of the right lumbar spine. Id. at 170, 176-77, 182. She also had episodes of shingles in November and December 2013. Id. at 174.

Moving to 2014, Petitioner had follow-up visits with her pulmonologist for her asthma in April and December 2014. She was diagnosed with “mild intermittent asthma, clinically stable,” and advised to continue her current regimen and her albuterol inhaler as needed. Pet. Ex. 3 at 216, 279. On July 9, 2014 and February 22, 2015, her pulmonologist, Dr. Scott M. Klares, wrote letters advising that Petitioner had “significant asthma that require[d] the use of a nebulizer. As a result of her nebulizer requirement, it [was] important that electrical service [] be maintained at

⁹ Proventil is trademark for albuterol which is a β -adrenergic agonist “administered by inhalation as a bronchodilator for the treatment and prophylaxis of bronchospasm associated with bronchitis, pulmonary emphysema, or other chronic obstructive airway disease, the treatment of asthma-associated bronchospasm, and the prophylaxis of exercise-induced bronchospasm.” Albuterol, Dorland’s Med. Dictionary Online, <https://www.dorlandonline.com/dorland/definition?id=1569> (last visited June 27, 2024); Proventil, Dorland’s Med. Dictionary Online, <https://www.dorlandonline.com/dorland/definition?id=41542> (last visited June 27, 2024).

¹⁰ An almost identical letter was written on July 22, 2015. Pet. Ex. 3 at 319.

her residence to aid in treatment of her underlying medical condition.” *Id.* at 236, 290. Thus, Petitioner had significant asthma and continued to require her nebulizer for treatment.

In September 2014, Petitioner continued to complain of “squeezing precordial chest discomfort with radiation down the arm” and was diagnosed with chest pain syndrome. *Pet. Ex. 3* at 246. Her asthma was described as “under good control.” *Id.* Diagnostic cardiac cauterization was recommended. *Id.* at 246-47. On November 12, 2014, Petitioner was evaluated for back, hip, and knee pain. *Id.* at 272. She complained of “numbness that radiate[d] down the right leg to her ankle, and occasionally she fe[lt] weakness with inability to lift up her foot when she [was] running and walking.” *Id.* She also complained of pain when using stairs, and right hip and groin pain. *Id.* Physical examination revealed deep tendon reflexes were “1 to 2+” in bilateral lower extremities with intact sensation. *Id.* Muscle testing was normal in all four extremities. *Id.* She had tenderness of the “right lumbar paraspinal” muscles. *Id.* Flexion and extension were limited. *Id.* Petitioner was diagnosed with “lumbar degenerative disk disease and mild lumbar radiculopathy”¹¹ and “right hip strain and arthritis.” *Id.*

In June 2015, Petitioner complained of right thumb pain and bilateral knee pain. *Pet. Ex. 3* at 304. MRI of the right knee revealed a tear of the medial meniscus, joint effusion, and popliteal cyst. *Id.* at 296. The left knee had a tear of the medial meniscus and small joint effusion. *Id.* at 297. Petitioner continued to seek treatment for her orthopedic problems throughout 2015.

Vaccine history included receipt of flu vaccinations on January 9, 2008, November 13, 2008, September 8, 2011, and September 25, 2012, and a tetanus, diphtheria, acellular pertussis (“Tdap”) vaccination on September 25, 2012. *Pet. Ex. 3* at 35, 115. There is no evidence to suggest that Petitioner suffered any adverse reactions to these vaccinations.

**b. Vaccination and Six-Month Period After Vaccination
(September 19, 2015 through March 2016)**

Petitioner received the flu vaccination at issue on September 19, 2015. *Pet. Ex. 1* at 1.

Several weeks later, on October 12, 2015, Petitioner saw her ophthalmologist, Dr. Howard Charles, with complaints of fluctuating bilateral blurred vision. *Pet. Ex. 3* at 346. Petitioner attributed the visual symptoms to “a cold and the medication she [was] currently taking for the cold.” *Id.* She was taking Tylenol Sinus medication. *Id.*

The following day, October 13, 2015, Petitioner presented to the Jacobi Medical Center (“JMC”) ED. *Pet. Ex. 4* at 6, 15. Chief complaints were shortness of breath, chest tightness, and a cough that produced yellow mucus for about six days. *Id.* at 6, 15, 20, 30, 33. Onset was Thursday, October 8, 2015. *Id.* at 6. Petitioner had a cough and wheezing but was “able to speak in full sentences.” *Id.* She reported “symptoms all started following the flu vaccination a

¹¹ Lumbar radiculopathy is “any disease of lumbar nerve roots, such as from disk herniation or compression by a tumor or bony spur, with lower back pain and often paresthesias.” Lumbar Radiculopathy, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=101394> (last visited June 20, 2024).

few weeks ago, progressed into a[n] [URI,] and [over the counter] med[ications] were not helping.” Id. at 20. She had gotten “[w]orse the past [four] days.” Id. Petitioner received three rounds of breathing treatments and Prednisone. Id. at 14-16. A chest X-ray was normal. Id. at 23. The diagnosis was asthma and Petitioner was discharged with a prescription for prednisone, 40mg for five days. Id. at 20-23. In a follow-up call on October 16, with the ED care manager, Petitioner stated she was able to see her PCP and was diagnosed with pneumonia.¹² Id. at 31. There was no report of numbness or tingling in the extremities. See id.

Petitioner presented to pulmonologist Dr. Klares on October 14, 2015. Pet. Ex. 3 at 349. Petitioner “was in her usual state of health until last week, she got a flu shot. She state[d] afterwards, she began to have some increasing cough, congestion, . . . increasing sinus pressure, [and] yellowish mucus.” Id. She reported she went to the ED where “they wanted to admit her, but due to insurance reasons . . . she was discharged.” Id. Petitioner stated her breathing was better, but she still had increased mucus, increasing sinus pressure, and sinus tenderness. Id. She did not report any neurological symptoms. See id. On examination, she had a normal temperature, moderate nasal mucosal edema, moderate sinus tenderness, and minimal cough and wheezing with forced expiration. Id. Dr. Klares’ impression was asthma exacerbation which he opined “appear[ed] [to be] related to the URI and acute sinusitis.” Id. He prescribed amoxicillin and instructed her to continue the prednisone and albuterol. Id. He also resumed her Asmanex inhaler and advised Petitioner to continue using her albuterol inhaler for the next two days and use fluticasone nasal spray for her upper airway congestion. Id. Petitioner was not diagnosed with pneumonia. See id. She did not report numbness or tingling of her extremities. See id.

On October 19, Petitioner called Dr. Klares’ office reporting that she “still ha[d] wheezing.” Pet. Ex. 3 at 353. On October 20, Petitioner again called Dr. Klares and reported she was still “not feeling much better.” Id. at 352. She also developed a fever up to 101.9°F the night before. Id. Dr. Klares wanted to evaluate her further that day, but Petitioner reported she did not have transportation to get to his office. Id.

On October 22, Petitioner returned to the ED complaining of shortness of breath and a cough. Pet. Ex. 4 at 43, 45. History indicated the “symptoms began while doing normal activity [two] weeks prior following flu shot earlier this month and suspected URI.” Id. at 43. There was also “change in the color of the sputum[,] initially clear now ‘yellowish’ exacerbated by deep inspiration and exertion.” Id. Petitioner tried an inhaler, nebulizer, and oral steroids without relief. Id. Since the start of October, Petitioner was using her rescue inhaler once per day, as compared to previously using it once every two weeks. Id. It was noted that the “[c]urrent symptoms [were] similar to a prior asthma exacerbation.” Id. She reported fevers, chills, fatigue, congestion, and runny nose. Id. at 44. She denied numbness, paresthias, and weakness. Id. Physical examination revealed bilateral upper lung wheezing and decreased air movement. Id. at 45.

Notes indicated that Petitioner’s “complaints of [shortness of breath] cough, and diminished activity with fevers[,] and chills could indicate URI/early pneumonia though no crackles were heard on auscultation.” Pet. Ex. 4 at 45. The attending physician also noted that depending on the pending bloodwork, infection could be a diagnosis. Id. at 45-46. Clinical

¹² There is no record of Petitioner being diagnosed with pneumonia.

course was also suspicious of asthma exacerbation. Id. at 46. Chest X-ray was normal while a bloodwork showed an elevated white blood cell count of 13 (normal range 3.5-11). Id. at 50-51, 53. On re-examination, Petitioner continued to have a dry cough. Id. at 46-48. During her visit to the ED, she received three nebulizer treatments and was offered admission but declined. Id.

On October 28, 2015, Petitioner called Dr. Klares' office reporting she had a flu vaccine on October 9, 2015,¹³ and was in the ED the next day. Pet. Ex. 3 at 354. She stated that she was being treated for asthma, pneumonia, and bronchitis. Id.

On November 4, 2015, Petitioner saw Dr. Klares and complained that her symptoms had gotten worse and she was unable to fill her prescription for Asmanex due to insurance issues. Pet. Ex. 3 at 355. She had "dyspnea with exertion, but no marked wheezing" or mucus. Id. Her general complaint was "overall weakness." Id. She was scheduled to finish her amoxicillin that day and taper her prednisone. Id. Notes also indicated it was recommended that she see a neurologist for "concern about some tingling in her hands." Id. On physical examination, Petitioner did not have wheezing and had normal extremity strength. Id. The impression was asthma exacerbation, although "[c]linically, it [was] markedly improved." Id. Dr. Klares questioned whether Petitioner's "tingling feeling in the fingertips" was related to her prednisone. Id. She was given a regimen for tapering her prednisone for another week and instructed to begin using Asmanex and continue with her albuterol. Id. Dr. Klares referred her for a neurology evaluation "[g]iven her concerns." Id. She was given a note excusing her from work from Sunday, October 27 to Tuesday, December 1, 2015. Id. at 360.

Petitioner was seen at the JMC asthma clinic on November 5 by Dr. Jared Liebelt and Dr. Chang Shim. Pet. Ex. 4 at 83. Petitioner reported her history of intermittent asthma which had been diagnosed in the 1990s with triggers including pollen, cold weather, exercise, and stress. Id. She also had seven dogs in her home. Id. She "developed URI symptoms following [flu] vaccine" with two subsequent ED visits for treatment. Id. She had just finished her most recent course of prednisone and had recently started a new job where she had exposure to dust and rodent droppings. Id. She still used her albuterol inhaler every four hours. Id. On examination, Petitioner appeared anxious, had an occasional cough, and some lung wheezing, but she was able to speak in full sentences and was not in distress. Id. at 84. Diagnosis was prolonged asthma exacerbation "likely provoked by viral URI." Id. A two-week course of prednisone was prescribed. Id. There is no documentation of numbness and tingling of the extremities. See id.

On November 11, 2015, Petitioner saw her PCP, Dr. Rogg. Pet. Ex. 2 at 81. The reason for the appointment was listed as "[g]ot flu shot, developed [URI], in and out of hospital." Id. Petitioner reported an "asthma attack" following the flu vaccine and being treated with prednisone, inhalers, and amoxicillin for pneumonia. Id. She reported ongoing reflux cough with weather changes. Id. "[T]ingling [bilateral] hands [and] feet since flu shot" was noted on review of symptoms. Id. at 82. Petitioner also had shortness of breath and cough, but denied wheezing, and general weakness. Id. at 81-82. Examination was normal except for occasional rhonchi on lung examination. Id. at 81. Dr. Rogg's assessment was mild persistent asthma

¹³ This date appears erroneous. Petitioner's records show that she received the flu vaccination on September 19, 2015.

without complication and dysesthesia.¹⁴ Id. at 82. He prescribed additional inhalers (Symbicort and Atrovent) as well as Singulair.¹⁵ Id. Assessment included dysesthesia. Id.

Petitioner returned to the JMC asthma clinic for a follow-up on November 12, 2015. Pet. Ex. 4 at 96. She reported generalized weakness, malaise, and exertional wheezing with shortness of breath. Id. On examination, she had poor inspiratory effort but no wheezing. Id. at 97. Dr. Liebelt noted that although Petitioner reported persistent symptoms, her peak flow¹⁶ was normal. Id. He stated that Petitioner had a prolonged viral illness but that her respiratory function “appear[ed] to be back at baseline.” Id.

Approximately nine weeks after vaccination, on November 24, 2015, Petitioner saw neurologist Dr. Leslie S. Saland. Pet. Ex. 3 at 366. Petitioner described that “she had a flu shot in September and about [three] weeks afterwards[,] developed upper respiratory symptoms with diagnosis of bronchial pneumonia and asthma exacerbation.” Id. She “recall[ed] around the same time the infection and asthma exacerbation developed[,] she noticed difficulty swallowing and also paresthesias in the fingers and also the toes bilaterally, more [in] the upper extremities.” Id. She noted “some decreased dexterity in the hands with difficulty grasping and she ha[d] dropped things recently, her balance [was] mildly off in her legs feel weak proximally.” Id. She reported numbness and tingling “prominent when she [woke] up in the morning but then [would] recur intermittently throughout the day, also the feet[,] predominantly in the toes[,] occur[ed] similarly and this ha[d] become less frequent since going off steroids.” Id. Petitioner also reported aching and pain in the upper and lower back that had improved. Id. She had been off steroids for approximately two and one-half weeks. Id. Review of symptoms was positive for extremity weakness and numbness, dyspnea, chest pain, back and joint pain, and negative for fatigue, malaise, and cough. Id. at 367.

On physical examination, Petitioner had normal cranial nerve function, normal strength, normal muscle tone, normal sensation, 1+ deep tendon reflexes “except 2-3+ at the knees,”

¹⁴ Dysesthesia is the “distortion of any sense, especially of that of touch . . . an unpleasant abnormal sensation produced by normal stimuli.” Dysesthesia, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=15186> (last visited June 20, 2024).

¹⁵ Singulair is trademark for montelukast sodium which is “a leukotriene receptor antagonist used as an antiasthmatic agent.” Montelukast Sodium, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=32122> (last visited June 27, 2024); Singulair, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=45902> (last visited June 27, 2024).

¹⁶ A peak flow meter is used for measuring “the flow of air in the early part of forced exhalation.” Peak Flow Meter, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=89029> (last visited June 27, 2024).

positive Tinel signs¹⁷ at both wrists and fibular heads, and normal coordination. Pet. Ex. 3 at 369. Gait was “[n]otable for kyphotic posture with a dropped head when ambulat[ing],” “diminished arm swing,” and “difficulty walking tandemly although Romberg [was] negative.” Id. Dr. Saland’s assessment was that Petitioner had “paresthesias in the hands and feet occurring intermittently and less frequently since [three] weeks after the flu shot when she also developed a severe exacerbation of her asthma in the setting of a pulmonary infection She also ha[d] proximal weakness in the legs and had some difficulty swallowing that was intermittent and ha[d] also improved.” Id. at 369-70. Dr. Saland opined that the etiology of Petitioner’s neurological symptoms was “not clear.” Id. at 370. Dr. Saland also questioned whether Petitioner’s symptoms could be related to her recent steroid use. Id. Dr. Saland noted there was no sign of cranial nerve dysfunction. Id. The diagnoses were paresthesias, steroid-induced myopathy, drug-induced myopathy, and dysphagia (problems swallowing). Id. at 371. Dr. Saland ordered lab testing, MRIs of the brain and cervical spine, and an EMG/NCS. Id. at 370. Lab testing results were normal including Lyme antibody, Lyme Western Blot, copper, folate, Sjogren’s antibodies (SSA/SSB), rheumatoid factor, anti-nuclear antibodies (“ANA”), anti-CCP, RPR, free T4, and TSH. Id. at 601-07. Her vitamin B12 level was a low-normal at 256 (normal 193-928) but methylmalonic acid¹⁸ was normal. Id. at 604, 608.

Petitioner underwent a preoperative evaluation on November 30, 2015, for surgery on her right thumb. Pet. Ex. 3 at 376. Petitioner did not report shortness of breath or any neurological symptoms. See id. Assessment was “mild intermittent asthma without complication.” Id. at 381. There was no reference to acute symptoms related to asthma or numbness and tingling in the extremities.

On December 4, 2015, Petitioner saw Dr. Rogg who noted that Petitioner was undergoing a “neurological evaluation [] for [GBS]” by Dr. Saland following the flu vaccine. Pet. Ex. 2 at 78. Dr. Rogg noted her symptoms started on October 5, and that she had shortness of breath and had “gone to the hospital.” Id. Petitioner complained of a low-grade fever and reported that her asthma was still “bothersome.” Id. She also had an eyelid infection. Id. On examination, she had coarse rhonchi. Id. Dr. Rogg diagnosed facial cellulitis, bronchitis, and mild persistent asthma. Id. at 78-79. He prescribed prednisone for her asthma. Id. at 79. At this visit Petitioner did not complain of numbness or tingling.

Petitioner returned to Dr. Rogg on December 14 because she “[could not] take a deep breath, [and got] winded easily.” Pet. Ex. 2 at 75. She reported ongoing asthma symptoms since receiving the flu vaccine as well as dysesthesias. Id. On examination, she had occasional lung rhonchi. Id. Dr. Rogg added unspecified fatigue to his list of diagnoses and ordered extensive

¹⁷ Tinel sign refers to “a tingling sensation in the distal end of a limb when percussion is made over the site of a divided nerve. It indicates a partial lesion or the beginning regeneration of the nerve.” Tinel Sign, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=106510> (last visited June 27, 2024).

¹⁸ Methylmalonic acid is “a carboxylic acid occurring in excess in the blood and other body fluids in methylmalonicacidemia.” Methylmalonic Acid, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=30997> (last visited June 27, 2024).

lab testing. Id. at 76. Testing showed a normal/negative CBC, sedimentation rate, C-reactive protein, rheumatoid factor, and ANA. Id. at 84-88.

On December 18, 2015, Dr. Saland performed a NCS on Petitioner's upper extremities for her complaints of paresthesias, right more than the left, "that began [three] weeks after a flu shot in September accompanied by a respiratory infection and asthma exacerbation." Pet. Ex. 3 at 386. History noted Petitioner had "now improved off the [p]rednisone for several weeks but with some residual paresthesias in right hand." Id. The NCS showed a "mild right median neuropathy at the wrist . . . consistent with carpal tunnel syndrome."¹⁹ Id. at 386-88. There was no evidence of a large fiber peripheral neuropathy in the upper extremities. Id. Petitioner was unable to stay for the EMG needle testing. Id. at 387-88.

Dr. Saland authored a letter dated December 24, 2015, stating Petitioner "experienced various neurological symptoms approximately [three] weeks after receiving the [flu] vaccine at work in September 2015. The possibility of an autoimmune response affecting her nervous system [was] considered likely and she [was] currently undergoing a workup for additional clarification." Pet. Ex. 3 at 392.

Petitioner returned to Dr. Rogg on January 5, 2016, and reported she had a tentative diagnosis of GBS.²⁰ Pet. Ex. 2 at 72. She had been on prednisone for about three days as her asthma was bothersome due to the cold weather. Id. Review of symptoms, physical examination, and diagnoses were consistent with those documented at her previous visits. Id. at 72-73. On January 13, Dr. Rogg wrote a letter stating Petitioner had developed symptoms after a flu vaccine which had not resolved and that she was being evaluated by a neurologist for an adverse reaction to the flu vaccine. Id. at 112. He stated that "it appear[ed] as though the vaccine had considerable influence on these symptoms." Id. Petitioner continued to see Dr. Rogg at monthly intervals throughout 2016 with Dr. Rogg writing "to whom it may concern" letters after several of these visits. See generally Pet Ex. 2.

On December 24, 2015 and January 13, 2016, Dr. Saland authored letters stating that Petitioner "experienced various neurological symptoms approximately [three] weeks after a [flu] vaccine at work" and the "possibility of an autoimmune response affecting her nervous system is considered likely." Pet. Ex. 3 at 392, 398. In the second letter, Dr. Saland stated "the [flu] vaccine was likely a substantial factor in provoking the autoimmune reaction that occurred. She currently [was] undergoing further workup for additional clarification." Id. at 398.

At a cardiology appointment on January 15, 2016 for the purpose of obtaining clearance for trigger finger surgery, Petitioner complained of her heart racing and symptoms of atypical chest pain but she did not report any other problems. Pet. Ex. 3 at 399. In review of systems,

¹⁹ Carpal tunnel syndrome is "an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow. Symptoms result from compression of the median nerve in the carpal tunnel." Carpal Tunnel Syndrome, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=110370> (last visited June 20, 2024).

²⁰ It is not clear what health care provider gave Petitioner the tentative diagnosis of GBS.

Petitioner gave a history of “a series” of asthma flares in September “after flu shot and the question of [GBS], which improved.” Id. at 399-400. Currently, she was using her asthma inhalers only as needed “which ha[d] been her baseline in recent years.” Id. at 400. She did not report of numbness or tingling of her extremities. See id. The cardiologist recommended that Petitioner have Holter monitor testing of her heart rhythm prior to undergoing elective thumb surgery. Id. at 401. No concerns were documented regarding any pulmonary or neurological conditions that would preclude surgery.²¹

On January 28, 2016, Petitioner presented for an urgent care visit after a chair fell on her toe. Pet. Ex. 3 at 406. Review of systems was negative for extremity weakness or numbness. Id. She was instructed to ice and elevate her toe and take pain medication as needed. Id. at 408. X-rays did not show any fracture. Id. at 411.

Petitioner saw Dr. Rogg on February 29, 2016 for follow-up of her breathing. Pet. Ex. 2 at 68. She reported that since her flu vaccine, she had been more reliant on her Proventil. Id. She reported a Zoster outbreak, and that she was undergoing an evaluation for GBS post-flu vaccination. Id. Assessment included dysesthesia. Id.

On March 2, 2016, Petitioner called Dr. Saland’s office to cancel the EMG that was scheduled that week because she had shingles that were very painful. Pet. Ex. 3 at 420.

On March 7, 2016, Petitioner saw endocrinologist Dr. Jeffrey Powell for an unrelated kidney issue. Pet. Ex. 3 at 421. As part of the history taken, Petitioner reported she got a flu shot and two weeks later developed an URI. Id. She “could not breathe” and “her asthma became severe.” Id. She also reported that “a few weeks after this flu shot, she developed pins-and-needles in her legs.” Id. She was referred to a neurologist (Dr. Saland) and “diagnosed with [GBS] from the flu shot. She [said] this [was] slowly getting better.” Id. at 421-22. On examination, her lungs were clear and she had normal deep tendon reflexes bilaterally in her upper extremities. Id. at 422.

Six months after the flu vaccination, on March 29, 2016, Petitioner returned to Dr. Saland for neurological follow-up. Pet. Ex. 3 at 433. Petitioner had not followed through with the brain and cervical spine MRIs and had “cancelled appointments to complete EMG as she ha[d] not been able to go back to work for pulmonary reasons related to her asthma.” Id. Petitioner reported “significant improvement” since her prior visit in November 2015, but “continue[d] to describe milder burning and tingling in the arms mostly forearms[,] left greater than right[,] as well as paresthesias in the fingers and toes mostly[,] the [third] and [fourth] fingers and also middle toes.” Id. Neurologic examination was normal and reflexes were “intact and symmetric.” Id. at 435. Dr. Saland noted that Petitioner’s earlier proximal leg weakness and dysphagia had resolved, that her upper extremity NCS was notable only for mild carpal tunnel syndrome. Id. at 436. Petitioner had not returned for a lower extremity NCS or needle EMG. Id. In the assessment, Dr. Saland concluded that “the etiology of [Petitioner’s] symptoms remain[ed] unclear and further work up [was] again suggested. Examination [was] essentially normal.” Id. Petitioner was informed of a neurology clinic where she could be seen for free or for lower cost based on financial ability to pay. Id.

²¹ Thumb surgery was scheduled for January 18, 2015. Pet. Ex. 3 at 389.

Also on March 29, 2016, Petitioner underwent a treadmill stress test for her symptom of heart racing. Pet. Ex. 3 at 557. Compared with her prior stress test done in 2012, her “exercise time had improved” and she was “overall stable/improved.” Id. There was no indication that Petitioner had shortness of breath or asthma symptoms during the stress test. Id. Based on the study, Petitioner was cleared for her hand surgery. Id.

c. April 2016 through September 2016 (Completion of One Year Post-Vaccination)

On May 2, 2016, Petitioner saw neurologist Dr. Sami Khella. Pet. Ex. 5 at 2. She repeated the history documented before, that Petitioner’s asthma had been well controlled for the past two-and-one-half to three years but that on September 19, 2015, she received a flu shot and two weeks later, developed “pins and needles in toes and hands and ankles” and had an asthmatic attack. Id. Petitioner reported she saw her pulmonologist who prescribed medications for bronchitis. Id. Her paresthesias increased and she developed leg weakness and trouble swallowing. Id. Petitioner also reported that had decreased reflexes, muscle weakness, difficulty with steps, and dropping things. Id. “She continued to progress for more than [eight] weeks but ha[d] since stabilized and improved but ha[d] residual weakness.” Id. Neurologic examination was normal. Id. at 3-5. She had normal strength, deep tendon reflexes, and sensation. Id. Dr. Khella’s impression was that Petitioner had “sensory motor symptoms and severe asthma that developed within [two to three] [weeks] of taking the trivalent flu vaccine.” Id. at 5. Dr. Khella noted Petitioner had a normal neurological examination when she was seen by Dr. Saland on November 25, 2015. Id. Dr. Khella concluded that Petitioner “continue[d] to have sensory symptoms but ha[d] a normal neurological examination. It [was] possible that she had [GBS]” but “[s]he [was] currently stable.” Id.

Dr. Rogg saw Petitioner on May 10, 2016 for “[l]eg heaviness.” Pet. Ex. 2 at 59. History noted that since Petitioner had been on Pravastatin,²² she was having “muscle aches, heaviness especially [in her] lower legs.” Id. Assessment was “[m]yalgia.” Id. Due to the complaint of myalgia, Dr. Rogg discontinued the Pravastatin. Id. Petitioner saw Dr. Rogg on May 16, 2016, complaining of “[w]orsening body aches” and “nausea.” Id. at 56. She was assessed with “[m]oderate persistent asthma with acute exacerbation” and “[v]iral syndrome.” Id. She had no neurological complaints.

On May 31, 2016, Petitioner saw Dr. Julia Shih at the JMC Primary Care Clinic. Pet. Ex. 4 at 119. Petitioner reported she “developed GBS symptoms (? autoimmune phenomenon from vaccine)” but those symptoms had since resolved. Id. She reported one asthma flare in the last month requiring oral steroids and stated that she had been “obtaining steroid monthly for

²² Pravastatin is “an antihyperlipidemic agent . . . used to lower blood lipid levels in the treatment of hypercholesterolemia and other forms of dyslipidemia and to reduce the risk of morbidity and mortality associated with atherosclerosis and coronary heart disease.” Pravastatin Sodium, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=40666> (last visited June 27, 2024).

asthma” since her reaction to the flu vaccine.²³ Id. at 120. Petitioner was referred to a pulmonologist due to her requirement for monthly steroids for asthma flares and was prescribed a steroid inhaler, albuterol inhaler, and Singulair. Id. at 121.

Petitioner returned to Dr. Rogg June 7 and June 14, 2016. Pet. Ex. 2 at 50, 53. On June 7, she complained of “pin, needles,” for two weeks. Id. at 53. Diagnosis was dysesthesia. Id. She also had a URI and mild asthma. Id. On June 14, she complained of “weakness in arms and legs.” Id. at 50. Over the weekend she had increased tingling and lost her balance and fell. Id. Petitioner returned to see Dr. Rogg on July 8 and August 15, 2016. Id. at 44-47.

d. October 2016 through 2018

On October 6, 2016, Petitioner reported to Dr. Rogg that her chest felt tight and congested and she continued to have dysesthesias in her hands and legs. Pet. Ex. 2 at 116. On examination, she had bilateral rhonchi. Id. Dr. Rogg diagnosed an asthma exacerbation and administered a systemic steroid injection. Id. He also diagnosed a vitamin B12 deficiency and ordered labs for parietal cell antibodies and intrinsic factor blocking antibody. Id.

On October 17, 2016, Dr. Rogg wrote another letter stating that Petitioner continued to be evaluated and treated for symptoms post-flu vaccine which included asthma and neuropathic changes. Pet. Ex. 2 at 103. He stated that she had been recently diagnosed with an asthma exacerbation and “found to have a significant vitamin B12 deficiency caused by an autoimmune reaction to the flu vaccine exacerbating her neurological symptoms.” Id.

At an appointment with Dr. Rogg on October 27, it was noted that Petitioner’s breathing had been fluctuating since the last visit. Pet. Ex. 2 at 41. It was also noted that the test for parietal cell antibodies was positive. Id. Diagnoses were acute asthma exacerbation and vitamin B12 deficiency. Id. at 41-42.

Petitioner returned to Dr. Rogg on December 9, 2016 for fluctuating asthma symptoms and continued paresthesias. Pet. Ex. 2 at 32. Dr. Rogg noted that Petitioner was seen by another provider in the office in November for cellulitis of the eye. Id. at 32, 34, 36. A pulmonary functions test was ordered but could not be completed because of Petitioner’s coughing and wheezing. Id. at 32. He diagnosed Petitioner with mild persistent asthma, B12 deficiency, dysesthesia, and GBS. Id. at 32-33. On December 13, Dr. Rogg wrote a letter stating that Petitioner’s flu vaccine caused an autoimmune response which resulted in asthma aggravation and exacerbation, neuropathic changes related to GBS, acute vitamin B12 deficiency, cellulitis of the face, and infection of the nasal mucosa. Id. at 102. Petitioner continued to see Dr. Rogg every one to two months throughout 2017 and 2018. See generally Pet. Ex. 2.

On May 16, 2017, Petitioner saw Dr. Eleanor Weinstein at the JMC Primary Care Clinic. Pet. Ex. 11 at 5. History repeated the notes entered at the clinic on May 31, 2016. Id.; see Pet. Ex. 4 at 119. Dr. Weinstein added that Petitioner had recently had issues with her asthma and was on prednisone a few times. Pet. Ex. 11 at 6. Dr. Weinstein’s assessment was mild persistent

²³ The medical records do not document that Petitioner had received oral steroids monthly for asthma flairs.

asthma, noting a reported “bad reaction to flu vaccine,” and questioning a behavioral health issue. Id. at 7. Lab testing showed a normal CBC, chemistry panel, and vitamin B12. Id. at 47-48.

Petitioner followed-up with Dr. Rogg on June 7, 2017. Pet. Ex. 2 at 19. Diagnoses at this visit included moderate asthma and neuropathy. Id. at 21. At an August 28 visit with Dr. Rogg, Petitioner had continued asthma and paresthesias and reported a recent episode of shingles. Id. at 16. On examination, her lungs were clear, and she had a resolving blistering rash on the right abdominal wall. Id. at 17. On September 29, 2017, Petitioner reported “recurring asthma symptoms,” as well as “recurrent heaviness in legs with tingling [and] fatigue.” Id. at 13. Dr. Rogg noted “stable, [c]hronic inflammatory demyelinating polyneuropathy material was published to portal,” suggesting that he provided such material to Petitioner. Id. at 14. On October 10, Petitioner reported to Dr. Rogg that she had two episodes of shingles in September, treated with Valtrex. Id. at 10. She also reported “ongoing congestion.” Id.

Dr. Weinstein saw Petitioner again in July, September, October, and November 2017, and throughout 2018. See generally Pet. Ex. 11. At her October visit, Petitioner reported taking prednisone for about five days every month due to asthma symptoms as well as regular use of inhalers and Singulair. Id. at 12. Petitioner reported intermittent tingling in her feet which she believed was “due to GBS from her flu vaccine in 2015.” Id.

On December 12, 2017, Petitioner complained to Dr. Rogg of ongoing fatigue, weakness, paresthesias, and twitching of her face. Pet. Ex. 2 at 7. On examination, Petitioner had occasional rhonchi and dysesthesias of her upper and lower extremities. Id. at 8. Dr. Rogg authored another letter stating the flu vaccine caused an autoimmune response and chronic immune dysregulation which caused Petitioner to have “continued volatile, overly vigorous inflammatory episodes” resulting in “uncontrollable” asthma, neuropathic changes related to GBS, acute B12 deficiency, cellulitis of the face, infections of the nasal mucosa, exacerbation of shingles, arthritis, muscle weakness/fatigue, and increased susceptibility to infection. Id. at 96.

At a visit on March 23, 2018, Dr. Rogg noted that Petitioner had no insurance and was on the waiting list to see a neurologist at JMC. Pet. Ex. 2 at 1. He stated that her symptoms were likely related to a GBS variant but that she needed additional evaluation to include testing for small fiber neuropathy. Id. He prescribed gabapentin. Id. On April 27, 2018, Dr. Rogg increased the gabapentin dosage and discussed the need for a pulmonary evaluation. Pet. Ex. 8 at 2.

On June 8, 2018, Petitioner saw Dr. Weinstein reporting “a resurgence of what she consider[ed] to be symptoms related to GBS” and more asthma symptoms requiring her to use more prednisone. Pet. Ex. 11 at 25-26. Dr. Weinstein diagnosed persistent asthma and referred her to a pulmonologist. Id. at 27. Dr. Weinstein noted that she had seen no documentation that Petitioner had GBS and referred her to a neurologist for evaluation. Id. Much of the care she received in June 2018, and later, was due to a fall Petitioner had on June 24, 2018, when she injured her right knee. Id. at 38-60.

e. Neurology Evaluations in 2020 and 2021

In 2020, Petitioner presented, via telehealth, to neurologist Dr. Steven Krieger. Pet. Ex. 65 at 10; Pet. Ex. 67 at 7. History noted Petitioner had “no remote neuro symptoms.” Pet. Ex. 65 at 2, 10. History also indicated Petitioner developed “limb and [right] face paresthesias and pain after flu shot and asthma exacerbation in Fall 2015.” Id. at 14; Pet. Ex. 67 at 11. Petitioner stated that she had an “upper extremity EMG” that was “non-specific” but “considered for GBS.” Pet. Ex. 65 at 10. Dr. Krieger suggested a possible clinically isolated syndrome as a diagnosis, but noted he needed Petitioner’s prior records and additional MRIs for further analysis. Id. at 14; Pet. Ex. 67 at 11. Dr. Krieger ordered MRIs “since symptoms began [in] 2015 and ha[d] not worsened.” Pet. Ex. 65 at 14.

On June 19, 2021, Petitioner had MRIs of her brain and cervical spine. Pet. Ex. 72 at 2-4. She did not have any demyelinating lesions in the cervical spinal cord. Id. at 3. The brain MRI showed a few nonspecific periventricular FLAIR hyperintense lesions. Id. at 4. Petitioner followed up with Dr. Krieger on June 22. Pet. Ex. 69 at 2; Pet. Ex. 71 at 6. He indicated Petitioner’s prior test results were unremarkable. Pet. Ex. 69 at 5. Dr. Krieger concluded that Petitioner’s reported history, “coupled with the absence of long-tract findings on exam (albeit limited in video visit context) with a non-diagnostic [b]rain and negative [cervical] spine MRI[s] preclude[d] a diagnosis of [multiple sclerosis] at [that] time.” Id. at 6. Further, Dr. Krieger felt that Petitioner’s brain MRI was inconsistent with acute disseminated encephalomyelitis (or similar conditions although he noted relevant event (2015 flu vaccine) had occurred six years earlier. Id. He referred Petitioner to another provider for an evaluation regarding whether she possibly had small fiber neuropathy.²⁴ Id.

On September 16, 2021, Petitioner attended a video evaluation with neurologist Dr. Vanessa Tiongson. Pet. Ex. 73 at 2. History notes indicated that seven days after a flu shot in 2015, Petitioner had upper respiratory symptoms, an asthma flair, and paresthesias in her hands and feet which progressively worsened. Id. at 2-3. Dr. Tiongson’s impression was that Petitioner’s paresthesia, “[i]f started after [the] flu shot, could have been GBS with residual symptoms [versus a] [chronic inflammatory demyelinating polyradiculoneuropathy (“CIDP”)]²⁵]-

²⁴ It does not appear Petitioner pursued this referral.

²⁵ CIDP is “a type of demyelinating polyneuropathy similar to [GBS] but progressing more slowly or in a fluctuating pattern.” Chronic Inflammatory Polyradiculoneuropathy, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=99422> (last visited June 27, 2024).

type picture.” Id. at 7. Dr. Tiongson also noted that Petitioner had a “vitamin B12 deficiency with potentially insufficient treatment.”²⁶ Id. at 7.

No other relevant medical records were filed.

2. Letters from Dr. Gary Rogg

In addition to medical records reflecting office visits, Dr. Rogg’s records also contain letters regarding Petitioner. There are several versions of the letters. The first set of letters are dated December 4, 2015, January 13, 2015, February 29, 2016, March 16, 2016, March 31, 2016, April 7, 2016, April 19, 2016, May 11, 2016, September 28, 2016, and October 17, 2016. Pet. Ex. 3 at 103-14. In these letters Dr. Rogg stated that due to Petitioner’s medical status she was unable to work. Some of these letters refer to symptoms that began after she received a flu vaccine in September and state that she was undergoing an evaluation by neurology for an adverse reaction. Several of the letters reference symptoms related to “uncontrolled asthma and neuropathic changes.” Id. at 103-07, 109-10.

Letters dated December 13 and December 22, 2016 include a more extensive list of problems attributed to the flu vaccine. Pet. Ex. 2 at 101-02. Dr. Rogg stated that the flu vaccine Petitioner received in October of 2015, caused an “autoimmune response, which resulted in: [a]ggravation and exacerbation of her previously controlled asthma of which is now uncontrollable,” “[n]europathic changes related to [GBS],” “[a]cute vitamin B-12 deficiency,” “[c]ellulitis of the face,” and “[i]nfections in the nasal mucosa.” Id. at 101. Dr. Rogg noted that due to financial hardships, Petitioner had been unable to receive medical care for these problems, and that she required follow-up care with specialists. He concluded that Petitioner was “released to only perform part-time work at home, sedentary desk employment, not to exceed 30 hours per week.” Id.

The next set of letters include an even longer list of problems attributed to the flu vaccine. Pet. Ex. 2 at 93-100. These letters are dated January 26, 2017, June 7, 2017, September 29, 2017, October 10, 2017, December 12, 2017, December 19, 2017, February 6, 2018, and March 23, 2018, in which Dr. Rogg again stated that Petitioner was under his care and treatment for “evaluation of symptoms starting post flu vaccine.” Id. at 93-94, 96-100. Dr. Rogg stated that the “flu vaccine . . . caused an autoimmune response and chronic immune dysregulation. As a result, [Petitioner] suffer[ed] from continued volatile, overly vigorous, inflammatory episodes” which in addition to the problems stated above, included “[e]xacerbation of [s]hingles,” “[m]uscle weakness and fatigue,” “[i]ncrease susceptibility to infection,” and arthritis. Id. Dr. Rogg noted that due to financial hardships, Petitioner had been unable to receive medical care for

²⁶ Neurologic symptoms can develop from a vitamin B12 deficiency. Larry E. Johnson, Vitamin B12 Deficiency, Merck Manual Online, <https://www.merckmanuals.com/professional/nutritional-disorders/vitamin-deficiency,-dependency,-and-toxicity/vitamin-b12-deficiency> (last visited July 3, 2024). “In early stages, decreased position and vibratory sensation in the extremities is accompanied by mild to moderate weakness and hyporeflexia. In later stages, spasticity, extensor plantar responses, greater loss of position and vibratory sensation in the lower extremities, and ataxia emerge.” Id.

these problems, and that she required follow-up care with specialists. He concluded that Petitioner was “temporarily, totally disabled and [] completely unable to work.” Id. at 93-100.

Additionally, Petitioner submitted further letters from Dr. Rogg as individual exhibits. Pet. Exs. 8-10, 12. On April 27, August 9, 2018, and November 14, 2018, Dr. Rogg authored letters stating he was Petitioner’s PCP, and that Petitioner was “still under treatment and evaluation for symptoms starting post flu vaccine.” Pet. Ex. 8 at 1; Pet. Ex. 9 at 1; Pet. Ex. 12 at 1. He wrote that Petitioner received the flu vaccine in September/October 2015²⁷ and that the flu vaccine “caused an autoimmune response and chronic immune dysregulation.” Pet. Ex. 8 at 1; Pet. Ex. 9 at 1; Pet. Ex. 12 at 1. These letters contain the same information as the letters summarized above. Again, Dr. Rogg noted that due to Petitioner’s “financial hardships and lack of insurance coverage she [was] unable to receive appropriate care to address the above symptoms,” but that she still required treatments and testing pending insurance coverage. Pet. Ex. 8 at 1; Pet. Ex. 9 at 1; Pet. Ex. 12 at 1.

On August 15, 2018, Dr. Rogg authored a letter again stating that Petitioner was under his care. Pet. Ex. 10 at 1. In this letter he opined “[t]he administration of the flu vaccine in September 2015 [] caused in [Petitioner] an autoimmune response and chronic immune dysregulation.” Id. He added that this “resulted in recurrent exacerbation of [s]hingles requiring Valtrex.” Id. Her initial outbreak of shingles occurred on November 13, 2013. Id.

3. Petitioner’s Affidavit

Petitioner averred that prior to receiving the flu vaccine on September 19, 2015, her health “was excellent with no physical restrictions.” Pet. Ex. 6 at ¶¶ 4-5. While she is an “asthmatic,” she had been “symptom free” from 2011 to 2012 and “until the time [she] received the [flu] vaccine administration [on] September 19, 2015.” Id. at ¶ 6. She had received the flu vaccine in prior years without any known complications. Id. at ¶ 7.

By October 3, 2015, Petitioner began experiencing “mild upper respiratory symptoms and ‘pins and needles’ in [her] hands/fingers and feet/toes.” Pet. Ex. 6 at ¶ 8. The symptoms “became progressively worse and greatly intensified by October 8, 2015.” Id. at ¶ 9. By October 13, 2015, Petitioner’s “attempts to self-medicate at home were unsuccessful” and she presented to the ED “with a full-blown asthmatic attack, upper respiratory symptoms, and intensifying ‘pins and needles.’” Id. at ¶ 10. In the ED, she received breathing treatments, oxygen, and steroids. Id. at ¶ 11. It was recommended she be admitted to the hospital, however, Petitioner declined because she did not have insurance. Id.

On October 14, 2015, Petitioner presented to her pulmonologist, Dr. Klares. Pet. Ex. 6 at ¶ 12. He revised her medications, put her on antibiotics, and referred her to Dr. Saland for her neurological symptoms. Id. Petitioner returned to the ED on October 22, 2015 for a “full-blown asthmatic attack/difficulty breathing.” Id. at ¶ 13. She again received breathing treatments, oxygen, and steroids, and declined admission due to insurance. Id. Petitioner again followed up with Dr. Klares on November 4, 2015. Id. at ¶ 14.

²⁷ Petitioner received the flu vaccine at issue on September 19, 2015. Pet. Ex. 1 at 1.

Petitioner averred that “[d]espite her visits to the [ED], [her] symptoms were not improving.” Pet. Ex. 6 at ¶ 15. Therefore, on November 5, 2015, Petitioner sought treatment at the JMC Asthma Clinic where she received breathing treatments, oxygen, and steroids. Id.

By November 1, 2015, Petitioner had been granted insurance from her employer. Pet. Ex. 6 at ¶ 16. On November 11, Petitioner saw her PCP Dr. Rogg for her “increased and intensifying symptoms” including difficulty breathing, walking, and swallowing; “[s]hortness of breath;” “[u]ncontrolled asthma with exacerbations;” “[i]ntensifying pins-and-needles in upper extremities;” “[m]uscle weakness in legs that spread upwards;” “[f]acial twitching;” “[r]apid heartbeat;” and fatigue. Id. He did blood tests and adjusted her medications. Id. at ¶ 17. The following day, Petitioner went to the JMC Asthma Clinic where they adjusted her asthma medications. Id. at ¶ 18.

Petitioner saw neurologist Dr. Saland on November 24, 2015. Pet. Ex. 6 at ¶ 19. Dr. Saland “did an extensive exam[ination] and ran blood tests due to the neurological symptoms [Petitioner] had been experiencing.” Id. She was waiting on approval for additional testing and imaging. Id.

Petitioner returned to Dr. Rogg on December 14, 2015 for cellulitis of her left eye and face. Pet. Ex. 6 at ¶ 21. On December 18, Petitioner went back to Dr. Saland for an upper extremity EMG. Id. at ¶ 22. At this time, Petitioner was still experiencing “[p]roblems with asthma and oxygen exchange,” “[s]hortness of breath,” “[d]ifficulty breathing,” “[c]ongestion in lungs,” and “[n]eurological symptoms.” Id.

On or about February 2, 2016, Petitioner suffered an outbreak of shingles and Dr. Rogg prescribed Valtrex. Pet. Ex. 6 at ¶ 24. On February 9, Petitioner saw Dr. Rogg again and at that time he was waiting approval for pulmonary rehabilitation. Id. at ¶ 25. On or about March 2, 2016, Petitioner suffered another outbreak and exacerbation of shingles. Id. at ¶ 26. She was again prescribed Valtrex. Id.

On March 29, 2016, Petitioner had a follow-up appointment with Dr. Saland. Pet. Ex. 6 at ¶ 27. Dr. Saland “performed another extensive exam[ination] (due to [Petitioner’s] continued neurologic symptoms) and ordered an EMG, MRI, and [s]wallowing [t]est.” Id. Petitioner reported that unfortunately, her “insurance ended on April 1, 2016, so [she] was unable to have these tests performed.” Id.

Petitioner followed up with Dr. Rogg on April 19, 2016. Pet. Ex. 6 at ¶ 29. At that time, Dr. Rogg was “still trying to stabilize [Petitioner’s] asthma with different medication regimes.” Id. Dr. Rogg also still wanted Petitioner to go for pulmonary rehabilitation, but due to Petitioner’s “lack of insurance and financial hardship, [she] was not able to go” and she was also “unable to afford some of [her] prescriptions.” Id.

On May 10, 2016, Petitioner presented to Dr. Rogg for an “unscheduled appointment” to “address symptoms related to a potential medication adverse reaction.” Pet. Ex. 6 at ¶ 31. Dr. Rogg determined it “might have been caused by the Pravastatin.” Id. Petitioner was still not feeling better by May 16 when she had another “unscheduled appointment” with Dr. Rogg. Id. at ¶ 32.

On May 31, 2016, Petitioner presented to Jacobi Medical. Pet. Ex. 6 at ¶ 33. “Due to lack of insurance and financial hardship, Jacobi Medical recommended their medical clinic for ‘reduced-cost’ medical treatment and medication.” Id.

At an appointment with Dr. Rogg on June 7, 2016, Dr. Rogg prescribed Petitioner branch chain amino acids as a supplement. Pet. Ex. 6 at ¶ 34. On June 14, Petitioner still was not feeling well so Dr. Rogg ordered a series of blood tests which came back normal. Id. at ¶ 35.

At a follow-up appointment with Dr. Rogg on August 15, Petitioner had “ongoing feelings of tingling in the extremities and issues with walking post-vaccine.” Pet. Ex. 6 at ¶ 37. She also had complaints of left abdominal pain. Id. On August 30, Petitioner had an abdominal ultrasound. Id. at ¶ 38. Petitioner reported “persistent, ongoing muscle aches and tingling—primarily in the lower extremities.” Id. The results of the abdominal ultrasound were “attributed to [Petitioner’s] persistent cough from [her] asthma.” Id.

On October 6, 2016, Petitioner had a follow-up with Dr. Rogg, who was “still trying to stabilize [Petitioner’s] asthma and persistent cough”. Pet. Ex. 6 at ¶ 39. Petitioner reported that her “chest felt tighter, more constricted[,] and congested.” Id. Dr. Rogg administered a Medrol injection. Id. Bloods tests showed a vitamin B12 deficiency and Dr. Rogg recommended weekly B12 injections and oral supplements. Id. At this visit, Petitioner again recalled having “persistent, ongoing tingling in [her] extremities and muscle aches.” Id. On October 14, Petitioner returned to Dr. Rogg for “exacerbation of [her] asthma and issues of fatigability and tingling in [her] extremities.” Id. at ¶ 40.

At a follow-up with Dr. Rogg on December 9, 2016, Petitioner reported that due to “fatigability and muscle weakness of [her] lower extremities, [she] fell on [her] right side (earlier in the week).” Pet. Ex. 6 at ¶ 43. An X-ray of Petitioner’s ribs was normal. Id.

By February 2017, Dr. Rogg was “still trying to stabilize [Petitioner’s] asthma and persistent cough with different medication regimes. . . . In addition, he still want[ed] [Petitioner] to go for pulmonary consult and rehabilitation, but due to [her] lack of insurance and financial hardship, [she was] not able to go to rehabilitation and [was] unable [to] fill some of the prescriptions.” Pet. Ex. 6 at ¶¶ 44-45. Petitioner was still having “continued issues of chronic fatigue and tingling in extremities (dropping objects).” Id.

On May 16, 2017, Petitioner had an appointment with Dr. Weinstein for follow-up for her “symptoms related to [her] flu vaccine injury.” Pet. Ex. 6 at ¶ 47. “Due to the loss of Charity Care, [Petitioner] was temporarily unable to be treated by Dr. Rogg.” Id. She continued to have follow-up visits with Dr. Weinstein, Dr. Charles, and Dr. Rogg. Id. at ¶ 48. In January 2018, Petitioner injured her toe from a fall “due to [her] fatigue and pins and needles in [her] lower extremities.” Id. at ¶ 49. In March 2018, Dr. Rogg prescribed Petitioner gabapentin for her “persistent neurologic symptoms.” Id. at ¶ 50.

As of the date Petitioner executed this affidavit, April 27, 2018, Petitioner “continue[d] to suffer with asthma symptoms, which are far worse than they were before [she] received the [flu] vaccine on September 19, 2015.” Pet. Ex. 6 at ¶ 51. She averred “[t]his can be verified by

seeing that [she] was not taking steroids and other medications for the asthma until after the receipt of the vaccine. In addition, [she had] tingling in [her] hands and feet, bilaterally.” Id. Petitioner wrote that she “truly believes that the injuries [she was] suffering [] are related to the [flu] vaccine she received on September 19, 2015.” Id. at ¶ 52.

4. Independent Medical Evaluation by Dr. Michael M. Conway²⁸

On October 8, 2016, Dr. Michael Conway reviewed Petitioner’s medical records from October 2015 to June 2016 and summarized her case from the pulmonary perspective. Pet. Ex. 7 at 5. He did not address the neurological issues. Id. Dr. Conway’s impression was that while Petitioner had an asthma exacerbation starting in October 2015, “the flu shot did not cause her asthma exacerbation.” Id. at 6-7. He stated that “[m]ultiple well-performed large studies reveal[ed] no increased incidence of asthma following flu vaccination.” Id. at 7. He opined “[a]ny impairment that flows from poorly controlled asthma is not related to the flu shot” and “[n]one of the treatment [Petitioner] ha[d] required [was] connected to her flu shot.” Id.

On November 1, 2016, Dr. Conway performed an independent medical evaluation (“IME”) on Petitioner to evaluate “the relationship[,] if any[,] between an apparent exacerbation of her underlying asthma and the flu shot she received in September 2015.” Pet. Ex. 7 at 1. He did not review any additional records from the ones previously reviewed on October 8, 2016. Id. Petitioner’s history, beginning in the mid 1980’s, eventually required regular medications including Advair, Singulair, and intermittent prednisone. Id. From 2013 to 2015, Petitioner only required the use of a rescue inhaler as needed. Id. In September 2015, she had a flu shot. Id. at 2. Dr. Conway noted Petitioner received one every year without difficulty in the past. Id. “Approximately two weeks later she noted symptoms of a[] [URI] along with numbness and tingling in her hands and feet. The URI symptoms were followed within [one to two] weeks by an asthma exacerbation prompting an [ED] visit where she was treated” with multiple rounds of albuterol nebulization, steroids and oxygen. Id. She was discharged with a prednisone taper and a rescue inhaler as needed. Id. The following day, Petitioner went to her pulmonologist who prescribed her an antibiotic and restarted her on Advair, Atrovent, and montelukast. Id. No pulmonary function test was performed. Id. Petitioner had returned to the ED two more times and had been on medication on and off since then. Id. “Her asthma remain[ed] poorly controlled since November 2015.” Id. “For much of the last year she has not had regular insurance covering medications, so at times she cannot afford to buy and use regular controller medications.” Id.

Petitioner’s symptoms at the time of the IME were dyspnea, wheezing, and coughing. Pet. Ex. 7 at 2. Specifically, she noted dyspnea after walking two blocks as well as at night. Id. She was not able to exercise and felt she could not work regularly because of her persistent asthma symptoms. Id. “Her neurologic symptoms ha[d] largely cleared.” Id. Review of symptoms also noted “intermittent palpitations, fatigue, weakness, leg heaviness, paresthesias, reflux esophagitis[,] and transient difficulty swallowing.” Id. at 3. Her physical examination was unremarkable, and Dr. Conway noted her chest X-ray from 2015 was clear. Id. He

²⁸ Dr. Conway opined that Petitioner could return to full time regular work without restrictions. He found “there is no reason her asthma precludes regular work as a pharmacist.” Pet. Ex. 7 at 4.

conducted a pulmonary function test and noted Petitioner had difficulty with the test because she “could not control her cough” and “was worse after [albuterol].” Id.

Dr. Conway opined his major finding had not changed from his October 8, 2016 review. Pet. Ex. 7 at 2. He specifically opined “[t]he URI and asthma exacerbation that began [two] plus weeks after the routine flu shot in September 2015 [were] clearly and definitely not secondary to the flu shot.” Id. His opinion was based on “strong epidemiologic studies that have found no association between [flu] vaccination and exacerbations of asthma, as well as on the clinical course of her symptoms.” Id. “She noted the URI symptoms at least two weeks after the flu shot and these symptoms were followed by an asthma exacerbation like she has noted in the past.” Id. Dr. Conway stated it was unclear why Petitioner “had such difficulty with her asthma from the 1980’s through 2013 and yet noted apparently spontaneous clearing from 2013 until 2015.” Id. His diagnosis was moderate persistent asthma. Id.

C. Expert Reports

1. Petitioner’s Expert, Dr. Omid Akbari, Ph.D.²⁹

a. Background and Qualifications

Dr. Akbari is currently a Professor of Allergy and Immunology and Professor of Medicine at Keck School of Medicine, University of Southern California. Pet. Ex. 13 at 2. He received his Ph.D. in cellular and molecular immunology at the National Institute for Medical Research in London, United Kingdom. Pet. Ex. 14 at 1. Thereafter he completed a postdoctoral fellowship at Stanford University. Id. Dr. Akbari’s research is “focused on the role of immune tolerance and how immune cells induce autoimmune and allergic diseases.” Pet. Ex. 13 at 2. Additionally, in his laboratory, there are research studies “relevant to the issue of understanding the medical theories involved in regard to how immunization may result in appropriate or dysregulated immune responses causing unwanted inflammation and adverse effects.” Id. He serves as an editor and reviewer on numerous journals and has authored or co-authored numerous publications. Id.; Pet. Ex. 14 at 4-5, 8-13. Dr. Akbari is not a medical doctor and is not qualified to diagnose or treat medical, pulmonary, and/or neurological conditions. See Pet. Ex. 14.

b. Diagnosis Opinion

Although Dr. Akbari is not a medical doctor, he opined Petitioner suffered from “neuroinflammation in the lungs and nervous system.” Pet. Ex. 13 at 1. He stated that she had “overly inflammatory episodes which resulted in asthma exacerbation and neuropathic changes related to [GBS].” Pet. Ex. 13 at 10. He based his opinions on the medical records and “conclusions by clinical team.” Id. at 10.

²⁹ Dr. Akbari provided one expert report. Pet. Ex. 13.

c. Causation Opinion

Dr. Akbari opined that the flu vaccination caused Petitioner “to develop inflammation in the lungs and nervous system,” and that “stimulation of the immune system . . . followed by the production of antibodies in response to the vaccines, [i]s a plausible medical theory causally linking the [flu] vaccination with the development of symptoms in [Petitioner] including asthma exacerbation and neuropathic symptoms.” Pet. Ex. 13 at 1, 16.

i. Althen Prong One

1. Neurological Condition

For how the flu vaccine can cause “neuroinflammation” and “neuropathic changes related to [GBS],” Dr. Akbari relied on the theory of molecular mimicry. Pet. Ex. 13 at 4, 10. He defined molecular mimicry as “the mechanism by which an immune stimulated response by infection or other method, i.e. vaccination, can trigger cross-reactive antibodies or T cells that cause the symptoms of autoimmune disease.” Id. at 4-5.

Then Dr. Akbari opined that from an “immunological and pathological perspective, considerable overlap exists between central and peripheral myelitis including multiple sclerosis, [GBS], acute disseminated encephalomyelitis.” Pet. Ex. 13 at 11. He stated these conditions are “characterized by inflammatory infiltration of both T cells and macrophages into the nervous system, as well as areas of demyelination.” Id. He used the terms neuroinflammation and demyelinating disease³⁰ interchangeably. Id. at 11-12. Dr. Akbari opined that autoimmunity in multiple sclerosis³¹ and neuromyelitis³² is “most likely mediated by antibodies directed against myelin antigens, along with autoreactive T cells and macrophages that invade the myelin sheath, axonal membranes, and/or the nodes of Ranvier.” Id. at 14. Additionally, he noted there is “strong evidence for an antigen driven, T-cell mediated attack against peripheral nerve tissue components in the pathogenesis of neuromyelitis and demyelinating diseases.” Id. at 15 (citing Pet. Ex. 63).³³

³⁰ A demyelinating disease is “any condition characterized by destruction of the myelin sheaths of nerves.” Demyelinating Disease, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=70251> (last visited July 3, 2024).

³¹ Multiple sclerosis is “a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter; symptoms usually include weakness, incoordination, paresthesias, speech disturbances, and visual complaints.” Multiple Sclerosis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=105130> (last visited July 3, 2024).

³² Neuromyelitis is “inflammation of nervous and medullary substance; myelitis attended with neuritis.” Neuromyelitis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=33789> (last visited July 3, 2024).

³³ Tanuja Chitnis, The Role of CD4 T Cells in the Pathogenesis of Multiple Sclerosis, 79 Int’l Rev. Neurobiology 43 (2007).

Dr. Akbari digressed from explaining the theory here to a general discussion of the immune system and development of autoimmune diseases. Pet. Ex. 13 at 6-8. He stated immunization with a vaccine causes a local inflammatory reaction mediated by cells of the innate immune system. Id. at 6. Thereafter, there is a recruitment of other immune cells by secreting cytokines and activation of the adaptive immune system. Id. Regulatory T cells, which help maintain tolerance to self-antigens and abrogate autoimmune disease, “actively suppress the immune system by the cytokines they secrete and direct cellular interactions with the cells that cause autoimmune disease.” Id. at 7. Dr. Akbari stated regulatory T cells “can suppress other immune cells such as B cells, T cells, and dendritic cells to prevent autoimmune disease.” Id. Therefore, he posited that alteration of the suppressive function of regulatory T cells is associated with autoimmune diseases including GBS and neuroinflammatory disorders. Id.

Dr. Akbari cited clinical studies which allegedly showed the number of regulatory T cells were significantly decreased in patients with neuroinflammation, specifically optic neuritis. Pet. Ex. 13 at 7 (citing Pet. Ex. 29;³⁴ Pet. Ex. 30).³⁵ He opined the decreased number of regulatory T cells “most likely is a main factor resulting in a person’s predisposition to develop neuro-inflammatory disease during activation of the immune system such as by receipt of a vaccine.” Id. at 8.

In contrast, he opined that an increased number of Th17 cells are seen with neuroinflammatory diseases. Pet. Ex. 13 at 8 (citing Pet. Ex. 19 at 1;³⁶ Pet. Ex. 33 at 1).³⁷ Dr. Akbari explained that Th17 cells secrete interleukin-17 (“IL-17”), a molecule known to induce inflammation, and are involved in the pathogenesis of autoimmune diseases. Id. (citing Pet. Ex. 32 at 1).³⁸ He opined this is particularly true in patients with GBS, thus suggesting it is an important factor in the pathogenesis of neuroinflammation and GBS. Id. (citing Pet. Ex. 33 at 1; Pet. Ex. 35 at 1).³⁹

³⁴ Hengri Cong et al., Change of Th17 Lymphocytes and Treg/Th17 in Typical and Atypical Optic Neuritis, 11 PLoS ONE e0146270 (2016).

³⁵ Guochun Chen et al., mTOR Regulates Neuroprotective Effect of Immunized CD4+Foxp3+T Cells in Optic Nerve Ischemia, 6 Sci. Reps. 37805 (2016).

³⁶ Marinos C. Dalakas, Future Perspectives in Target-Specific Immunotherapies of Myasthenia Gravis, 8 Therapeutic Advances Neurological Disorders 316 (2015).

³⁷ Shujuan Li et al., Circulating Th17, Th22, and Th1 Cells are Elevated in the Guillain-Barré Syndrome and Downregulated by IVIg Treatments, 2014 Mediators Inflammation 740947.

³⁸ José Francisco Zambrano-Zaragoza et al., Th17 Cells in Autoimmune and Infectious Diseases, 2014 Int’l J. Inflammation 651503.

³⁹ F. Jadidi-Niaragh & A. Mirshafiey, Th17 Cell, the New Player of Neuroinflammatory Process in Multiple Sclerosis, 74 Scandinavian J. Immunology 1 (2011).

He then again digressed and opined “[w]hen homeostasis is disrupted and the immune system responds in favor of activation, . . . the host becomes susceptible to autoimmunity.” Pet. Ex. 13 at 8. He added the disrupted balance leaves individuals “susceptible to an adverse autoimmune reaction upon stimulation of the immune system” from either an infection or immunization. Id.

As to the specific mechanism of disruption by vaccination here, Dr. Akbari returned to his theory of molecular mimicry, “a mechanism in which the host and the microbe share an immunologic epitope by either sequence or conformational homology.” Pet. Ex. 13 at 5 (citing Pet. Ex. 17).⁴⁰ He opined that while it was “originally believed that similarity of a significant portion of the protein peptide sequence between putative pathogens and self peptides” was required to implicate molecular mimicry, Dr. Akbari believed “conversion of only a few crucial residues can allow for cross-reactivity of immune cells.” Id. (citing Pet. Ex. 18).⁴¹ According to Dr. Akbari, “proteins of dissimilar sequence may have a common structure which elicits an autoimmune response.” Id. “In spite of dissimilar sequence homology between self and foreign peptide, weak electrostatic interactions between foreign peptide and the MHC can also mimic self peptide to elicit an autoimmune response within the host.” Id. at 6. He concluded molecular mimicry can occur “between two recognized peptides that have similar antigenic surfaces in the absence of primary sequence homology.” Id.

Dr. Akbari proposed that flu viruses A and B are components contained in the flu vaccine. Pet. Ex. 13 at 10. These components trigger an “immune response to myelin proteins and complex sugar” associated with gangliosides. Id. “The immune response elicited to gangliosides mainly targets the sugars on the vaccine, which are also a component of the myelin sheath.” Id.

He cited two studies to show that cross-reactive T cells in response to flu vaccination have been shown to cause demyelinating disease. Pet. Ex. 13 at 10-11. Markovic-Plese et al.⁴² proposed cross-reactivity of a CD4+ T-cell clone specific for the immunodominant flu virus hemagglutinin peptide (sequence RYVKQSTLKL) derived from a patient with neuromyelitis and demyelinating disease. Id. (citing Pet. Ex. 41 at 1). Wucherpfennig et al.⁴³ tested peptides containing protein sequences that share a similar structure with myelin basic protein to see if they stimulated the production of T-cells. Pet. Ex. 43 at 1. The results showed that the flu A

⁴⁰ Robert S. Fujinami et al., Molecular Mimicry, Bystander Activation, or Viral Persistence: Infections and Autoimmune Disease, 19 *Clinical Microbiology Revs.* 80 (2006).

⁴¹ Adam P. Kohm et al., Mimicking the Way to Autoimmunity: An Evolving Theory of Sequence and Structural Homology, 11 *Trends Microbiology* 101 (2003).

⁴² Silva Markovic-Plese et al., High Level of Cross-Reactivity in Influenza Virus Hemagglutinin-Specific CD4+ T-Cell Response: Implications for the Initiation of Autoimmune Response in Multiple Sclerosis, 169 *J. Neuroimmunology* 31 (2005).

⁴³ Kai W. Wucherpfennig et al., Recognition of the Immunodominant Myelin Basic Protein Peptide by Autoantibodies and HLA-DR2-Restricted T Cell Clones from Multiple Sclerosis Patients, 100 *J. Clinical Invest.* 1114 (1997).

peptide sequence (among others) stimulated T-cells. Id. From these studies, Dr. Akbari concluded the flu vaccine at issue “contains a protein that cross-reacts with myelin based antigens in humans who had demyelinating disease.” Pet. Ex. 13 at 11.

Additionally, Dr. Akbari proposed another peptide to the major protein in the myelin sheath known as myelin basic protein in the flu A vaccines. Pet. Ex. 13 at 11. He opined the amino acid sequence of the hemagglutinin, FYKNLI, has “high homology” with the myelin basic protein, FFKNIV, with the only variations being one aromatic amino acid “F” for “Y” and two aliphatic amino acids, leucine and isoleucine. Id. He stated this is “another undeniable example of a molecular mimicry with [flu] A strains appeared in vaccine that [Petitioner] received.” Id.

Relying on medical literature, Dr. Akbari opined this sequence is significant due to the high homology of the amino acid sequence of hemagglutinin to myelin basic protein. Pet. Ex. 13 at 11. Gautam et al.⁴⁴ found that homology at just five amino acids with a self peptide can induce clinical signs experimental autoimmune encephalomyelitis (“EAE”). Pet. Ex. 44 at 1; see also Pet. Ex. 43. He opined this “clearly indicate[s] that a viral peptide with homology of [five] amino acids with a self-peptide is sufficient to induce clinical signs of neuromyelitis and demyelinating disease in animal models.” Pet. Ex. 13 at 11 (citing Pet. Exs. 43-44).

For further support of vaccine causation, Dr. Akbari cited medical literature documenting post-vaccination inflammatory diseases. Pet. Ex. 13 at 10. Karussis and Petrou conducted a PubMed search from 1979 to 2013 and found 71 cases of a temporal association between an inflammatory central nervous system demyelinating disease and the administration of a vaccine. Pet. Ex. 40 at 1. Of these 71 cases, 21 were associated with the flu vaccine. Id. at 1, 4-5 tbl.2. The symptoms of the demyelinating syndromes and signs of neuroinflammation including GBS often appeared a few days following vaccination with a mean of 14.2 days. Pet. Ex. 13 at 10 (citing Pet. Ex. 40 at 2).

2. Asthma Exacerbation

For how the flu vaccine can cause asthma exacerbation, Dr. Akbari relied on an auto-reactive T cell mechanism. Pet. Ex. 13 at 1, 12-14. Dr. Akbari opined that vaccination caused an exacerbation in Petitioner’s asthma by inducing lung inflammation. Id.

Then Dr. Akbari opined that “neuroimmune interaction has long been discussed in the pathogenesis of allergic airway diseases, such as allergic asthma. Mediators released during inflammation can alter the function of both sensory and parasympathetic neurons innervating the airways.” Pet. Ex. 13 at 12. He did not explain how this opinion about neurons related to asthma exacerbation.

⁴⁴ Anand M. Gautam et al., A Viral Peptide with Limited Homology to a Self Peptide Can Induce Clinical Signs of Experimental Autoimmune Encephalomyelitis, 161 J. Immunology 60 (1998).

Additionally, Dr. Akbari cited literature purportedly showing lung inflammation induced by flu vaccination. Pet. Ex. 13 at 12. Hibino and Kondo⁴⁵ described two cases of interstitial pneumonia secondary to the 2014-2015 seasonal flu vaccine which contained the A(H1N1) antigen. Pet. Ex. 46 at 1. The patients had no history of allergy, inhalation exposure, smoking, or family history of pulmonary diseases. *Id.* at 3-4. Serological tests were negative for autoimmune markers. *Id.* at 4. However, the patients met the diagnostic criteria for drug-induced interstitial lung disease.⁴⁶ *Id.* “Based on these findings, interstitial pneumonia associated with the [flu] vaccine was diagnosed after excluding other causes of secondary interstitial pneumonia, such as infectious and connective tissue disease. The pathophysiology of drug-induced interstitial pneumonia, although not obvious, is believed to be cytotoxic or immune-mediated lung injury.” *Id.* The authors did not reach a conclusion as to a causal association, if any, between the flu vaccine and interstitial pneumonia. *Id.* at 4-5. And there was no discussion of asthma exacerbation.

Watanabe et al.⁴⁷ described a patient who developed a fever one week after receiving a flu vaccine. Pet. Ex. 47 at 1. Her chest X-ray revealed “patchy airspace infiltrates in both lungs.” *Id.* She had no prior history of pulmonary disease and her chest X-ray the month prior was normal. *Id.* The temporal relationship between vaccination and clinical symptoms suggested a causative role. *Id.* The authors also reviewed six cases of flu vaccine-induced interstitial lung disease. *Id.* at 2-3. Four of the cases had pre-existing lung diseases. *Id.* The authors hypothesized that pre-existing lung diseases, flu vaccination, and genetic background may be risk factors for interstitial lung disease but noted further studies were needed to evaluate the association of vaccine-related interstitial lung disease. *Id.* at 3. There was no reference to exacerbation of asthma.

Bhurayanontachi⁴⁸ described a patient who developed multiple organ failure, including acute respiratory distress, five days after an H1N1 vaccination. Pet. Ex. 49 at 1. All vasculitic screening was negative. *Id.* The diagnosis of the patient remained unclear; however, the authors noted “vasculitis or an autoimmune disease [was] unlikely, and a severe adverse event following the H1N1 vaccination could not be completely excluded.” *Id.* There was no mention of asthma exacerbation.

⁴⁵ Makoto Hibino & Tetsuri Kondo, Interstitial Pneumonia Associated with the Influenza Vaccine: A Report of Two Cases, 56 *Internal Med.* 197 (2017).

⁴⁶ Interstitial lung disease is “a heterogeneous group of noninfectious, nonmalignant disorders of the lower respiratory tract, affecting primarily the alveolar wall structures but also often involving the small airways and blood vessels of the lung parenchyma; slowly progressive loss of alveolar-capillary units may lead to respiratory insufficiency and death.” Interstitial Lung Disease, *Dorland’s Med. Dictionary Online*, <https://www.dorlandsonline.com/dorland/definition?id=70466> (last visited July 3, 2024).

⁴⁷ Satoshi Watanabe et al., Influenza Vaccine-Induced Interstitial Lung Disease, 41 *Eur. Respiratory J.* 474 (2013).

⁴⁸ Rungsun Bhurayanontachi, Possible Life-Threatening Adverse Reaction to Monovalent H1N1 Vaccine, 14 *Critical Care* 422 (2010).

Umeda et al.⁴⁹ described a case of acute exacerbation of idiopathic pulmonary fibrosis⁵⁰ after a flu A H1N1 vaccination. Pet. Ex. 50 at 1. Two days after vaccination, the patient was admitted to the hospital for aggravation of dyspnea and fever. Id. The patient was already diagnosed with idiopathic pulmonary fibrosis and was a former smoker. Id. Prior to the vaccination, chest X-ray did not show any worsening of his pre-existing respiratory condition. Id. After his vaccination and hospital admission, chest X-ray showed “diffuse bilateral ground-glass opacities superimposed on preceding reticular opacities.” Id. After examination (crackles were audible in the bilateral lung bases) and lab testing, a diagnosis of exacerbation of idiopathic pulmonary fibrosis was confirmed. Id. at 1-2. After extensive treatment, including steroids, his symptoms improved but long-term oxygen therapy was required. Id. at 2. The authors concluded the flu vaccine was “the most likely cause” of the acute exacerbation. Id. at 4. First, they reasoned the patient received a seasonal flu vaccine one month prior to receiving the pandemic (flu A H1N1) vaccination and a “second exposure to the same antigen might elicit a response within a shorter period.” Id. Second, no other cause of deterioration was found. Id. They noted flu vaccination was reported to induce inflammatory cytokines and implicated bystander activation. Id. However, the authors also noted that while the patient had no worsening of his respiratory symptoms prior to the flu A H1N1 vaccine, he did have a low-grade fever prior and cautioned administering vaccines based on patients’ conditions. Id. There was no mention of asthma or asthma exacerbation.

Audrit et al.⁵¹ described inflammatory lung disease, including asthma, but the article relates to the nervous system of airways and how it is affected by inflammatory lung disease. Pet. Ex. 51 at 1. The authors do not discuss how vaccines in general, or the flu vaccine specifically, can exacerbate asthma.

ii. Althen Prongs Two and Three

Dr. Akbari opined, “to a high degree of certainty, and by a preponderance of scientific evidence,” that “had it not been for the flu vaccination, [Petitioner] would not have developed symptoms such as neuropathy and asthma exacerbation.” Pet. Ex. 13 at 15. Based on his review of the record, Dr. Akbari stated, “the presence of symptoms is essentially based on the temporal relationship between the administration of the flu vaccine and the development of asthma exacerbation and neuropathic changes in [Petitioner].” Id. at 16. “To a high degree of medical certainty, had it not been for the flu vaccination, [Petitioner] would not have developed [asthma exacerbation and neuropathic changes].” Id.

⁴⁹ Yukihiro Umeda et al., Acute Exacerbation of Idiopathic Pulmonary Fibrosis After Pandemic Influenza A (H1N1) Vaccination, 49 *Internal Med.* 2333 (2010).

⁵⁰ Idiopathic pulmonary fibrosis is “chronic inflammation and progressive fibrosis of the pulmonary alveolar walls, with steadily progressive dyspnea, resulting finally in death from oxygen lack or right heart failure.” Idiopathic Pulmonary Fibrosis, *Dorland’s Med. Dictionary Online*, <https://www.dorlandsonline.com/dorland/definition?id=75788> (last visited July 3, 2024).

⁵¹ Katrin Julia Audrit et al., The Nervous System of Airway and Its Remodeling in Inflammatory Lung Disease, 367 *Cell Tissue Rsch.* 571 (2017).

2. Respondent's Expert, Dr. Arnold I. Levinson, M.D.⁵²

a. Background and Qualifications

Dr. Levinson is board certified in internal medicine and allergy and clinical immunology. Resp. Ex. B at 1; Resp. Ex. C at 2. He received his M.D. from the University of Maryland. Resp. Ex. C at 1. He completed fellowships at the Johns Hopkins Hospital and the University of Pennsylvania School of Medicine, and post-doctoral fellowships in immunology at the University of Pennsylvania School of Medicine and the University of California, San Francisco Medical Center. Id. Dr. Levinson is currently an Emeritus Professor of Medicine and Neurology at the Perelman School of Medicine at the University of Pennsylvania. Resp. Ex. B at 1. During his 37-year tenure at University of Pennsylvania, Dr. Levinson “conducted a clinical practice in which [he] evaluated and treated patients with a broad range of immune-mediated diseases including autoimmune, hypersensitivity, and immunodeficiency disorders.” Id. Dr. Levinson has authored or co-authored numerous publications. Resp. Ex. C at 10-21.

b. Diagnosis Opinion

Dr. Levinson agreed Petitioner had an exacerbation of her asthma. Resp. Ex. B at 11-12. However, he disagreed it was caused by her flu vaccination. Id. Instead, he opined her worsening was caused by a URI. Id.

Dr. Levinson disagreed that Petitioner suffered from neuroinflammation or GBS. Resp. Ex. B at 6. He did not believe Petitioner suffered from any autoimmune demyelinating disorder or definable neuroinflammatory disorder. Id. at 12.

Regarding GBS, Dr. Levinson explained it is a “syndrome that encompasses many variants that most commonly present as an acute immune-mediated polyneuropathy following an infectious illness.” Resp. Ex. B at 6 (citing Resp. Ex. B.1 at 1). The most common variants are acute inflammatory demyelinating polyneuropathy (“AIDP”) and acute motor axonal neuropathy (“AMAN”). Id. (citing Resp. Ex. B.1 at 1). A characteristic diagnostic finding in GBS is albuminocytologic dissociation⁵³ on CSF analysis. Id. at 7. Additionally, EMG/NCS studies can show evidence of an acute demyelinating polyneuropathy or evidence of an axonal neuropathy. Id.

“All GBS variants are considered to be autoimmune, i.e., caused by an immune-mediated reaction against peripheral nerve constituents.” Resp. Ex. B at 7. “In particular, peripheral nerve injury is considered to be mediated by complement-dependent IgG antibodies and T cells targeted to unknown antigenic epitopes on peripheral nerve Schwann cells and myelin in the

⁵² Dr. Levinson provided one expert report. Resp. Ex. B.

⁵³ Albuminocytologic dissociation is the “increase of protein with normal cell count in the spinal fluid.” Albuminocytologic Dissociation, Dorland's Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=71273> (last visited July 3, 2024).

AIDP form of GBS and primarily peripheral nerve glycolipid antigens in the other variants.” Id. Dr. Levinson opined the most common event linked to GBS is an antecedent infection. Id.

Dr. Levinson took issue with Dr. Akbari’s use of the term neuroinflammation to characterize Petitioner’s neurological symptoms. Resp. Ex. B at 7. While he believed it is appropriate to use this “non-specific term” in some instances, such as in relation to multiple sclerosis, acute disseminated encephalomyelitis, and GBS, “where inflammatory demyelination is operative,” he explained “there is no basis for applying this term to what ailed [] [P]etitioner neurologically.” Id. This is because Petitioner’s medical records do not provide evidence that “her neurological symptoms were/are caused by an underlying neuroinflammatory process.” Id. And he pointed out that GBS was never diagnosed by Petitioner’s neurologists. Id. at 7-8.

In evaluating Petitioner’s neurology records, Dr. Levinson noted that Dr. Saland “considered the possibility” that Petitioner’s paresthesias may have been the result of “an autoimmune process possibly caused by the vaccination. However, no discussion/characterization of the speculated autoimmune process was offered and GBS, per se, was not diagnosed.” Resp. Ex. B at 8. Similarly, Dr. Khella assessed the “possibility” that Petitioner had GBS. Id. Dr. Levinson opined that the “possibility [was] extremely remote.” Id. He opined that Petitioner’s clinical complaints, neurological examination, and nerve conduction testing results were “highly inconsistent” with GBS. Id. Moreover, Dr. Levinson observed that Petitioner’s “most vexing symptom” was paresthesias in her hands and toes which had improved by the time of her visit with Dr. Saland. Id.

Further, there was no progression of Petitioner’s neurologic symptoms which is usually common in GBS. Resp. Ex. B at 8. And Dr. Levinson opined there were no signs of a peripheral neuropathy on neurological examination other than right median nerve entrapment, which was diagnosed as carpal tunnel syndrome. Id. The nerve conduction study, done at the time she was symptomatic, did not show evidence of an inflammatory/demyelinating neuropathy. Id. According to Dr. Levinson the study also ruled out a large fiber peripheral polyneuropathy. Id.

To support his opinions about diagnosis, Dr. Levinson cited a study by Fokke et al. that evaluated the diagnostic characteristics of 494 patient with GBS and affirmed the diagnostic criteria for GBS developed by the National Institute of Neurological Disorders and Stroke (“NINDS”) and the Brighton Collaboration.⁵⁴ Resp. Ex. B.2 6 tbl.5. Only 1% of the patients presented with normal strength, only 2% presented with normal tendon reflexes in the legs, zero patients had normal reflexes at the nadir of their illness, 15% had normal CSF cell count, and only 1% had a normal nerve conduction study. Id. In contrast, physical examinations of Petitioner revealed normal strength, normal reflexes, normal cell count, and normal NCS; thus, using these diagnostic findings, Petitioner’s diagnostic studies were not consistent with GBS. Id.

⁵⁴ The Brighton Collaboration is “a community aiming to promote and improve vaccine safety. [They] enhance the science of vaccine research by providing standardized, validated, and objective methods for monitoring vaccine safety and benefit-risk profiles.” Brighton Collaboration, <https://brightoncollaboration.org/> (last visited July 3, 2024).

Dr. Levinson concluded “the preponderance of medical evidence strongly militates against the diagnosis of GBS as defined by inclusionary criteria established by the Brighton Collaborative Group guideline[s].”⁵⁵ Resp. Ex. B at 8 (citing Resp. Ex. B.2). He further opined there is no evidence she suffered an autoimmune response, immune dysregulation, or any autoimmune demyelinating disorder. Id. at 8-9.

c. Causation Opinion

i. Neurological Condition

Dr. Levinson opined that while Dr. Akbari’s proposed theory of molecular mimicry is widely accepted by immunologists, it is not relevant here because Petitioner did not suffer from a definable neuroinflammatory autoimmune disease. Resp. Ex. B at 8-9. Accordingly, he opined the literature is not relevant. Id.

Dr. Akbari relied on Markovic-Plese et al. and Wucherpfennig et al. to opine that the flu vaccine Petitioner received “contains a protein that cross-reacts with myelin based antigens in humans who had demyelinating disease.” Pet. Ex. 13 at 11. Dr. Levinson opined this conclusion drawn from publications is conflated and misleading. Resp. Ex. B at 9. “Whether or not [the flu] vaccine contains a protein that cross-reacts with human-based myelin expressed proteins, the theoretical possibility that said cross-reactivity might cause demyelination in some humans is immaterial in this case.” Id. He reasoned this is because it is “highly unlikely” Petitioner suffered an autoimmune demyelinating disorder. Id.

ii. Asthma Exacerbation

Dr. Levinson agreed Petitioner had an exacerbation of her asthma but he disagreed that it was caused by the vaccine. Resp. Ex. B at 11. Instead, based on “the well-defined role of viral [URIs] in asthma exacerbations and the lack of reliable data that speak to a role for the flu vaccine in such exacerbations,” Dr. Levinson opined that “the [URI] experienced by [] [P]etitioner [two to three] weeks post vaccination was the overwhelming cause of that exacerbation.” Id. at 12.

Dr. Levinson questioned Dr. Akbari’s discussion surrounding autoreactive T cells and asthma because Dr. Levinson opined that asthma—allergic or non-allergic—is not an autoimmune disease. Resp. Ex. B at 10. Rather, “[t]he T cells that do promote allergic asthma react to exogenous allergens not self-antigens.” Id. Thus, Dr. Levinson opined that Dr. Akbari’s causation theory “is totally incongruent with the pathophysiologic basis of asthma” and that there is “no basis to consider that autoimmune reactions contribute to acute exacerbations or chronic persistence of asthma symptomatology.” Id. at 10, 12.

⁵⁵ In support, Dr. Levinson noted Petitioner had intact deep tendon reflexes, normal motor and sensory examinations, normal NCS, and “no physical signs of an underlying peripheral neuropathy on neurological examination other than . . . carpal tunnel syndrome.” Resp. Ex. B at 8.

While Dr. Akbari referred to publications on the worsening of idiopathic pulmonary lung disease following H1N1 vaccinations to support his position, Dr. Levinson opined “the clinicopathologic characteristics of [those] disorders are quite different from those of asthma.” Resp. Ex. B at 9. Dr. Levinson stated there is no literature reporting an asthma exacerbation following an inactivated flu vaccine or a plausible biological mechanism for such alleged outcome. Id. Moreover, Dr. Levinson added that “[n]o reliable data” were provided to support Petitioner’s claim that the vaccination caused the asthma to pursue a chronic course, and “no plausible biologic mechanism was offered to explain the worsened disease pattern.” Id. at 10.

Rather, Dr. Levinson cited a 2011 Institute of Medicine (“IOM”)⁵⁶ report rejecting a causal relationship between the inactivated flu vaccine and asthma exacerbation. Resp. Ex. B at 9-10 (citing Resp. Ex. A). The IOM report addressed whether the inactivated flu vaccine caused asthma exacerbation and determined there was no association with “a high degree of confidence in the epidemiologic evidence based on nine studies with validity and precision to assess an association between inactivated influenza vaccine and asthma exacerbation or reactive airway disease episodes in children and adults.” Resp. Ex. A at 350.

1. Alternate Cause

Dr. Levinson believed Dr. Akbari “ignored the ‘elephant in the room,’ i.e., the [URI] that preceded the exacerbation of [Petitioner’s] asthma.” Resp. Ex. B at 11. He stated that many of Petitioner’s healthcare providers noted the occurrence of the “likely virus-induced” URI in documenting the chain of events following Petitioner’s September 19, 2015 flu vaccination. Id.

Dr. Levinson cited medical literature for support that URIs are common precipitants of asthma. Resp. Ex. B at 11. Busse et al.⁵⁷ wrote “[r]espiratory viral infections can also have a significant influence on those patients with established asthma, where viral respiratory infections are found in association with asthma exacerbations in nearly 80% of these episodes.” Resp. Ex. B.3 at 2. Further, the “association between viral respiratory infections and asthma exacerbations is seen in both children and adults.” Id.

According to Dr. Levinson, the reasoning for this is because both viral infections and allergic inflammations can damage the airway epithelium and allergic inflammation can impede anti-viral defense mechanisms. Resp. Ex. B at 11.

Therefore, Dr. Levinson agreed with Dr. Conway that the URI, not the vaccination, was the cause of Petitioner’s asthma exacerbation. Resp. Ex. B at 11. Dr. Levinson opined “to a degree of medical certainty” that Petitioner’s URI two to three weeks after the flu vaccination “was the overwhelming cause” of Petitioner’s asthma exacerbation. Id. at 12.

⁵⁶ Inst. of Med., Influenza Vaccine, in Adverse Effects of Vaccines: Evidence and Causality 293, 309 (Kathleen Stratton et al. eds., 2012).

⁵⁷ William W. Busse et al., The Role of Viral Respiratory Infections in Asthma and Asthma Exacerbations, 376 Lancet 826 (2010).

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” Rooks v. Sec’y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner’s burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec’y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee’s injury is “due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec’y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

“Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case.” Flores v. Sec’y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec’y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner’s evidence on a requisite element of the [P]etitioner’s case-in-chief.”); Pafford, 451 F.3d at 1358-59 (“[T]he presence of multiple potential causative agents makes it difficult to attribute ‘but for’ causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.”).

B. Factual Issues

Petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec’y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records).

Medical records, specifically contemporaneous medical records, are presumed to be accurate and generally “warrant consideration as trustworthy evidence.” Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec’y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that “medical records are accurate and complete as to all the patient’s physical conditions”); Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) (“[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” (quoting Murphy v. Sec’y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff’d per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den’d after remand, 105 Fed. Cl. 353 (2012), aff’d mem., 503 F. App’x 952 (Fed. Cir. 2013). The weight afforded to contemporaneous records is due to the fact that they “contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.” Id. To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is “consistent, clear, cogent, and compelling.” Sanchez v. Sec’y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec’y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)), mot. for rev. denied, 142 Fed. Cl. 247 (2019), vacated on other grounds & remanded, 809 F. App’x 843 (Fed Cir. 2020).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec’y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) (“[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking.”); Lowrie v. Sec’y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (“[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner’s symptoms. Valenzuela v. Sec’y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec’y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) “must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports,

diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them”).

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show 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 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received actually caused her injury. To do so, Petitioner must establish, by preponderant evidence: “(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.” Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A). The special master must weigh the submitted evidence and the testimony of the parties’ proffered experts and rule in Petitioner’s favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.”); Althen, 418 F.3d at 1280 (noting that “close calls” are resolved in Petitioner’s favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec’y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

D. Significant Aggravation

The elements of an off-Table significant aggravation case are set forth in Loving. See Loving, 86 Fed. Cl. at 142-44; see also W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that “the Loving case provides the correct framework for evaluating off-table significant aggravation claims”). The Loving court combined the Althen test, which defines off-Table causation cases, with a test from Whitecotton. Whitecotton v. Sec’y of Health & Hum. Servs., 17 F.3d 374 (Fed. Cir. 1994), rev’d sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995) (concerning on-Table significant aggravation cases). The resultant test has six components:

(1) the person’s condition prior to administration of the vaccine, (2) the person’s current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person’s current condition constitutes a ‘significant aggravation’ of the person’s condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

The statute defines “significant aggravation” as “any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health.” § 33(4).

V. DIAGNOSIS ANALYSIS

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since “each prong of the Althen test is decided relative to the injury[.]” determining facts relating to the claimed injury can be significant. Id. Here, the parties dispute Petitioner’s neurological diagnosis, including whether she “developed any definable neuroinflammatory diseases” or “suffered a neurological injury.” Thus, it is appropriate to resolve this issue first.

Prior to her flu vaccination on September 19, 2015, records from 2012 show that Petitioner had lumbar radiculitis, falls, a coccyx fracture, and knee and ankle injuries. After these falls, Petitioner developed bilateral numbness of her thighs, and pain and numbness of her left fourth and fifth fingers. She had decreased sensation in the distribution of the left C7 nerve root. X-rays showed degenerative changes of her intervertebral discs. Records from 2014 show that Petitioner had back, hip, and knee pain, and complained of radiating numbness down her right leg to her ankle, and weakness with an inability to lift her foot when running and walking. She was diagnosed with lumbar degenerative disk disease and mild lumbar radiculopathy.

Petitioner received the flu vaccine at issue on September 19, 2015. On October 13, she presented to the ED for shortness of breath, chest tightness, cough, and wheezing. She reported

having a URI. The diagnosis was asthma. The records do not document any neurological symptoms or concerns. The next day, Petitioner saw Dr. Klares, her pulmonologist, for her asthma exacerbation. Dr. Klares did not document any neurology symptoms or concerns. Petitioner returned to the ED on October 22 with shortness of breath and cough. At the visit, Petitioner denied numbness, paresthesias, or weakness.

The first reference to any neurological symptoms was November 4, 2015, when Petitioner returned to see her pulmonologist. Dr. Klares noted that Petitioner was concerned about some tingling in her fingertips. Dr. Klares questioned whether the tingling symptom was related to her steroid use, but due to Petitioner's concerns, he referred her to a neurologist. The records do not state the onset of Petitioner's tingling in her fingers. However, when Petitioner saw Dr. Rogg the following week, on November 11, 2015, she related her tingling back to the receipt of the flu shot. She reported that she had bilateral tingling of her hands and feet "since flu shot." Pet. Ex. 2 at 82. At that visit, Dr. Rogg's assessment included dysesthesia.

Petitioner saw neurologist Dr. Saland on November 24, 2015 and reported paresthesias in her fingers and toes, some decreased dexterity, that her balance was mildly off, and her legs felt weak. She also complained of some intermittent difficulty swallowing that had improved. Dr. Saland also noted that Petitioner's symptoms were becoming less frequent since she had discontinued her steroids. Moreover, Petitioner's neurological evaluation was normal. She had normal strength, normal muscle tone, normal sensation, and she did not have areflexia or the loss of her deep tendon reflexes. Dr. Saland questioned whether Petitioner's symptoms could be due to recent steroid use. Diagnoses included paresthesias, steroid-induced myopathy, drug-induced myopathy, and dysphagia. Dr. Saland concluded that the cause of Petitioner's neurological symptoms was not clear. Therefore, as of November 24, 2015, Petitioner's neurological symptoms were "paresthesias." Dr. Saland did not reach a diagnosis of neuroinflammation or neuropathic changes associated with GBS.

Petitioner underwent a NCS of her upper extremities for her paresthesias on December 18. At that visit, it was noted that the onset of these symptoms began three weeks after her vaccination. The NCS showed mild right median neuropathy consistent with carpal tunnel syndrome. It did not show evidence of an acute demyelinating condition such as GBS. It did not show large fiber neuropathy. In a letter dated December 24, 2015, Dr. Saland noted Petitioner was undergoing testing and referenced "the possibility of an autoimmune response" but gave no further diagnosis. Pet. Ex. 3 at 392. And in a letter dated January 13, 2016, although Dr. Saland stated that the flu vaccine was "likely a substantial factor in provoking the autoimmune reaction," there was no diagnosis given, and instead Dr. Saland again stated that Petitioner was undergoing "further workup for additional clarification." *Id.* at 398. Thus, there was no neurological diagnosis at that time other than carpal tunnel syndrome, which was not attributed to vaccination.

Petitioner cancelled the EMG scheduled in March 2016 because she had shingles. She also did not have the brain and spine MRIs Dr. Saland ordered. On March 29, 2016, Petitioner reported significant improvement; her neurological examination was normal and her reflexes were intact and symmetric. Petitioner's leg weakness and difficulty swallowing had resolved. Petitioner had mild burning and tingling mostly in the forearms, paresthesias in the fingers, mostly the third and fourth fingers, and the middle toes. Neurological examination was

completely normal and Petitioner's reflexes were intact and symmetric. Therefore, by March 2016, Petitioner's neurological symptoms had resolved except for the paresthesias in her fingers and toes. Dr. Saland concluded that Petitioner's symptoms "remain[ed] unclear" and he suggested further workup. Pet. Ex. 3 at 436. Dr. Saland did not attribute these symptoms to neuroinflammation or neuropathic changes related to GBS.

Two months later, May 2, 2016, Petitioner saw another neurologist, Dr. Khella, who also concluded that Petitioner had a normal neurological examination. Dr. Khella opined that it was "possible" that Petitioner had GBS, but that she was "currently stable." Pet. Ex. 5 at 5. After that visit to Dr. Khella, it does not appear that Petitioner returned to see a neurologist until 2020, which was a telemedicine visit with Dr. Krieger. MRIs were done the following year, in June 2021, and they did not show any demyelinating lesions. Dr. Krieger also documented that Petitioner's prior test results were normal. Dr. Krieger did not diagnose Petitioner with neuroinflammation, neuropathic changes related to GBS, or any demyelinating disease.

Based on the records, it appears that the last neurologist to evaluate Petitioner was Dr. Tiongson, on September 16, 2021, six years after vaccination. The visit was conducted via telemedicine. Based on the history reported by Petitioner, Dr. Tiongson opined that if Petitioner's paresthesias started after the flu shot, it "could have been GBS with residual symptoms" or a "CIDP-type picture." Pet. Ex. 73 at 7. Dr. Tiongson also opined, however, that Petitioner had a vitamin B12 deficiency which had potentially been treated insufficiently. Dr. Tiongson did not reach a conclusive diagnosis, and specifically, she did not diagnose Petitioner with neuroinflammation or neuropathic changes related to GBS.

Before vaccination, Petitioner had numbness of her left fourth and fifth fingers, decreased sensation in the distribution of the left cervical (C7) nerve root, radiating numbness down her right leg to her ankle, and diagnoses of lumbar radiculopathy and degenerative spine disease. Petitioner's pre-vaccination symptoms of numbness and tingling were not attributed to neuroinflammation or GBS, but to her cervical and lumbar spine. In 2015, Petitioner was diagnosed with carpal tunnel syndrome on the right side. This condition can cause numbness and tingling of the fingers. Petitioner's carpal tunnel syndrome was not attributed to her vaccination and Petitioner does not allege that it was caused by her flu vaccination.

After vaccination, there is no evidence to show that Petitioner had neuroinflammation. None of her diagnostic laboratory tests showed any abnormality to suggest any inflammation. As explained by Dr. Levinson, there was no evidence in Petitioner's records to suggest that any of her symptoms were caused by an underlying neuroinflammatory process. The undersigned agrees and finds that Dr. Levinson's opinions are more persuasive since they accurately reflect the records and diagnostic testing.

Further, there is not preponderant evidence that Petitioner had GBS after her vaccination. In 2015 and 2016, during the relevant time frame post-vaccination, Petitioner was seen by two different neurologists who both conducted physical examinations that showed normal strength and intact reflexes. Diagnostic studies did not show GBS or other evidence of any demyelinating condition.

Regarding records that include a history given by Petitioner to the effect that she had been diagnosed with GBS, the undersigned does not find these constitute reliable evidence of a diagnosis of GBS. For example, in March 2016, Petitioner reported to her endocrinologist, Dr. Powell, that her neurologist, Dr. Saland, had diagnosed her with GBS. Petitioner's report of GBS is not reliable evidence of her diagnosis because it is inconsistent with physician records and diagnostic testing.

To the extent that Petitioner's histories noted in the medical records are inconsistent with and contradicted by the physicians' objective physical examinations or diagnostic testing, the undersigned defers to the contemporaneous physician findings as the most reliable source of information. See Cucuras, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight"); Doe/70 v. Sec'y of Health & Hum. Servs., 95 Fed. Cl. 598, 608 (2010); Stevens v. Sec'y of Health & Hum. Servs., No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (noting that "clear, cogent, and consistent testimony can overcome such missing or contradictory medical records"); Vergara v. Sec'y of Health & Hum. Servs., No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."); see also Rothenberg v. Sec'y of Health & Hum. Servs., No. 16-696V, 2018 WL 2731639, at *16 (Fed. Cl. Spec. Mstr. Apr. 19, 2018) ("Program petitioners cannot establish a diagnosis simply by citing to records in which they informed physicians of a diagnosis that the evidence does not corroborate—any more than they can prevail in a case simply based on their own averments." (emphasis omitted)).

Further, the undersigned finds that the letters authored by Dr. Saland and Dr. Rogg do not provide persuasive evidence that Petitioner was diagnosed with neuroinflammation or neuropathic changes related to GBS. For example, in 2015 and 2016, Dr. Saland authored letters stating that Petitioner experienced neurological symptoms after receiving the flu vaccine, and the "possibility of an autoimmune response affecting her nervous system was likely." Pet. Ex. 3 at 392, 398. However, Dr. Saland qualified the statement by adding that Petitioner was undergoing further "workup for additional clarification." Id. at 398. Petitioner never underwent the EMG, and MRI studies did not show evidence of GBS or other demyelinating condition. Thus, the language used by Dr. Saland in the letters reveal that the diagnosis was dependent on further workup.

Moreover, Dr. Saland's statement that includes the words "possibility" and "likely" is internally inconsistent, since these two words have distinct and different meanings. And opinions expressed only to a possibility fall short of establishing preponderant evidence. Possibilities are not sufficient to establish causation. See, e.g., Waterman, 123 Fed. Cl. at 573-74; Moberly, 592 F.3d at 1322.

As for Dr. Rogg's statements and letters stating that the flu vaccine caused an "autoimmune response" that caused "neuropathic changes related to [GBS]," the undersigned finds these to be erroneous and inconsistent with the opinions of the Petitioner's treating neurologists. Pet. Ex. 2 at 101. Further, the statements are not persuasive because they are not based on the opinions of the treating neurologists who specialize in diagnosing and treating neuropathic conditions. See Koehn v. Sec'y of Health & Hum. Servs., No. 11-355V, 2013 WL

3214877, at *32 (Fed. Cl. Spec. Mstr. May 30, 2013) (“In weighing the persuasiveness of opinion testimony, special masters may consider the relative expertise of the witness.”), aff’d, 773 F.3d 1239 (Fed. Cir. 2014); Pafford, 451 F.3d at 1359 (affirming the special master’s rejection of expert’s testimony because he lacked proper qualifications in the specialty areas in which he testified).

In conclusion, the undersigned finds that Petitioner had prior complaints of numbness and tingling in the context of pre-existing C7 nerve root pathology, lumbar radiculopathy and degenerative disk disease. She also had carpal tunnel syndrome. After vaccination, Petitioner also complained of numbness and tingling. But Petitioner did not prove by preponderant evidence that she had neuroinflammation, or that she had GBS. And because she did not prove that she had GBS, then she also did not prove that she had neuropathic changes due to GBS.

VI. CAUSATION ANALYSIS

A. Neurological Injury

Because Petitioner did not prove by preponderant evidence that she had a diagnosis of a neuroinflammatory condition, GBS, or neuropathic changes related to GBS, a causation analysis pursuant to Althen is not necessary. See Lombardi v. Sec’y of Health & Hum. Servs., 656 F.3d 1343, 1352-53, 1356 (Fed. Cir. 2011) (affirming a special master’s decision to forego an Althen analysis after determining that the petitioner did not suffer from any the alleged injuries); Stillwell v. Sec’y of Health & Hum. Servs., 118 Fed. Cl. 47, 56 (2014) (noting “that if the special master finds, as a preliminary matter, that petitioner has failed to substantiate the alleged injury, the special master need not apply the Althen test for causality” (citing Broekelschen, 618 F.3d 1339)).

However, even if Petitioner had established the alleged neurologic injury, she failed to establish Althen prong two.⁵⁸ Petitioner has failed to prove by preponderant evidence a logical sequence of cause and effect showing that the flu vaccine caused her neuroinflammatory condition, GBS, or neuropathic changes related to GBS.

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence since they are

⁵⁸ For purposes of this Decision, the undersigned assumes that she has proven Althen prongs one and three.

created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the “diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); Snyder ex rel. Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. 706, 746 n.67 (2009). “As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases.” Welch v. Sec’y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at *8 (Fed. Cl. Spec. Mstr. July 2, 2019).

As detailed above, the undersigned finds that Petitioner has failed to prove that she suffered neuroinflammation or neuropathic changes related to GBS, and thus, she has not provided preponderant evidence of a cognizable claim. In addition, there is evidence of alternative causes to explain Petitioner’s symptoms of numbness and tingling which call into question causation.

Petitioner’s pre-vaccination medical records show that in 2012, she was diagnosed with lumbar radiculitis, a coccyx fracture that occurred after a fall, and left knee and ankle injuries that occurred after a fall. After these falls, Petitioner had bilateral numbness of her thighs and pain and numbness of her left fourth and fifth fingers. She also had decreased sensation in the left C7 nerve root. In 2013, she was diagnosed with neuroforaminal stenosis of the right lumbar spine. Moving to 2014, Petitioner complained of numbness down her right leg to the ankle, and weakness and inability to lift her foot. She was diagnosed with lumbar degenerative disk disease and mild lumbar radiculopathy. And in 2015 (post-vaccination), Petitioner had a NCS of both upper extremities for her numbness and tingling complaints, right more than left, and it showed that she had mild right median neuropathy at the wrist consistent with carpal tunnel syndrome.

In the records, Petitioner’s relevant symptoms are referenced as numbness, tingling, paresthesias, or dysesthesias. These sensations can be caused by several of the conditions set forth above. For example, Dorland’s defines lumbar radiculopathy as “any disease of lumbar nerve roots, such as from disk herniation or compression by a tumor or bony spur, with lower back pain and often paresthesias.” Lumbar Radiculopathy, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=101394> (last visited June 20, 2024). And spinal stenosis is defined as “narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication.” Spinal Stenosis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=108389> (last visited June 20, 2024). And numbness and tingling can also be caused by carpal tunnel syndrome, which is defined as “an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow. Symptoms result from compression of the median nerve in the carpal tunnel.” Carpal Tunnel Syndrome, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=110370> (last visited June 20, 2024).

The physicians, particularly the neurologists, who evaluated Petitioner after her vaccination did not attribute her numbness and tingling to Petitioner’s pre-existing lumbar radiculitis, neuroforaminal stenosis, lumbar degenerative disk disease, or lumbar radiculopathy.

However, Petitioner's prior history of these conditions is not documented in the post-vaccination records. Thus, this history may not have been known to them.

Carpal tunnel syndrome can also cause numbness and tingling of the fingers. Dr. Saland's records state that the NCS test showed a "mild right median neuropathy at the wrist . . . consistent with carpal tunnel syndrome." Pet. Ex. 3 at 386-88. Petitioner has not alleged, nor does the evidence support a finding that her carpal tunnel syndrome was vaccine related.

Further, Dr. Saland questioned whether Petitioner's symptoms could be due to recent steroid use. His differential diagnoses included paresthesias, steroid-induced myopathy, and drug-induced myopathy. Other alternative causes included Petitioner's vitamin B12 deficiency. The "presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination." Pafford, 451 F.3d at 1358-59; see also Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1151 n.4 (Fed. Cir. 2007) ("Where multiple causes act in concert to cause the injury, proof that a particular vaccine was a substantial cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine."). As such, the undersigned finds Petitioner failed to prove that the flu vaccine was the "but for" cause of Petitioner's condition.

Further, as described in the section on diagnosis above, Petitioner's clinical course is not consistent with vaccine-related neuroinflammation or neuropathic condition related to GBS, since she was not diagnosed with GBS.

Accordingly, the undersigned finds that even if Petitioner had established she suffered from a neurological condition (such as neuroinflammation), Petitioner failed to satisfy her burden under Althen prong two. Because Petitioner has failed to prove that she had neuroinflammation, GBS, or neuropathic changes related to GBS, and the evidence raises questions about alternative causes for her numbness and tingling, the undersigned finds that Petitioner has failed to prove Althen prong two. Thus, even assuming that Petitioner could prevail on Althen prongs one and three, her claim for neurological injury fails.

B. Asthma

The parties agree that Petitioner had a long-standing history of asthma prior to vaccination, but they dispute whether the flu vaccination significantly aggravated Petitioner's preexisting asthma. Even if Petitioner had a significant aggravation of asthma after her flu vaccine, Respondent contends it was due to a factor unrelated to vaccination, "an intervening [URI]." Joint Submission at 2.

1. Loving Factor One: What Was Petitioner's Condition Prior to Administration of the Vaccine?

The first step in the Loving test is to determine Petitioner's condition prior to the administration of her flu vaccine on September 19, 2015. The parties agree and stipulate that at the time of vaccination, Petitioner "already had an approximately [20-year] history of asthma, which included hospitalization in 2011 and an [ED] visit in 2012." Joint Submission at 1. Petitioner's records show that in October 2012, she had mild to moderate asthma, for which she

was prescribed Singular, Asmanex, Flonase, ProAir HFA Aerosol inhaler, and Proventil as needed. Petitioner lost a significant amount of weight in 2013, resulting in significant improvement of her asthma. In 2014, she saw her pulmonologist for her asthma in April and December and was diagnosed with mild asthma that was clinically stable. However, on July 9, 2014, and February 2015, Petitioner's pulmonologist wrote letters advising that Petitioner had "significant asthma that require[d] the use of a nebulizer," noting it was important that she have electrical service at her residence to treat this underlying medical condition. Pet. Ex. 3 at 236, 290.

In her affidavit, executed in April 2018, Petitioner asserts that prior to vaccination, relative to her asthma, she had been "symptom free." Pet. Ex. 6 at ¶ 6. This statement is inconsistent with the letter by her pulmonologist, stating in 2014 and 2015 that she had significant asthma that required the use of a nebulizer.

When the testimony of a petitioner made later in time (like the affidavit here) conflicts with the contemporaneous records or statements of a treating physician, the undersigned generally finds the contemporaneous evidence, and particularly the statements of a treating physician to be more accurate and reliable. See Cucuras, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight"); Doe/70, 95 Fed. Cl. at 608; Stevens, 1990 WL 608693, at *3 (noting that "clear, cogent, and consistent testimony can overcome such missing or contradictory medical records"); Vergara, 2014 WL 2795491, at *4 ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.").

Based on Petitioner's medical records and the letters authored by her pulmonologist, the undersigned finds that in 2014 and 2015, prior to vaccination, Petitioner had stable but "significant asthma that require[d] the use of a nebulizer." Pet. Ex. 3 at 236, 290.

2. Loving Factor Two: What Is Petitioner's Current Condition (or Her Condition Following the Vaccination, If Also Pertinent)?

The second part of the Loving test is to discuss "the person's current condition (or condition following the vaccination if that is also pertinent)." Loving, 86 Fed. Cl. at 144. Here, Petitioner's condition related to her asthma, following vaccination from September 19, 2015, through 2016 is most pertinent.

Over four weeks after vaccination, on October 13, 2015, Petitioner presented to the ED with shortness of breath, chest tightness, and cough that progressed to a URI with an onset of October 8. Chest X-ray was normal, and although she was wheezing, she was able to speak in full sentences. Petitioner was diagnosed with asthma, given breathing treatments, and discharged with prednisone. The next day (October 14) she saw her pulmonologist and reported onset of symptoms the past week. Her breathing was improved but she had increased mucus, and sinus pressure and tenderness. She had minimal cough and wheezing on forced expiration. Petitioner's pulmonologist diagnosed asthma exacerbation related to a URI and acute sinusitis. She was treated with antibiotics, Prednisone, albuterol, and her other asthma medications.

On October 19, Petitioner called her pulmonologist and reported that she had a fever the night before and was not feeling much better. She returned to the ED on October 22, stating that her current symptoms were like her prior asthma exacerbation. She had wheezing but her chest X-ray did not show any abnormalities. Petitioner returned to see her pulmonologist on November 4, reporting that her symptoms had worsened, and she complained of shortness of breath on exertion. On physical examination, Petitioner did not have any wheezing. Impression was asthma exacerbation, with marked improvement. The next day, November 5, 2015, Petitioner was seen at the asthma clinic where she was diagnosed with an exacerbation of her asthma, “likely provoked by a viral URI.” Pet. Ex. 4 at 84. Petitioner returned to the asthma clinic on November 12, 2015, reporting persistent symptoms. After testing, Petitioner’s respiratory function “appear[ed] to be back at baseline.” *Id.* at 97.

It does not appear that Petitioner returned to see her pulmonologist or returned to the asthma clinic for treatment of her asthma exacerbation after November 12, 2015. She underwent a pre-operative evaluation on November 30, 2015, for surgery on her right thumb. During that evaluation, she did not report shortness of breath, wheezing, or any other respiratory symptoms related to her exacerbation of her asthma.

The undersigned finds that Petitioner had a URI, acute sinusitis, and exacerbation of her underlying asthma, with an onset on or about October 8, 2015, which required treatment with antibiotics, prednisone, and asthma medications. On November 12, 2015, she was evaluated at the asthma clinic and her respiratory function was back to her baseline. She did not have any symptoms on November 30, 2015. Therefore, the undersigned finds Petitioner had an exacerbation of her asthma from approximately October 8 to November 12, 2015, when she returned to her baseline respiratory function.

3. Loving Factor Three: Does Petitioner’s Current Condition (or Condition After Vaccination) Constitute a “Significant Aggravation” of Her Condition Prior to Vaccination?

The next factor of the Loving test is to determine whether there is a “significant aggravation” of Petitioner’s condition by comparing her condition before vaccination to her condition after vaccination. The statute defines “significant aggravation” as “any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health.” § 33(4). Using this definition, the undersigned finds that Petitioner had a significant aggravation of her underlying condition of asthma from approximately October 8 to November 12, 2015.

4. Loving Factor Four/Althen Prong One

The fourth Loving factor has its origins in Althen prong one, and Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1379; Pafford, 451 F.3d at 1355-56. Petitioner’s theory of causation need not be medically or scientifically certain, but it must be informed by a “sound and reliable” medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec’y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is

both “relevant” and “reliable”). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 (“The special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories.”); Perreira v. Sec’y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an “expert opinion is no better than the soundness of the reasons supporting it” (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

Petitioner’s expert, Dr. Akbari, posits that the flu vaccine causes a worsening of asthma via an autoreactive T cell mechanism that induces lung inflammation. Respondent’s expert, Dr. Levinson disagrees, explaining that asthma is not an autoimmune disease, and that the T cells that promote asthma react to exogenous allergens and not self-antigens. In other words, Dr. Levinson opines that Dr. Akbari’s suggested mechanism is “totally incongruent with the pathophysiologic basis of asthma.” Resp. Ex. B at 10. The undersigned finds Dr. Levinson’s opinions to be more persuasive than those offered by Dr. Akbari for several reasons.

First, Dr. Akbari does not provide persuasive evidence that asthma is an autoimmune disease, that auto-reactive T cells promote asthma exacerbation, or that molecular mimicry is involved in this exacerbation. He cites several articles, but none of these are on point. See Pet. Ex. 13 at 12 (citing Pet. Exs. 46-51). For example, the article by Hibino and Kondo discusses two case reports of interstitial pneumonia associated with the flu vaccine. See Pet. Ex. 46. The article is not about asthma or exacerbation of asthma. Both patients had very abnormal chest X-rays with patchy consolidation and/or infiltrates, and patient number one had CT that showed ground-glass opacities in the lungs. Neither patient had a history of asthma and neither patient was diagnosed with asthma or an exacerbation of asthma. The second article referenced, by Watanabe et al., also deals with a case report of interstitial lung disease. The patient did not have any history of asthma and was not diagnosed with asthma. See Pet. Ex. 47.

The article by Hibbs et al., related to vaccination error reports to the Vaccine Adverse Event Reporting System (“VAERS”), does not relate to autoreactive T cell mechanisms, or asthma. It does not appear relevant to any issue in this case. Bhurayanontachi reported a case of respiratory failure, where chest X-rays showed diffuse bilateral lung infiltrates, and the patient had bloody secretions. She was diagnosed with acute lung injury and pulmonary hemorrhage. The author concluded that autoimmune disease was unlikely. The diagnosis and mechanism were unknown. Umeda et al. reported a case of pulmonary fibrosis that occurred after a H1N1 flu vaccination. Pulmonary fibrosis is not at issue here. Lastly, the article by Audrit et al. relates to inflammatory lung disease, including asthma, but the article relates to the nervous system of airways and how it is affected by inflammatory lung disease. The authors do not discuss how vaccines in general, or the flu vaccine specifically, can exacerbate asthma. They discuss how respiratory infections can contribute to “long lasting changes in the pulmonary nervous system.” Pet. Ex. 51 at 5.

Notably, Audrit et al. explain that “[a]llergic asthma is an inflammatory disease of the airways that is associated with many symptoms, including a reversible bronchoconstriction, dyspnea[,] and cough[,] and is generally associated with [airway hyperactivity].” Pet. Ex. 51 at 5. The authors note that “immune cells alone are not able to evoke the symptoms that mostly

require central reflex activity.” Id. And “bronchial biopsies from patients with allergic asthma often show no signs of inflammation despite the presence of symptoms.” Id.

In short, Petitioner filed no medical literature to support the proposition that the flu vaccine can exacerbate asthma. The case studies that were filed do not relate to asthma but to interstitial lung disease and pulmonary fibrosis, different conditions. And Dr. Akbari does not explain why cases about other illnesses are relevant here.

Second, at times, Dr. Akbari mispresents the literature he cites. For example, he states “pandemic [flu] A (H1N1) vaccine may be associated with the occurrence of lung inflammation and asthma.” Pet. Ex. 13 at 12. However, none of the articles cited state such an opinion or finding. He also states that “neuroimmune interaction has long been discussed in the pathogenesis of allergic airway diseases, such as allergic asthma.” Id. However, Dr. Akbari has not offered a theory of neuroimmune interaction as it relates to how the flu vaccine can cause an exacerbation of asthma.

Third, Dr. Akbari offered no other evidence to support his theory that the flu vaccination can exacerbate asthma.

Fourth, Dr. Akbari’s expert report, as it relates to how the flu vaccine can exacerbate asthma, is a meandering discussion of various topics that do not relate to how the flu vaccine can exacerbate asthma. It is difficult to understand and offers no cohesive theory that can be thoughtfully analyzed.

Finally, there are no Vaccine Program cases where a petitioner has been awarded entitlement to compensation based on a claim that the flu vaccine can cause significant aggravation of asthma. While the undersigned is not bound by other Program cases, they can be instructive and insightful. And given the undersigned’s experience and knowledge, when there are no other similar cases, it may be because the theory is inappropriate, or the alleged injury has not been shown by the medical or scientific community to be vaccine related.

There is one reasoned decision where a petitioner alleged significant aggravation of asthma after the flu vaccination. See Green v. Sec’y of Health & Hum. Servs., No. 16-008V, 2020 WL 2954939 (Fed. Cl. Spec. Mstr. Apr. 30, 2020). But there, the theory alleged was aligned with what is known to cause some forms of asthma and its exacerbations. Id. at *10-19. Although the petitioner in Green alleged an appropriate theory (hypersensitivity or IgE mediated immune response), she did not prevail because the onset of her exacerbation occurred too long after vaccination to be consistent with the theory, and thus she failed to prove an appropriate temporal association. Id. at *19-22. She also failed to prove a logical sequence of cause and effect since diagnostic testing showed insignificant levels of IgE generally. Id. at *22-27. In other words, there was no evidence of an IgE-mediated reaction. Further, there was evidence that the asthma exacerbation was caused by alternative factors, including obesity and sleep apnea. Id. While the Green case is quite different, it illustrates the difficulty pursuing this type of claim, even when the theory is appropriate and well explained.

In addition to Green, there are two reasoned decisions where petitioners alleged that vaccinations caused their asthma; petitioners in those cases did not prevail. See Jennings v.

Sec’y of Health & Hum. Servs., No. 16-779V, 2020 WL 9258304 (Fed. Cl. Spec. Mstr. July 8, 2020); DeJesus Rezzonico v. Sec’y of Health & Hum. Servs., No. 99-498V, 2004 WL 3049765 (Fed. Cl. Spec. Mstr. Dec. 17, 2004). In Jennings, the petitioner alleged that a human papillomavirus (“HPV”) vaccine caused her to develop asthma. Jennings, 2020 WL 9258304 at *1. However, petitioner’s symptoms of exercise-induced asthma began approximately one month before her first HPV vaccination. Id. at *14-18. The special master dismissed the case due to the factual finding that petitioner’s onset of asthma occurred prior to vaccination. Id. In the second case, the petitioner alleged that a hepatitis B vaccination caused his asthma by either an allergic reaction or a “skewing of the immune system.” DeJesus Rezzonico, 2004 WL 3049765 at *5. Respondent’s expert explained that asthma is caused by an IgE-antibody mediated response which is caused within several hours after exposure (receipt of vaccination). Id. at *5-6. Finding Respondent’s expert to be more credible, the special master found that onset of symptoms the day after vaccination was too late to be vaccine related. Id. Regarding petitioner’s theory based on an abnormal immune response, the special master found that a one-day onset was too short. Id. In summary, limited case law provides three examples where petitioners did not prevail due to inappropriate causal theories or facts. The present case fails for both reasons.

Therefore, the undersigned finds that Petitioner has failed to prove by preponderant evidence a sound and reliable theory to explain how the flu vaccine can cause exacerbation of asthma.

5. **Loving Factor Five/Althen Prong Two**

Under Loving factor five and Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. Petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

Regarding the fifth Loving factor/second Althen prong, the undersigned finds that Petitioner has failed to show by preponderant evidence that the flu vaccination significantly aggravated her pre-existing asthma. The primary reason for this finding is because the

Respondent has shown by preponderant evidence that Petitioner's URI, a factor unrelated to vaccination, was the cause of her exacerbation. This finding is discussed below.

6. Loving Factor Six/Althen Prong Three

The last element in the six-part Loving test has origins in Althen prong three. As stated in Loving, this element is "a showing of a proximate temporal relationship between vaccination and the significant aggravation." 86 Fed. Cl. at 144. Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. A proximate temporal relationship has been equated to mean a "medically acceptable temporal relationship." Id. Petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen prong one). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542.

Based on the case law cited above, this factor/prong consists of two parts. Petitioner must first establish the time frame within which it is medically acceptable to infer causation. And secondly, she must show that the onset of the worsening or aggravation of her illness occurred during this time frame. Since Petitioner has not shown a sound and reliable theory of causation, she is also unable to prove what the appropriate temporal association would be for that theory. Loving factor six/Althen prong three is dependent on the medical theory required by Loving factor four/Althen prong one. Therefore, Petitioner's inability to meet her burden under Loving factor four/Althen prong one effectively precludes her from being able to meet her burden under the sixth Loving factor/third Althen prong.

Because Petitioner failed to prove a sound and reliable mechanism to explain how the flu vaccination can cause an exacerbation of asthma, the undersigned finds that she has failed to prove by preponderant evidence an appropriate temporal onset.

C. Asthma Alternative Causation

Petitioner's medical records establish that she had an URI that began approximately October 8, 2015 and she was diagnosed with acute sinusitis on October 14, 2015. On October 14, Petitioner's pulmonologist, Dr. Klares, opined that her asthma exacerbation appeared to be "related to the URI and acute sinusitis." Pet. Ex. 3 at 349. Dr. Klares prescribed an antibiotic for the infection. Respondent's expert, Dr. Levinson, agreed and opined that the "[URI] experienced by [P]etitioner [two to three] weeks post vaccination was the overwhelming cause" of her asthma exacerbation. Resp. Ex. B at 12.

Under the Vaccine Act, compensation shall be awarded where the petitioner demonstrates the requirements set forth under the Act by a preponderance of the evidence, and "there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine." § 13(a)(1)(A)-(B). The Act provides that "factors unrelated to the administration of the vaccine" are those "which are shown to have been the agent . . .

principally responsible for causing the petitioner’s illness, disability, injury, condition or death.” *Id.* § 13(a)(2)(B). To satisfy the burden of showing an alternative cause of Petitioner’s injuries, Respondent is “required not only to prove the existence of [a factor unrelated], but also to prove by a preponderance of the evidence that the [factor unrelated] actually caused” the alleged injury. *Knudsen*, 35 F.3d at 549 (emphasis omitted). “Furthermore, [Respondent] also ha[s] to present sufficient evidence to prove that the alternative factor was the sole substantial factor in bringing about the injury.” *Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs.*, 717 F.3d 1363, 1368 (Fed. Cir. 2013) (citing *de Bazan*, 539 F.3d at 1354). “Thus, to establish alternative causation, [Respondent] must satisfy the three prongs of *Althen*, by a preponderance of evidence.” *Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs.*, No. 05-306V, 2011 WL 6935504, at *33 (Fed. Cl. Spec. Mstr. Dec. 9, 2011), *aff’d*, 105 Fed. Cl. 583 (2012), *aff’d*, 717 F.3d 1363.

Although Petitioner has failed to prove that the flu vaccine exacerbated her asthma, even if she had prevailed, Respondent has proven by preponderant evidence that an alternative factor, a factor unrelated to the flu vaccination, caused Petitioner’s asthma exacerbation.

1. Loving Factor Four/Althen Prong One

Dr. Levinson opined, “to a degree of medical certainty [] the [URIs] experienced roughly two weeks post-vaccination, not the flu vaccine, triggered the [P]etitioner’s acute asthma exacerbation.” Resp. Ex. B at 12. He explains that “viral infections are frequent precipitants of asthma exacerbation,” and that this cause is “widely supported by the scientific literature.” *Id.* at 11.

In support of his opinion, Dr. Levinson cites a paper published by Busse et al. that provides an overview about the role of viral respiratory infections in asthma and exacerbations of the illness. Resp. Ex. B.3. The authors state that “[w]heezing illnesses are closely associated with viral respiratory infections in patients or all ages.” *Id.* at 2. They explain that since the advent of polymerase chain reaction (“PCR”) technology which can identify specific strains of virus, an expanded group of respiratory viruses have been detected in association with episodes of worsening asthma. *Id.* at 5. In one study, 85% of children with asthma flares had detectable viral respiratory infections upon testing. *Id.* These viruses include flu, respiratory syncytial virus (“RSV”), and human rhinoviruses (“HRV”). *Id.* While the pathogenesis of how respiratory viruses cause asthma exacerbations is not completely understood, studies reveal that increased “bronchial hyperreactivity and eosinophilic lower airway inflammation” occurs in those with asthma flares as compared with normal controls. *Id.* at 7. Further, “allergy and viral infections synergistically increase the risk for acute exacerbations.” *Id.* Importantly, IgE-dependent responses have been observed to “contribute to the development of wheezing” in those patients with URIs. *Id.* at 7-8.

Petitioner did not file any evidence to rebut Dr. Levinson’s opinion that respiratory viruses can cause an exacerbation of asthma. And Petitioner did not file any evidence to dispute Dr. Levinson’s opinion or the Busse et al. article explaining how URIs are thought to worsen asthma.

Therefore, the undersigned finds that Respondent has provided preponderant evidence showing that an URI can cause an exacerbation of asthma. Accordingly, Respondent has satisfied Loving factor four/Althen prong one.

2. Loving Factor Five/Althen Prong Two

The opinions of Petitioner's treating physicians are afforded substantial weight. Capizzano, 440 F.3d at 1319-20. Notably, Petitioner's treating physicians associated her asthma exacerbation to her URIs. See, e.g., Pet. Ex. 3 at 349 (Dr. Klares, on October 14, 2015, noting Petitioner's asthma exacerbation did "appear [to be] related to the URI and acute sinusitis"); Pet. Ex. 4 at 85 (Dr. Liebelt, on November 5, 2015, opining Petitioner's asthma was "[l]ikely provoked by viral URI"); Pet. Ex. 3 at 421 (Dr. Powell, on March 7, 2016, associating Petitioner's asthma exacerbation with a preceding URI).

In his expert report, Dr. Levinson explains that "[t]he occurrence of [Petitioner's] likely virus-induced [URI] was described by just about every member of the health care team (Drs. Klares, Liebelt, Powell), who probed the chain of events that followed the vaccination of [Petitioner] on September 19, 2015." Resp. Ex. B at 11. The opinions of Petitioner's treating physicians as set forth above, as well as that of Dr. Levinson, are further confirmed by the medical literature cited by Dr. Levinson which indicates that Petitioner's clinical course was consistent with post-viral exacerbation of her asthma.

Therefore, the undersigned finds that Respondent has provided preponderant evidence of a logical sequence of cause and effect showing that Petitioner's URI caused the exacerbation of her asthma. Accordingly, Respondent has satisfied his burden under Loving factor five/Althen prong two.

3. Loving Factor Six/Althen Prong Three

Dr. Levinson opines that "given the well-defined role of viral [URIs] in asthma exacerbations and the lack of reliable data that speak to the role for the flu vaccine in such exacerbations, [he] believe[s] to a degree of medical certainty that the [URIs] experienced by the [Petitioner] [two to three] weeks post vaccination was the overwhelming cause of that exacerbation." Resp. Ex. B at 12.

Likewise, because Petitioner's treating physicians believed that Petitioner's asthma worsening was caused by her URI, they presumably considered the temporal interval to be medically acceptable. See Contreras v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 280, 299 (2012); Andreu, 569 F.3d at 1376. Further, Dr. Akbari did not disagree or offer a rebuttal opinion showing that the temporal association between Petitioner's URI and her asthma exacerbation was not medically acceptable.

Therefore, the undersigned finds that Respondent has provided preponderant evidence that the interval between Petitioner's URI and the onset of her asthma exacerbation is a medically acceptable timeframe to infer causation. Accordingly, Respondent has satisfied his burden under Loving factor six/Althen prong three.

VII. CONCLUSION

For the reasons discussed above, the undersigned finds that Petitioner has not established entitlement to compensation and her petition must be dismissed. In the absence of a timely filed motion for review filed pursuant to Vaccine Rule 23, the clerk is directed to enter judgment consistent with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Special Master