In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 17-0059V
(to be published)

L.J.,	*	Chief Special Master Corcoran
Petitioner,	*	
	*	Filed: December 2, 2021
v.	*	
	*	Ruling on Entitlement;
	*	Causation-in-Fact;
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Influenza (Flu) vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)
Respondent.	*	

Ronald Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Voris Johnson, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 13, 2017, L.J. filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"[2]). ECF No. 1. Ms. J alleges that the influenza ("flu") vaccine that she received on October 20, 2014, caused her to suffer a shoulder injury related to vaccine administration ("SIRVA") – a Table claim. Petition at ¶1.

[1] This Ruling will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Ruling will be available to anyone with access to the internet**. Otherwise, the entire Ruling will be available to the public in its current form. Vaccine Rule 18(b).

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

After the filing of the Petition, the parties engaged in settlement discussions, but could not come to any agreement, resulting in the filing of several expert reports. The parties participated in additional settlement efforts via a discontinued mediation program, but again could not agree on terms. Thereafter, I invited Petitioner to file a Motion for Ruling on Record, which she did on January 29, 2021. ECF No. 79 ("Mot."). Respondent opposed the Motion on March 15, 2021. ECF No. 80 ("Opp."). Petitioner filed a reply on March 30, 2021. ECF No. 81 ("Reply"). The Motion is now ripe for resolution.

After reviewing all of the medical records, affidavits, and expert witness reports, I find that Petitioner has presented preponderant evidence that the October 20, 2014 flu vaccination caused a right SIRVA injury, despite Respondent's objections. As discussed in greater detail herein, although Petitioner has not presented preponderant evidence that her SIRVA caused the full range of symptoms and treatment alleged, such issues bear on damages rather than entitlement.

I. Medical History

Relevant Pre-Vaccination Events

Ms. J was 41 years old at the time of the relevant vaccination. She was generally healthy, worked as a physical therapist, and was an avid exerciser, working out daily. Ex. 30 at ¶1. She had three children and a history of gestational diabetes. Ex. 4 at 2; Ex. 30 at ¶1. In or around January 2014, she was fitted with a custom nightguard for chronic clenching and grinding her teeth. Ex. 14 at 2. On October 3, 2014, a little over two weeks prior to vaccination, she presented to her doctor with a small mass on her left forearm, thought to be a cyst. Ex. 4 at 19. Ms. J had no history of shoulder pain, inflammation, or dysfunction.

Vaccination, Symptoms, and Fall 2014 Treatment

On October 20, 2014, Petitioner presented to her employer's medical provider, Novant Health, and received the flu vaccine in her right deltoid. Ex. 1 at 1. Ms. J returned to employee health nine days later, on October 29, 2014, complaining of right shoulder and arm pain, with numbness and change in sensation in her right hand. Ex. 5 at 8. She visited again on November 5, 2014, with continued complaints of right-hand numbness and tingling since her flu shot. Ex. 5 at 9. She was prescribed a Medrol Dosepak, referred to physical therapy, and referred to her primary care provider ("PCP") if her symptoms did not improve. *Id.* Ms. J did not immediately start the medication.

On November 7, 2014, Ms. J presented to her PCP, Dr. Jamalla David, with complaints of right arm pain and nausea. Ex 4 at 29. Petitioner saw Dr. David again five days later, on November 12, 2014, with continuing nausea, and expressed significant concern about her right arm pain. *Id* at 33. Dr. David "strongly suspected uncontrolled anxiety as a factor in some of her sxs" and prescribed Klonopin, but did not substantively assess Ms. J's right

arm pain because she had an appointment with an orthopedist the same day. *Id.* at 41. Petitioner saw her gynecologist, Dr. Deena Castillion on November 17, 2014 with similar complaints along with fatigue, loose stools, and lack of appetite. Ex. 2 at 40. Dr. Castellion did not believe Petitioner's symptoms were anxiety, but a reaction to her recent vaccination. *Id.* at 41.

On November 12, 2014, Ms. J presented to physician's assistant ("PA") Richard Richardson at OrthoCarolina, complaining of "right arm pain; fairly acute onset secondary to flu injection." Ex. 8 at 12. PA Richardson found that although Petitioner had full range of motion in her shoulders and elbows and full strength, "a close observation of the sensory testing today shows some decreased sensation in the ulnar nerve path of the right upper extremity." *Id.* He ordered x-rays of her cervical spine, which were normal. *Id.* at 13. PA Richardson's diagnosis was ulnar neuritis. *Id.*

On November 21, 2014, Ms. J presented to Dr. Meredith Snapp at Novant Health Neurology Specialists. Ex. 7 at 6. Dr. Snapp found reduced strength in Petitioner's right triceps, decreased sensation to light touch, temperature and vibration in Petitioner's neck, and decreased sensation in Petitioner's right lateral forearm. *Id.* at 7-8. She diagnosed "neuropathic pain in right arm after onset of flu shot," adding that the proximal progression of symptoms could be "secondary muscle tension," but disputing that the GI symptoms were likely related. *Id.* at 8. Dr. Snapp ordered MRIs of Ms. J's brain and cervical spine,[3] EMG and nerve conduction studies, and prescribed Gabapentin. *Id.* The EMG revealed abnormalities suggesting carpal and cubital tunnel syndromes. Ex. 28 at 7.

On December 2, 2014, Ms. J sought the opinion of another orthopedist, Dr. Eric Warren. Ex. 10 at 2. Dr. Warren found full cervical strength and range of motion. *Id.* On Petitioner's right shoulder he found a small "soft tissue mass," but full range of motion, full strength without pain, and negative impingement tests. *Id.* Dr. Warren reviewed Ms. J's brain and cervical spine MRI reports, and her recent lab reports. *Id.* at 4. He concluded that Ms. J's was a "complicated, concerning clinical picture overall though this may just be a subacromial/subdeltoid bursitis with a fibrotic scar tissue mass potentially related to her injection." *Id.* He opined that "it is certainly very possible she has a compensatory cubital tunnel syndrome or a previously undiagnosed ulnar nerve subluxation issue that is resulting in her symptoms." *Id.*

Ms. J returned to Dr. Warren on December 11, 2014, to review the MRI and the abnormal nerve study results. Ex. 10 at 6. Dr. Warren felt that the "overall clinical picture was

[3] Ms. J underwent cervical spine and brain MRIs on November 25, 2014. Ex. 28 at 4-5. The cervical spine MRI revealed a normal cervical spine, but a "large left paracentral disc protrusion at T3-4 with cord compression." *Id.* at 5. The brain MRI revealed a possible small pituitary cyst and "small air fluid level in the right maxillary sinus." *Id.* at 4. The thoracic disc issue was later determined to be stable and did not require further treatment. Ex. 12 at 12-13.

consistent with likely cascade effect with likely post-inflammatory reaction from flu vaccine which led to less use of shoulder leading to weakness and therefore change in biomechanics with resulting impingement." *Id*. at 7. He felt the EMG and nerve conduction studies revealed "almost certainly pre-existing conditions." *Id.*

Treatment in 2015

On January 1, 2015, Ms. J presented to the emergency room complaining of "parethesias in her right arm that have now progressed to her right neck and right face," as well as nausea and loose stools, but was discharged. Ex. 13 at 9-11. The next day, Ms. J presented to Dr. Faye Sherwood Campbell at her PCP complaining of "burning pain down the entire arm, right side of neck, right occipital area and now the right side of her face." Ex. 15 at 6. She also reported feeling "very anxious and nervous, shaky" and nauseous, with blurred vision. *Id.* Dr. Sherwood Campbell suggested that Petitioner cease all medications and follow up with neurology. *Id.* at 7. Dr. Sherwood Campbell saw Petitioner again on January 14, 2015 for numerous complaints including her right arm pain and numbness, and nausea, headache, sore throat, congestion, and cough. *Id.* at 17. Dr. Sherwood Campbell "suspected some of the symptoms of parethesias may be related to anxiety, which she clearly has. She is also exhibiting symptoms of depression." *Id.* at 18. She prescribed Cymbalta. *Id.*

On January 5, 2015, Petitioner presented to the Charlotte Headache Center with complaints of "moderate throbbing and burning headaches of the right temporal, occipital, and frontal areas . . . for the last two to three months with pain of the side and back of the neck, pain in and behind the eyes." Ex. 14 at 2. Petitioner placed her symptoms onset after her flu shot in October, with "arm pain then radiated to neck, head, face." *Id.* The records note that Petitioner was "aware of chronic clenching and grinding" of her teeth, with TMJ symptoms appears 2-3 years prior, and that she had a custom night guard "made about a year ago" which she "uses nightly past 2 months." *Id.* A bilateral MRI of the temporomandibular joint ("TMJ") was ordered and performed on January 6, 2015, which showed abnormalities. *Id.;* Ex. 28 at 11. Ms. J underwent a Trudenta treatment plan for her TMJ pain, having 14 treatments between January 13, 2015 and May 5, 2015. *Id.* at 3-7. At her one month follow up appointment, on June 2, 2015, Petitioner reported a 75% improvement in her symptoms and no continued therapy was recommended. *Id. at 7.*

On January 23, 2015, Petitioner returned to OrthoCarolina, seeing Dr. Erika Gantt. Ex. 8 at 10. Dr. Gantt noted that Ms. J's nerve tests showed "mild carpal tunnel syndrome and mild ulnar neuropathy," and that "most of her pain is on the lateral side of the elbow." *Id.* She diagnosed right lateral epicondylitis and recommended a brace, but did not opine that Petitioner's symptoms had "anything to do with her getting a flu shot in the arm," and adding that Petitioner seemed "somewhat frustrated that she cannot make the connection between the flu shot." *Id.*

Ms. J presented to Dr. Ki Jung, a neurologist, on March 17, 2015, for pain in her right upper extremity, as well as her right posterior scalp and face. Ex. 20 at 5. Dr. Jung noted that Ms. J had "high anxiety about her symptoms." *Id.* Dr. Jung "suspected that she indeed has a post-vaccination inflammatory syndrome that may have exacerbated already pre-existing underlying right cubital tunnel syndrome and TMJ issues. I do not think she has any underlying sinister neurological disorder at this time." *Id.* at 7. Dr. Jung recommended that Ms. J follow up with psychiatry and that she avoid future flu vaccinations. *Id.*

Petitioner returned to OrthoCarolina on June 12, 2015, after her TMJ treatment ended. On that date, she saw Dr. Raymond Gaston, who noted that Petitioner's pain had persisted with bracing and a home exercise program. Ex. 8 at 7. Dr. Gaston prescribed occupational therapy ("OT") for her elbow. *Id.* Ms. J saw Dr. Gaston again on July 23, 2015, when she reported some improvement through OT and use of a splint. *Id.* at 4. Dr. Gaston officially diagnosed carpal tunnel syndrome and cubital tunnel syndrome and administered an injection to provide relief. *Id.* Ms. J completed 11 OT sessions between June 22, 2015 and July 30, 2015. *Id.* at 31, 41-61. She returned to Dr. Gaston on September 15, 2015, reporting resolution of the majority of her symptoms with the exception of some finger numbness. Ex. 8 at 2. He prescribed Mobic and ordered an MRI of Petitioner's right elbow, which revealed "distal triceps tendinopathy and potential punctuate interstitial partial thickness tearing present." Ex. 8 at 2; 28 at 20.

Physical Therapy and Other Treatment Efforts

Ms. J, who is herself a physical therapist, participated in physical therapy ("PT") sessions throughout her lengthy treatment, with sessions with several providers overlapping during the same periods of time.

Ms. J began her first PT course at Owens PT on November 6, 2014, approximately three weeks after her vaccination. Ex. 25 at 2. At the initial evaluation, Petitioner was found to have "severe restriction of B B Scales, UT, Deltoid with reproduction of pt's sx's (N+T down RUE) on palpation of mid-deltoid." *Id.* On Physical therapist, Denise Owens, noted "limited cervical and R shldr AROM" with "R shldr flex 163 deg." *Id.* By December 4, 2014, Ms. J's active range of motion decreased to 149 degrees. Ex. 25 at 9. Ms. J had 12 physical therapy sessions through January 1, 2015. *See* Ex. 25.

She returned to Owens PT from April 1, 2015 through September 28, 2015, completing another 15 sessions. Ex. 21 at 2-19. Upon returning, Petitioner reported "onset October 2014 post-flu shot to R arm . . . R shoulder pain and parethesias including temperature changes at hand, which persist." *Id.* at 2. At her final visit, Ms. J had full right shoulder ROM, full cervical ROM, and had decreased the frequency, intensity, and duration of her symptoms. *Id.* at 19.

Ms. J also received concurrent PT treatments at OrthoCarolina, starting on December 26, 2014. Ex. 8 at 38. She complained of "neck, shoulder, and right upper extremity radicular symptoms" that "began on or around 20 October 2014 following a flu vaccine administration." *Id.* The physical therapist found reduced range of motion in Ms. J's cervical spine and positive impingement signs in her right shoulder. *Id.* at 39. Physical therapist, Chris Dollar, noted "positive and diminished Hawkins-Kennedy test." *Id.* She had nine physical therapy sessions through January 26, 2015. *Id.* at 63-77. She returned to OrthoCarolina for an additional two sessions between August 6, 2015 and September 3, 2015. Ex. 8 at 28-30.

In addition, Petitioner received PT from other providers. She participated in 21 sessions of PT at the Novant Health Rehabilitation Center between February 4, 2015 and May 7, 2015. Ex. 23 at 3-158. At her initial visit, she reported "diffuse arm/neck/face pain R that began last fall." *Id.* at 3. By March 2015, Ms. J had improved ROM and an overall decrease in symptoms and was encouraged to return to her normal lifestyle. *Id.* at 67, 97. Ms. J began PT at Roper PT on February 25, 2015 and completed 13 sessions through December 14, 2015. Ex. 22 at 2-27. At her final visit, Ms. J reported her symptoms as 85% better. *Id.* at 27. And she completed 26 sessions at Kane Training between June 4, 2015 and October 6, 2016. Ex. 29 at 2-6. By November 2015, Ms. J had returned to running without significant issues. *Id.* at 4. In total, Ms. J participated in 100 physical therapy sessions between November 6, 2014 and December 14, 2015.

In addition to extensive PT, Ms. J also sought care from an acupuncturist for her right arm pain, decreased sensation, TMJ, headaches and anxiety. *See* Ex. 24. She had 33 sessions of acupuncture between January 27, 2015 and June 23, 2015. *Id.* at 8-40. And Ms. J received eight sessions of chiropractic treatment between February 18, 2015 and March 6, 2015. Ex. 19 at 2-16.

Relevant Affidavit Testimony

Ms. J submitted an affidavit in support of her Petition on January 19, 2017. Ex. 30. She described herself as an "active and health person," who "enjoyed working out daily, including CrossFit and running," prior to her flu shot. *Id.* at ¶1.

Ms. J stated that on October 20, 2014 she went to the employee health office to get her mandatory flu shot. *Id.* at ¶2. She said she was advised not to remove her long-sleeved shirt, but to pull her collar to the side to expose her upper arm. *Id.* When the injection was administered, Ms. J recalled that "it hurt more than a shot has ever hurt before." *Id.* "Immediately the site was very painful and locally she felt a burning sensation." *Id.* She took ibuprofen, but within a couple of hours began to experience numbness and tingling in the fingers of her right hand. *Id.* at ¶2-3. She was unable to complete her regular workout or give her daughter a bath that evening

because she could not "lift her arm above her head without excruciating pain." *Id.* at ¶3.

Although Ms. J initially thought her symptoms would resolve, she began to seek medical treatment. *Id.* at ¶4. She felt the doctors she saw were "not very helpful and seemed to write her off as being anxious." *Id.* at ¶6. She felt that they "did not understand that she was fine one second before that shot was stuck in her arm, and she had not been fine since." *Id.* She kept going to different doctors "trying to find answers." *Id.* at ¶10. She tried "physical therapy, acupuncture and even chiropractors trying anything that would get back normal function in her right arm." *Id.* at ¶11.

Ms. J explained that she "began to lose hope," lost weight, "could not sleep at night due to the pain," and "became depressed." *Id.* She had to seek treatment from "a psychiatrist and start taking antidepressants." *Id.* at ¶12.

II. Petitioner's Expert Opinions

A. *Dr. Marko Bodor*

On February 18, 2018, Dr. Marko Bodor provided an initial expert report on behalf of Petitioner. Ex. 24; ECF No. 35 ("First Bodor Rep."). He provided two supplemental reports, on July 24, 2017 (filed as Ex. 35; ECF No. 44 ("Second Bodor Rep.")) and on January 31, 2019 (filed as Ex. 27; ECF No. 52 ("Third Bodor Rep.")) respectively, addressing concerns raised in Respondent's expert reports.

Dr. Bodor obtained his Bachelor of Arts degree from Harvard University in 1982, and his M.D. from the University of Cincinnati Medical School in 1987. *See* CV, filed as Ex. 35 (ECF 35-5 ("Bodor CV")) at 1. He thereafter completed a residency in physical medicine and rehabilitation at the University of Michigan. *Id.* He is board certified in Physical Medicine and Rehabilitation (1994), Neuromuscular and Electrodiagnostic Medicine (1997), Pain Management (2004), and Sports Medicine (2010). *Id.* Since 1995, Dr. Bodor's primary practice has been treating patients "with a variety of neuromuscular, musculoskeletal, and pain problems. *Id.* at 2. Dr. Bodor's practice "has been an APPMR approved fellowship" taking on two fellows per year, whom he averages approximately 12 hours per week teaching and supervising. *Id.* at 7. Dr. Bodor has written several articles and given numerous presentations on varying neuromuscular and musculoskeletal issues, testing, and treatments. *Id.* at 3-5, 7-9.

Notably, Dr. Bodor co-authored an article in 2007 specifically addressing vaccine-related shoulder injury. Bodor CV at 8. Dr. Bodor has provided expert opinions in several previous Vaccine Program cases, and his expertise to do so has been recognized. *See,* e.g., *Hardy v. Sec'y of Health & Human Servs.*, No. 17-232V, 2018 WL 6822356 at *3 (Fed. Cl. Spec. Mstr. November 26, 2018).

First Expert Report

Dr. Bodor's first report observed that Ms. J's health was generally good pre-vaccination, but that she "developed right shoulder pain starting immediately after a flu vaccination that was provided high into her right deltoid." First Bodor Rep. at 2. In his view, Ms. J's "small thin body" and low BMI were contributing factors to the injury, since "the injection could have easily penetrated into the subdeltoid/subacromial bursa, as well as into the teres minor and infraspinatus tendons of the rotator cuff at their insertions on the humerus." *Id.* at 4. He also opined that Ms. J's numbness into her lower arm, neck and face could have resulted from her brain "down-regulating" her shoulder pain from the vaccination. *Id.* He thus concluded that Ms. J's "ongoing symptoms are a result of a persistent immune-mediated inflammation post-vaccination." *Id*. at 5.

To support this opinion, Dr. Bodor provided two of his own articles, as well as one co-authored by Respondent's expert. *See* S. Atanasoff *et al., Shoulder Injury Related to Vaccine Administration (SIRVA*), Vaccine, 2010 Nov 29;28(51):8049-52 (Ex. 34, Tab A) ("Lightfoot Art."); American Academy of Physical Medicine and Rehabilitation, San Diego, California, 11/2008: T. Lee & M. Bodor, *Numbness in the Hand and Arm Related to Shoulder Dysfunction: A Case Series* (Ex. 34, Tab B); M. Bodor & E. Montalvo, *Vaccine-Related Shoulder Dysfunction,* Vaccine, 2007 Jan 8;25(4):585-7 (Ex. 34, Tab C).

Second Expert Report

Dr. Bodor's second report specifically addressed the contention of Respondent's expert that Ms. J's symptoms were the product of a centrally-mediated syndrome rather than SIRVA. *See generally* Second Bodor Rep. Even though Ms. J had a normal MRI and normal lab studies, the Lightfoot Article itself described a study of 13 SIRVA patients in which 61% also had normal or significantly normal MRIs. *Id.* at 2. Moreover, the Lightfoot Article did not note the lab results of other SIRVA patients. *Id.* Thus, it could not be assumed that these kinds of normal results ruled out SIRVA.

Dr. Bodor agreed that Ms. J may have "a centrally-mediated syndrome, causing symptoms beyond the shoulder region and into the face and down the arm." Second Bodor Rep. at 2-3. However, Dr. Bodor deemed the syndrome to be the *result* of Ms. J's SIRVA, rather than the cause. *Id.* at 3. In support of his opinion, Dr. Bodor highlighted that Ms. J "had reduced passive and active range of shoulder range of motion noted by her physical therapists, consistent with frozen shoulder, which has been documented in SIRVA cases, but is not a feature of centrally mediated pain syndrome." *Id.*

Third Expert Report

In his final supplemental report, Dr. Bodor again pointed out what he viewed as a likely relationship between Ms. J's symptoms of frozen shoulder and any centrally-mediated pain syndrome. Third Bodor Rep. at 2-3. He noted that although two orthopedists did not find reduced range of motion in Petitioner's shoulder, Ms. J's physical therapist had made such findings between November 2014 and April 2015, and that physical therapists are in the "best position to accurately identify decreased range of motion" because "monitoring reduced range of motion is a primary focus of physical therapists." *Id.* Dr. Bodor did accept that reduced range of motion "is not a typical feature of centrally mediated pain syndrome." *Id.* at 3. Dr. Bodor further pointed out that, even though Dr. Warren, an orthopedist, did not find reduced range of motion, he did "agree that [Ms. J] suffered from impingement and also agreed with the mechanism of an injury" from vaccination. *Id.*

B. *Dr. Robert Lightfoot*

On June 21, 2018, Dr. Robert Lightfoot provided an initial expert report on behalf of Respondent. ECF No. 41 ("First Lightfoot Rep."). He provided two supplemental reports, on October 28, 2018 (filed at ECF No. 48 ("Second Lightfoot Rep.")) and March 28, 2019 (filed at ECF No. 54) ("Third Lightfoot Rep.")) respectively, addressing concerns raised in Dr. Bodor's supplemental expert reports.

Dr. Lightfoot earned his Bachelor of Arts degree in 1958 and his medical degree in 1961, both from Vanderbilt University. ECF No. 41-3 at 1. After, he trained in internal medicine and rheumatology at Columbia-Presbyterian Medical Center and Vanderbilt University Hospital between 1961 and 1966. *Id*. Dr. Lightfoot served in the U.S. Army Medical Corps from 1966 to 1968. *Id.* He is board certified in Internal Medicine (1968) and Rheumatology (1972). *Id.* He consistently held faculty appointments at medical schools as an instructor, assistant professor, professor, chief, division director, and associate chairman from 1966 through 2003. *Id.* at 2. He had several hospital administrative appointments and served on several hospital committees. *Id.* at 10. Dr. Lightfoot has authored or co-authored numerous articles and book chapters throughout his career on topics such as rheumatoid arthritis, lupus, osteoarthritis, vasculitis, and Lyme disease. *Id.* at 16- 26. Notably, Dr. Lightfoot co-authored the SIRVA-related Lightfoot Article discussed by Dr. Bodor. *Id*. at 20. Dr. Lightfoot continues to practice, seeing patients and supervising and teaching fellows at his rheumatology clinic a couple of days each week. First Lightfoot Rep. at 2.

First Expert Report

Dr. Lightfoot's initial report begins with a lengthy review of Ms. J's medical history (and the fact that she did have some relevant preexisting conditions). First Lightfoot Rep. at 3. As he notes, "Petitioner's mother was said to have trigeminal neuralgia, an extremely painful facial

disorder." *Id.* In addition, certain symptoms were present prior to the vaccination, including "a small 'mass' on her left medial forearm," and "extreme fatigue and nausea." *Id.* And other symptoms were not likely SIRVA-related; Petitioner's description of resulting pain and "numbness/paresthesias in her right fourth and fifth digits," suggested "involvement of the ulnar peripheral nerve or spinal cord lesion." *Id.*

Dr. Lightfoot highlights, throughout his report, the absence of any objective evidence in Ms. J's medical records that might corroborate the existence of a vaccine-caused injury. Thus, "blood tests for inflammation . . . on several occasions showed no elevations." *Id.* at 4. He concluded that "none of the accepted laboratory evidence of inflammation – objective physical signs of inflammation, anemia, elevated platelet count, elevated ESR, elevated CRP-have been abnormal in Petitioner." *Id.* at 5. And Ms. J was treated with oral steroids, "perhaps the most inflammatory drugs to be had," without substantial effect, weighing against an inflammatory process. *Id.* As such, he cannot conclude that she has "post-inflammatory anything." *Id.* In addition, Ms. J's MRIs, including the right shoulder, brain, cervical spine, thoracic spine, brachial plexus, right forearm/wrist, right elbow, and bilateral TMJ, revealed only a herniated disc at T3-4, which was not related to her upper extremity symptoms. *Id.* at 4. He further points out that "different providers comment on her anxiety and hypervigilance about her symptoms," including continuing fatigue. *Id.* at 5. Indeed, in Dr. Lightfoot's estimation there is a "preponderance of subjective findings (e.g. fatigue, weakness, pain)" in Petitioner's medical records. *Id.*

Dr. Lightfoot concluded that Ms. J more likely suffered from a "central sensitivity syndrome," such as fibromyalgia. First Lightfoot Rep. at 5. In his experience, patients with such syndromes "often start with more regional involvements and develop more widespread symptoms" and "have symptoms and impairments out of proportion to the objectively demonstrable abnormalities or imaging studies." *Id.* at 5-6. Like Petitioner, many of these patients also suffer from anxiety, depression, sleep disturbance, parethesias, and "trigger points." *Id.* at 6. Further, as many of these central sensitivity syndromes have a genetic component, Petitioner's mother had been diagnosed with "an illness classically lacking objective abnormalities on physical exam or imaging and affecting the cheek and jaw area." *Id.*

In addressing Dr. Bodor's first expert report, Dr. Lightfoot again highlighted the lack of evidence of inflammation or shoulder injury on objective medical tests, adding that the case studies provided were ultimately unhelpful. First Lightfoot Rep. at 6. In conclusion, Dr. Lightfoot opined that Petitioner was most likely suffering from symptoms of a central sensitivity syndrome "at least months if not a year or more" prior to her vaccination, which spread "due to loss of pain control mechanisms centrally in the central nervous system," and that "Petitioner probably suffered at most what was in effect a stab wound by the vaccinating needle," comparing the injury to fibromyalgia. *Id.* D. Clauw, "Fibromyalgia and Related Syndromes," Chapter 91 in *Rheumatology*, Hochberg, et al., eds. 7th edition, Elsevier, P. 736-745 (2018) (ECF No. 41, Exhibit A, Tab 1).

Second Expert Report

Dr. Lightfoot's next report addressed some of the assertions in Dr. Bodor's first supplemental report. Regarding the significance of evidence of inflammation, Dr. Lightfoot noted that "while it is possible that some undeterminable percentage of the shoulders . . . may have inflammatory changes too minimal to be detected by MRI, to draw the conclusion in the absence of any objective anatomical changes would require that we believe shoulder injury in absence of any objective changes of same." Second Lightfoot Rep. at 1. He therefore opined that the lack of objective abnormalities supports his conclusion of a central sensitivity syndrome, where "it has been said of such patients that 'the patient *is* the disease.'" *Id.* at 2.

In addition, Dr. Lightfoot reiterated his observation that Ms. J's pre-vaccination symptoms of fatigue and nausea, plus the "widespread subjective neurological symptoms," as "precisely characteristic of CSS." *Id.* He further noted that "while a local inflammatory reaction can be normal in many patients with repeated influenza vaccinations over years, such reactions are typically brief and very focal," Petitioner's widespread symptoms "were already evolving prior to the vaccination." *Id*. Thus, in his view all of her "chronic and progressive symptoms" reflected classic features of CSS. *Id.*

Third Expert Report

Dr. Lightfoot's final supplemental report, dated March 28, 2019, focused almost entirely on the question of range of motion and its bearing on whether Petitioner's injury was SIRVA or not. In it, he noted that the records cited by Dr. Bodor largely referred to Petitioner's active, rather than passive, range of motion, and thus it was subjective to conclude ROM was in fact limited. Third Lightfoot Rep. at 1. Dr. Lightfoot also questioned Dr. Bodor's assumption that the observations of physical therapists deserved the same weight as those of orthopedists, noting that "orthopedists are fully capable of measuring joint range of motion." *Id* at 2. Dr. Lightfoot ultimately reiterated his overall opinion that "Petitioner had many features strongly suggestive of CSS." *Id.*

III. Procedural History

This matter was initiated on January 13, 2017 and assigned to the Special Processing Unit ("SPU"). ECF No. 1, 5. On June 22, 2017, Respondent indicated his willingness to engage in litigative risk settlement discussions and the parties engaged in settlement negotiations for most of the remainder of 2017. ECF No. 20. On December 27, 2017, Petitioner requested permission to file an expert report in an attempt to facilitate settlement. ECF No. 33. After Petitioner filed her expert report by Dr. Bodor (ECF No. 35), Respondent was no longer amenable to settlement and filed his Rule 4(c) Report and expert report on June 27, 2018. ECF No. 40, 41. Due to the

complexity of the case and the disparate views of the parties, the case was transferred out of SPU and assigned to Special Master Sanders. ECF No. 42, 43.

As noted, expert reports were filed and (after the matter had been assigned to my docket) the claim went through a mediation program, but the parties could not settle the matter.

On December 9, 2020, I held a status conference to discuss how to move this case toward resolution and invited the parties to request an entitlement hearing or to propose a briefing schedule if they wished to proceed via a ruling on the record. The parties briefed the claim, and the matter is now fully ripe for resolution.

IV. Parties' Respective Arguments

The parties agree that Petitioner's claim should be analyzed as causation-in-fact rather than as a Table claim, because the Petition was filed prior to the time when SIRVA was added to the Vaccine Table. Mot. at 22; Opp. at 12. Nevertheless, both parties utilize or refer to the Table criteria in making their arguments regarding Petitioner's alleged SIRVA (and I concur that they bear on how the claim is resolved). *Id.*

Respondent argues that Petitioner has failed to preponderantly establish that she suffered from a SIRVA, noting "the lack of objective, abnormal findings on MRI imaging, nerve conduction testing, and testing for inflammatory markers," "the assessment of normal shoulder range of motion by two qualified orthopedists, and "the presence of symptoms not consistent with SIRVA." Opp. at 1. Respondent goes on to argue that even if Petitioner did suffer a SIRVA, she has not proven that the flu shot caused it. *Id.* Respondent relies heavily on the opinion of his expert, Dr. Lightfoot, that Petitioner's symptoms reflect a central sensitivity syndrome, rather than an injury caused by her flu vaccine. *Id.* at 14.

Petitioner, by contrast, argues that that she has presented a sound mechanism for SIRVA caused by vaccination, and that there is a clear preponderance of evidence that her flu shot more likely than not caused her symptoms. *See* Mot., Repl. Petitioner also argues that she suffered "sequalae following the onset of her SIRVA, including fatigue, as well as TMJ and GI issues," related to her shoulder and arm pain. Mot. at 31. Petitioner argues that all of her symptoms are the result of her SIRVA and caused by the pain associated with the injury. *Id.*

V. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove that: (1) they suffered an injury falling within the Vaccine Injury Table (i.e., a "Table Injury"); or (2) they suffered an injury actually caused by a vaccine (i.e., a "Non-Table Injury.) *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1371, 1320 (Fed. Cir. 2006). As noted, Petitioner does not assert a Table claim.

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

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non–Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Each *Althen* prong requires a different showing and is discussed in turn along with the parties' arguments and my findings.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or

scientifically certain." *Id.* at 549.

However, the Federal Circuit has *repeatedly* stated that the first prong requires a preponderant evidentiary showing. *See Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) ("[w]e have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard"); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010). This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted). If a claimant must *overall* meet the preponderance standard, it is logical that they be required also to meet each individual prong with the same degree of evidentiary showing (even if the *type* of evidence offered for each is different).

Petitioners may offer a variety of individual items of evidence in support of the first *Althen* prong, and are not obligated to resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). No one "type" of evidence is required. Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu,* 569 F.3d at 1380. Nevertheless, even though "scientific certainty" is not required to prevail, the individual items of proof offered for the "can cause" prong must *each* reflect or arise from "reputable" or "sound and reliable" medical science. *Boatmon,* 941 F.3d at 1359-60.

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

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (stating it is not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06–522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356–57 (2011), *aff'd without opinion*, 475 F. App'x. 765 (Fed. Cir. 2012).

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

B. *Law Governing Analysis of Fact Evidence*

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

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

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people are likely to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are automatically deemed accurate, or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual

predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence

that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

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

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

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

E. *Disposition of Case Without Hearing*

I am resolving this claim on the papers, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991). In this case, however, the parties were given the opportunity for a hearing, but elected to have a ruling on the record. *See* ECF No 75.

ANALYSIS

I. Petitioner has provided preponderant evidence to prevail under the *Althen* test.

A. *Petitioner has proven a sound and reliable medical theory (Althen prong one).*

In evaluating the evidence relating to *Althen* prong one, I take judicial notice of the fact that Respondent added SIRVA to the Vaccine Injury Table for claims filed after March 21, 2017. Such recognition by Respondent of the evidence supporting a causal link between vaccine and injury – since the very decision to add a claim reflects Respondent's determination that valid

science supports revising the Table - has been held to support the establishment of the theory required by the first *Althen* prong. *See Doe 21 v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013).

In addition, Petitioner has offered strong expert evidence on the "can cause" prong. Dr. Bodor is a leading expert in SIRVA science, having "done considerable research on the subject and demonstrated significant knowledge of the specific anatomy involved in SIRVA injuries and the potential for a standard vaccine needle to reach the underlying structures when the shot is administered in the top third of the deltoid" and having testified in several vaccine cases. *Desai v. Sec'y of Health & Human Servs.*, No. 14-811V, 2020 WL 4919777 at *18 (Fed. Cl. Spec. Mstr. July 30, 2020). The literature he has authored, and that has been filed in this case, presents a clear mechanism by which a vaccine administered too high in the deltoid (especially for a susceptible individual) can enter the subdeltoid bursa, causing shoulder injury. Ex. 34, Tab A.

By contrast, Dr. Lightfoot's expertise is in internal medicine and rheumatology. ECF No 41-3. And he also has authored articles that support SIRVA as a vaccine injury. *See generally* Lightfoot First Rep. Dr. Lightfoot does not otherwise deny that the flu vaccine can cause SIRVA injuries. *Id.* Instead, he concludes that Petitioner does not have a SIRVA injury, but another condition. *Id.*

Based upon all of the above, I find the evidence discussed above comprises preponderant evidence sufficient to show that the influenza vaccine can cause SIRVA injuries, and thus Petitioner has satisfied the first *Althen* prong.

B. *Petitioner has provided preponderant evidence that her vaccination caused a SIRVA injury (Althen prong two).*

The second *Althen* prong requires a showing of "a logical sequence of cause and effect," usually supported by Petitioner's medical records. *Althen*, 418 F.3d at 1278. As explained herein, it appears that Petitioner's vaccination did cause a SIRVA injury.

Although this is a non-Table case, the Table Qualifications and Aids to Interpretation ("QAI") for SIRVA injuries provide some insight into the factors deemed sufficient by Respondent to establish a claim in which causation is presumed – and thus what would be strong evidence of a vaccine injury in the relevant context. *See* 42 C.F.R. § 100.3(b)(10). The Table QAIs for SIRVA require: (1) no history of pain, inflammation, or dysfunction of the affected shoulder prior to intramuscular vaccine administration; (2) pain occurs within 48 hours of the vaccine administration; (3) pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (4) no other condition or abnormality is present that would explain Petitioner's symptoms. *Id.* Even though Petitioner is not literally obligated to meet

these requirements under the circumstances, some brief review of them helps illuminate the kinds of symptoms that would be associated with a Table SIRVA -- particularly since Respondent's expert, Dr. Lightfoot, opines that Petitioner did not suffer a SIRVA at all. Lightfoot First Rep. at 6.

There is no dispute that Petitioner has satisfied the first two QAI Table criteria. 42 C.F.R. § 100.3(b)(10)(i-ii). Neither expert found any indication in Ms. J's medical records suggesting any prior pain, inflammation, or dysfunction in her right shoulder prior to her vaccination in October 2014. Lightfoot First Rep. at 3; Bodor First Rep. at 1. Further, neither expert disputes Ms. J's claims of immediate pain upon vaccine administration. In fact, Dr. Lightfoot concedes that Ms. J suffered "a stab wound by the vaccinating needle" upon vaccination. Lightfoot First Rep. at 6. Nor did Respondent show that Petitioner's preexisting symptoms were likely associated with the alleged post-vaccination SIRVA symptoms.

The third QAI Table criteria requires Petitioner's pain and limited range of motion to be limited to the vaccinated shoulder. 42 C.F.R. § 100.3(b)(10)(iii). Here, Ms. J presented with shoulder pain and reduced range of motion in the relevant shoulder soon after her vaccination. Her first visit to a medical provider was on October 29, 2014, nine days after her vaccination, at which time she complained of shoulder pain not relieved by ibuprofen and worsened with movement. Ex. 5 at 8. On November 6, 2014, physical therapist, Denise Owens, noted "limited cervical and R shldr AROM" with "R shldr flex 163 deg." Ex. 25 at 2.

By December 4, 2014, Ms. J's active range of motion had decreased to 149 degrees, noted by Dr. Bodor as evidence of adhesive capsulitis or frozen shoulder. Ex. 25 at 9; Ex. 52 at 3. On December 26, 2014, another physical therapist, Chris Dollar, noted "positive and diminished Hawkins-Kennedy test," which Dr. Bodor noted is "commonly performed to assess impingement." Ex. 8 at 39. While Respondent's expert, Dr. Lightfoot, mentions that two orthopedists failed to find reduced range of motion, one of those orthopedists, Dr. Warren, actually diagnosed Petitioner with "impingement" and opined that her clinical picture was consisted with a "post-inflammatory reaction from flu vaccine." Lightfoot Third Rep. at 1; Ex. 10 at 7. The records clearly show that Ms. J had both pain and limited range of motion in her right shoulder after her flu vaccination on October 20, 2014, which weighs in favor of a finding that she suffered a SIRVA injury as alleged.

In his expert reports, Dr. Bodor opined that Petitioner's reduced range of motion, as noted by her physical therapists, and impingement as noted by Dr. Eric Warren, were not symptoms of the centrally-mediated syndromes proposed by Dr. Lightfoot to explain Petitioner's symptoms. Bodor Second Rep. at 3. Dr. Lightfoot did not effectively counter the point. In his first supplemental report, Dr. Lightfoot does not address the range of motion issue at all. *See* Lightfoot Second Rep. In his final supplemental report, Dr. Lightfoot does not discuss how decreased range

of motion fits into his diagnosis, other than noting that the reduced range of motion in Ms. J's records were via active ROM testing, rather than passive, or a subjective measure rather than objective. Lightfoot Third Rep. at 2-3. He argues thus fits into his diagnosis because "the patient is the disease." *Id.* at 3. Dr. Bodor concluded that Ms. J had "reduced active and passive shoulder range of motion noted by her physical therapists, consistent with frozen shoulder, which has been documented in SIRVA cases, but is not a feature of centrally mediated pain syndrome."[4] Bodor Second Rep. at 3. On this point, I find Dr. Bodor more persuasive.

Problematic for Petitioner's claim, however, is the fact that she also had pain and symptoms *outside* of her right shoulder. From her initial complaints after her vaccination, Ms. J complained of pain and numbness radiating down her right arm and into her hand. Ex. 5 at 8-9; Ex. 4 at 22. She also reported pain in her elbow, neck, head, scalp, ear, and face, facial numbness, and sensation changes in her right hand. Ex. 7 at 6.

Dr. Bodor has opined that Ms. J's SIRVA injury caused these additional symptoms. Bodor Second Rep. at 3. As explained below, these symptoms were considered by Ms. J's treating physicians and found to be related to her vaccination. In addition, Dr. Bodor provided a theory by which Ms. J's body "down regulated her pain by effectively making her arm numb." Bodor First Rep. at 4. His explanation was that Ms. J's brain compensated for the shoulder pain by creating numbness in her arm and face.[5] *Id.* Under Dr. Bodor's theory, Ms. J's symptoms outside of her right shoulder were still directly related and caused by her SIRVA injury.

While I find this theory persuasive to a degree, the pre-existing conditions discussed below suggest that some of her symptoms were not caused by her SIRVA or were in fact unrelated to it. The lack of localization to the shoulder does not, however, defeat Ms. J's entitlement to compensation under a causation-in-fact theory, as Petitioner has provided preponderant proof of the injury to her shoulder *generally*. The pre-existing conditions and diffuse symptoms create additional considerations on the issue of damages (and they will be considered when determining damages), but they do not defeat a finding in Petitioner's favor on the second *Althen* prong.

The fourth Table QAI criterion requires that there be no other condition or abnormality that would explain Petitioner's symptoms. While Dr. Lightfoot offers the theory that Petitioner likely suffers from a chronic, systemic, centrally-mediated syndrome, none of Petitioner's treating providers made, or even offered, that diagnosis. In fact, a majority of Petitioner's treating

[4] Dr. Lightfoot included a chapter on fibromyalgia with his expert report. ECF No 41-2. Notably, the article does not include reduced range of motion as a symptom of fibromyalgia or other centrally-mediated pain syndrome.

[5] Dr. Bodor provided his article, "Numbness in the Hand and Arm Related to Shoulder Dysfunction: A Case Series," as support of his theory that pain in Petitioner's shoulder caused numbness in her lower arm and hand. Ex. 34, Tab C.

physicians linked her broad symptoms to her vaccination or, at a minimum, believed that her pain was neuropathic and would improve with time and treatment.[6]

Thus, on November 21, 2014, Dr. Meredith Snapp, a neurologist, examined Ms. J's complaints of "burning pain that gradually progressed to the right lateral neck, occipital region, scalp, ear, and right side of face. Ex. 7 at 6. Dr. Snapp concluded "neuropathic pain in right arm onset after flu shot." *Id.* at 8. On December 2, 2014, orthopedist Dr. Eric Warren, evaluated Ms. J's right shoulder pain. Ex. 10 at 2-8. Dr. Warren noted that Petitioner's case was complicated, but thought her symptoms "may just be subacromial/subdeltoid bursitis with fibrotic scar tissue, potentially related to injection." *Id.* at 8.

Later, at a follow up visit on December 11, 2014, Dr. Warren concluded that Ms. J's symptoms were "likely cascade effect with likely post-inflammatory reaction from flu vaccine which led to less use of shoulder leading to weakness and therefore changes in biomechanics with resultant impingement." Ex. 10 at 7. On January 13, 2015, Dr. Farrukh Sair examined Ms. J's complaints of aching, burning pain in her head, right arm, and neck, and numbness and change of sensation in her right hand, and determined that her "pain is neuropathic" and "can be improved with time." Ex. 17 at 4. He encouraged her to continue physical therapy. *Id.* On January 20, 2015, Dr. Elizabeth Moore noted Petitioner's challenging situation with "RUE numbness, cold hand, burning and weakness" and concluded Ms. J was suffering from neuralgia. Ex. 18 at 17. The records show that a majority of Ms. J's treating physicians believed she was suffering from an acute injury that would resolve over time, rather than a chronic centrally-mediated syndrome. Dr. Bodor agrees. Bodor Third Rep. at 3.[7]

I thus find that Petitioner has satisfied *Althen* prong two, by providing preponderant evidence that her October 2014 vaccination caused her right shoulder injury.

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[6] At least one doctor, Dr. Erika Gantt, an orthopedist, diagnosed Ms. J with right lateral epicondylitis, and did not believe her symptoms were related to her flu vaccine. Ex. 8 at 10. However, even Dr. Gantt did not suggest a systemic condition.

[7] In addition, Ms. J's affidavit testimony is adamant that there is no explanation for her symptoms other than a vaccine injury from her October 20, 2014 flu shot. See Ex. 30. Ms. J described herself as a "fitness enthusiast who enjoys working out daily," noting that "she rarely went to the doctor" prior to her flu vaccination. Id. at ¶1. She stated that she tried to explain to medical providers that she "was fine one second before that shot was stuck in my arm, and I had not been fine since."¶6. Finally, after extensive treatment, Ms. J's symptoms greatly improved. By March 2015, about five months post-vaccination, Ms. J had improved AROM and an overall decrease in symptoms, and was encouraged to return to her normal lifestyle. Ex. 23 at 67, 97. By September 28, 2015, 11 months post-vaccination, Ms. J had "full R shldr AROM, full cervical AROM, and decreased frequency, intensity, and duration of symptoms." Ex. 21 at 19. By November 2015, she returned to running without significant issues. Ex. 29 at 4. And by December 14, 2015, Petitioner had achieved 85% improvement in symptoms. Ex. 22 at 27. Ms. J's consistent improvement in symptoms in just over a year after her vaccination weighs against a finding of a systemic syndrome and in favor of an acute SIRVA injury.

C. *Petitioner has demonstrated that the timeframe for onset of her symptoms was medically acceptable (Althen prong three).*

The third *Althen* prong requires "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact. *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). For Table SIRVA injuries, the QAI require the onset of pain within 48 hours of vaccination. 42 C.F.R. § 100.3(c)(10)(ii).

In this case, Ms. J received her flu vaccination on October 20, 2014. Ex. 1 at 2. She has stated that "immediately the site was very painful and locally she felt a burning sensation." Ex. 30 at ¶2. Then, "within a few hours," she could no longer "do a pushup or lift her arm overhead without excruciating pain." *Id.* at ¶3. Only nine days after her vaccination, on October 29, 2014, Ms. J presented to employee health complaining of "symptoms from flu vaccine," including pain, heaviness, numbness, and tingling. Ex. 5 at 8.

Admittedly, there is not an abundance of specific evidence establishing an immediate reaction. But again, this is not a Table claim. And there is preponderant evidence to establish the onset of Petitioner's symptoms immediately upon vaccine administration. As this would satisfy the onset requirement in a Table claim, it is also sufficient for Ms. J to satisfy the third *Althen* prong.

II. Petitioner has not provided preponderant evidence that her TMJ and carpal/cubital tunnel syndromes were vaccine related.

In addition to her right shoulder symptoms, Petitioner reports to have suffered from the following (some of which are record-supported): anxiety and depression; nausea; TMJ; and carpal and cubital tunnel syndromes. While I have found that Petitioner has preponderantly established that she suffered a right SIRVA injury after her vaccination, she has not provided preponderant proof that *all* of her complained-of symptoms were caused by her SIRVA.

Admittedly, Ms. J's medical records reveal no history of anxiety, depression, or significant gastrointestinal issues. But several of her treating physicians expressed concern about her mental state while seeking treatment for her SIRVA. The records, as a whole, suggest that Petitioner's injury had an emotional impact, and this facet of her claim can be addressed in the pain and suffering component of damages.

I do not, however, also find that other symptoms or injuries have in this case been linked to the SIRVA. In particular, Ms. J's medical records establish that her TMJ and carpal and cubital tunnel syndromes were either pre-existing or not vaccine related. Although Ms. J

argues that her TMJ was SIRVA-associated because her shoulder pain caused her to clench her jaw, the records reveal that she had TMJ symptoms up to 2-3 years *prior* to her vaccination. Ex. 14 at 2. Indeed, Ms. J also obtained a custom mouth guard for chronic clenching of her jaw and grinding of her teeth in approximately January 2014, several months prior to her vaccination. *Id.*

Further, Ms. J's EMG and nerve conduction study revealed that carpal and cubital tunnel syndromes were present but asymptomatic prior to her vaccination. Ex. 28 at 7-8, 17. In fact, Dr. Warren (who the record establishes theorized that much of Ms. J's symptoms were likely related to her vaccination) also noted that the carpal and cubital tunnel findings were likely pre-existing conditions. Ex. 10 at p 7. It is not clear to what extent Ms. J's lower arm symptoms are attributable to her carpal and cubital tunnel syndromes, rather than reflective of a SIRVA exacerbation. And although Petitioners may allege significant aggravation of pre-existing conditions and receive compensation, Petitioner has not made any such argument here (and I do not otherwise find the record would support such a claim). *See W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352 (Fed. Cir. 2013); *Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135 (2009). It is simply more likely that these conditions, which may also have caused Petitioner pain, were concurrent but distinguishable from the SIRVA injury.

Petitioner should keep the above in mind in attempting to resolve damages in light of this ruling. While she is entitled to damages associated with the SIRVA itself and the pain and suffering it caused her, injuries not related to that SIRVA will not be compensated.

III. Conclusion

Based on the entire record in this case, I find that Petitioner has preponderantly established that her vaccination caused-in-fact her shoulder injuries. Petitioner is therefore entitled to compensation in this case. A separate damages order will be issued.

IT IS SO ORDERED.

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