In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 29, 2025

ASTOU GUEYE,	*	No. 18-1739V
Petitioner,	*	Special Master Young
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Seth D. Bader, Bloomberg, Steinberg & Bader, New York, NY for Petitioner.
Katherine Edwards, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On November 8, 2018, Astou Gueye ("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). Petitioner alleged that she suffered a left shoulder injury related to vaccine administration ("SIRVA") as the result of an influenza ("flu") vaccination administered on November 10, 2015. Pet. at 1, ECF No. 1. Respondent argued against compensation, asserting that Petitioner could not establish a SIRVA Table claim or causation-in-fact claim. Resp't's Rept., ECF No. 22.

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, I find that (1) Petitioner does not satisfy the SIRVA Table criteria, but (2) Petitioner has provided preponderant evidence that the flu vaccine caused her left shoulder injury, which satisfies her causation-in-fact burden of proof under *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

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

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

I. Procedural History[2]

Petitioner filed her petition alleging a SIRVA injury, an affidavit, medical records, and an expert report from pediatric neurologist Marcel Kinsbourne, M.D., on November 8, 2018. Pet.; Pet'r's Exs. 1–5, ECF No. 38. Due to the allegations of the petition, the case was originally assigned to the Special Processing Unit ("SPU") for expedited resolution under Chief Special Master Dorsey. ECF No. 5. Following an Initial Order from the Chief Special Master, Petitioner filed a statement of completion on November 15, 2018. ECF. No. 6; ECF No. 8.

On March 6, 2019, the Chief Special Master held a status conference with the parties and SPU to discuss the completeness of Petitioner's records. Following the status conference, Petitioner filed updated medical records, a supplemental affidavit, and an amended petition on August 13, 2019. ECF No. 20; First Am. Pet., ECF No. 21; Pet'r's Exs. 6–13, ECF No. 39.

Respondent filed his Rule 4(c) report, opposing compensation, on September 30, 2019. Resp't's Rept. With regard to Petitioner's Table claim, he first argued that Petitioner had not established the onset of her symptoms to be within 48 hours of vaccination as required by the Table. *Id.* at 15. Second, Respondent argued that Petitioner's symptoms were not a result of SIRVA, but rather cervical radiculopathy. *Id.* at 16. Regarding Petitioner's causation-in-fact claim, Respondent argued the claim does not meet any of *Althen*'s three prongs and that Dr. Kinsbourne's report was "inadequate to meet her burden." *Id.* at 16–19.

On October 7, 2019, the case was assigned to me. ECF No. 24. Following a Rule 5 conference on December 5, 2019, I issued an order directing Petitioner to file documentation from an experienced orthopedist to confirm Petitioner's diagnosis. Order, dated Dec. 5, 2019, ECF No. 25. On February 24, 2020, Petitioner filed an expert report from physical medicine specialist Naveed Natanzi, D.O., along with a second supplemental affidavit and second amended petition. Second Am. Pet.; ECF No. 26-1; Pet'r's Ex. 14, ECF No. 40. She then filed supporting medical literature on July 1, 2020. Pet'r's Ex. 15, Tabs 1–23, ECF No. 41.

Respondent filed a responsive expert report from orthopedic surgeon Paul J. Cagle, M.D., and supporting medical literature on October 1, 2020. Resp't's Ex. A, ECF No. 28; Resp't's Ex. B, Tabs 1–13, ECF No. 29. From November 20, 2020, to March 31, 2021, the parties submitted several responsive supplemental expert reports from Dr. Natanzi and Dr. Cagle, primarily addressing Petitioner's underlying diagnosis. Resp't's Ex. C, ECF No. 32; Resp't's Ex. D, ECF No. 34; Pet'r's Ex. 16, ECF No. 42; Pet'r's Ex. 17, ECF No. 43; Pet'r's Ex. 18, ECF No. 44.

Petitioner filed a Motion for a Ruling on the Record on January 16, 2024, and Respondent filed his response on March 1, 2024. Pet'r's Mot., ECF No. 48; Resp't's Br., ECF No. 49. Petitioner did not file a reply.

This matter is now ripe for consideration.

[2] On April 16, 2021, I ordered Petitioner to refile all exhibits used in her case so they were properly paginated and identified. Non-PDF Order, docketed Apr. 16, 2021. Petitioner refiled these exhibits as Exhibits 1–18. ECF Nos. 38–45. For ease of citation, all citations to Petitioner's exhibits in this opinion will cite to the refiled exhibits located in the docket at ECF Nos. 38–45.

II. Factual History

A. Pre-Vaccination Medical History

Petitioner's pre-vaccination medical history includes heartburn, benign hypertension, right knee osteoarthritis, dyspepsia,[3] low back pain, and atrial fibrillation. Pet'r's Ex. 2 at 23–25, 33, 40, 45. On January 7, 2015, Petitioner presented to her primary care provider ("PCP"), Dr. Francisco Santoni, with complaints of nerve pain and numbness in her right arm. *Id.* at 23. Dr. Santoni observed Petitioner had bilateral hypothenar[4] atrophy, diagnosed her with carpal tunnel syndrome[5] vs interosseous syndrome,[6] and referred her to neurology. *Id.* at 25. At a follow-up appointment on August 19, 2015, Dr. Santoni noted Petitioner had missed her neurology appointment. *Id.* at 41. Dr. Santoni also diagnosed Petitioner with a chronic thyroid nodule and referred her to endocrinology. *Id.* at 40.

B. Vaccination

On November 10, 2015, Petitioner presented to Dr. Santoni with complaints of "stabbing" in the right side of her neck. Pet'r's Ex. 2 at 46–48. She reported no musculoskeletal pains, and Dr. Santoni noted no cyanosis,[7] clubbing,[8] or edema[9] upon physical examination. *Id.* at 46. Dr. Santoni also noted no facial or limb numbness was present. *Id.* Petitioner was diagnosed with essential (primary) hypertension and received a flu vaccine in her left shoulder. *Id.* at 47–48.

C. Post-Vaccination Medical History

Petitioner presented to endocrinologist Joyce Alase two days later, on November 12, 2015, for treatment regarding her dyspepsia. Pet'r's Ex. 6 at 502. The day after, on November 13, 2015, Petitioner presented to ophthalmologist Joaquin De Rojas for an appointment regarding potential hypertensive retinopathy in her right eye. *Id.* at 543. Neither visit reported a physical examination or any complaints by Petitioner of left shoulder pain.

On December 30, 2015, Petitioner presented to the emergency department ("ED") at Harlem Hospital Center ("HHC") with complaints of left shoulder pain. Pet'r's Ex. 7 at 297. Petitioner's chart recorded two different onset dates for her symptoms: entries from triage nurses

---

[3] Dyspepsia is the "impairment of the power or function of digestion." *Dorland's* at 573.
[4] The hypothenar is "the fleshy eminence on the palm along the ulnar margin." *Dorland's* at 895.
[5] 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." *Dorland's* at 1794.
[6] Anterior interosseous syndrome is "a complex of symptoms caused by a lesion of the anterior interosseous nerve, resulting usually from fracture or laceration but sometimes from an entrapment neuropathy; symptoms include pain in the proximal forearm and weakness of the muscles innervated by the nerve." *Dorland's* at 1790–91.
[7] Cyanosis is "a bluish discoloration, especially of the skin and mucous membranes, due to excessive concentration of deoxyhemoglobin in the blood." *Dorland's* at 447.
[8] Clubbing is "a digital deformity produced by proliferation of the soft tissues about the terminal phalanges of the fingers or toes, with no constant osseus changes." *Dorland's* at 369–70.
[9] Edema is "the presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body, usually referring to subcutaneous tissues." *Dorland's* at 587.

at 11:34am and 11:49am noted Petitioner's left shoulder pain began one month ago, while the entry from Nurse Practitioner ("NP") Mavis Thomas at 1:51pm noted a reported onset beginning two months ago. *Id.* at 298–99, 302. Petitioner reported she had been taking Tylenol for the pain, but it had not gone away. *Id.* at 302. NP Thomas reported Petitioner described the pain "in the triceps muscles" and observed "no numbness or tingling in the fingers." *Id.* at 302. NP Thomas further noted "[n]o pain to elbow or shoulder joints" and discharged Petitioner with a prescription for acetaminophen and methocarbamol. *Id.* at 303–04.

Petitioner presented to Dr. Santoni with complaints of left shoulder pain on January 5, 2016. Pet'r's Ex. 2 at 51. Dr. Santoni observed Petitioner had pain in her left shoulder with abduction and motion, but negative Neer, Hawkins, and Empty Bucket tests. *Id*. at 51–52. He further reported Petitioner had preserved range of motion in her shoulder and no paracervical tenderness. *Id.* Dr. Santoni referred Petitioner to orthopedics and cancelled her re-referral to endocrinology because her neck pain was "eradicated." *Id.* at 53. Petitioner saw Dr. Santoni again on January 14, 2016, and again reported left shoulder pain. *Id.* at 56. At this visit Dr. Santoni noted no cervicalgia. *Id.*

Per Dr. Santoni's referral, Petitioner presented to physician's assistant ("PA") Mayra Sanchez on February 9, 2016, for her left shoulder pain. Pet'r's Ex. 7 at 119. Petitioner reported her pain was "getting worse since [November] 2015," and could not recall any specific injury that may have caused the pain. *Id.* at 120. PA Sanchez noted Petitioner had "active [range of motion] to 110 degrees and then pain start[ed] to radiate from shoulder into elbow." *Id.* Petitioner denied any numbness and stated she had weakness in her shoulder if she tried to "hold an object up for mor[e] than a few minutes." *Id.* An X-ray of Petitioner's shoulder revealed "mild acromioclavicular joint arthrosis with mild widening of the AC joint suggestive of prior injury." *Id.* PA Sanchez diagnosed Petitioner with AC joint arthrosis and left shoulder tendinosis and referred her to physical therapy. *Id.*

On March 22, 2016, Petitioner presented to neurologist Edwin Kwakugah for lower back pain. Pet'r's Ex. 6 at 478. Petitioner reported "left shoulder pain which started about [five] months ago. Pain started after she took the flu shot. It started at the site of injection and the[n] gradually involved the shoulder joint and the surrounding muscles." *Id.* Petitioner further reported the pain was aggravated by movement and denied weakness or numbness. *Id.* at 479. She further reported swelling in her left wrist for five days that was "associated with pain," but it had improved by the time of the visit. *Id.* Dr. Kwakugah noted there was "no acute neurologic involvement" to Petitioner's symptoms and discharged her to follow up with orthopedics. *Id.* at 481. Dr. Kwakugah's attending physician, Anne Kleiman, reviewed Petitioner's examination and noted her symptoms "seem vaccine related and without neurologic dysfunction." *Id.* at 482.

Petitioner presented to Dr. Santoni again on March 25, 2016, and reported no pain of any kind. Pet'r's Ex. 2 at 59. Dr. Santoni characterized Petitioner as asymptomatic and in "good spirits," and noted that she reported: "I feel well." *Id.* Petitioner saw Dr. Santoni again on April 9, 2016, April 21, 2016, and June 23, 2016, for routine blood pressure checks regarding her hypertension. *Id.* at 63, 69, 73. There was no physical examination or report of pain at any of these visits.

On April 15, 2016, Petitioner followed-up with orthopedist Jacquelin Emmanuel for her left shoulder pain. Pet'r's Ex. 4 at 60. Dr. Emmanuel observed that Petitioner still displayed tenderness "on extreme of range of motion of the left shoulder" and re-referred her to physical therapy. *Id.* Petitioner attended her first physical therapy session on May 5, 2016. Pet'r's Ex. 8 at 18. The provider noted "[left] arm swelling and shoulder pain which [Petitioner] state[d] came on from insidious onset in November" but that it was "[d]ifficult to gather full information for [Petitioner due to] language barrier."[10] *Id.* The report further noted that Petitioner related her pain to the flu shot she received. *Id.* On examination the provider noted Petitioner's shoulder presented with limited range of motion, and that Petitioner had painless range of motion within normal limits of her cervical spine and left elbow. *Id.* Left shoulder pain was continuously reported with inconsistent improvements at nine physical therapy sessions between May 19, 2016, and July 5, 2016. *Id.* at 2–17.

On July 16, 2016, Petitioner underwent magnetic resonance imaging ("MRI") of her left shoulder at the order of Dr. Santoni. Pet'r's Ex. 2 at 127. The MRI revealed mild joint effusions, bicipital tenosynovitis,[11] subcoracoid bursitis,[12] partial rotator cuff tear vs tendinitis, and questionable mild soft tissue fullness about the acromioclavicular joint with mild impingement.[13] *Id.* at 127–28.

Petitioner presented to Dr. Arthur Dove to establish care with a new PCP for her hypertension on August 1, 2016. Pet'r's Ex. 9 at 10. During the visit, Petitioner reported "no pain in [her] left shoulder" and "no severe aches and pains in [her] shoulders." *Id.* Petitioner underwent an electromyogram ("EMG") the next day, which was normal. *Id.* at 67. Petitioner followed up with Dr. Dove on August 29, 2016, and at this appointment she complained of pain in her left shoulder. *Id.* at 8. Dr. Dove noted there was "[n]o limitation in [range of motion] in the left arm. Arm just hurts a lot." *Id.* Dr. Dove diagnosed Petitioner with "bursitis of left shoulder" and prescribed her anti-inflammatory medication. *Id.* at 9. Petitioner followed up with Dr. Dove again on September 7, 2016, and continued to complain of pain in her left shoulder. *Id.* at 5. Dr. Dove noted stiffness in her left arm and limited range of motion in her left shoulder. *Id.*

Petitioner returned to Dr. Santoni on September 29, 2016, and complained of pain in her left arm. Pet'r's Ex. 2 at 76. Dr. Santoni noted Petitioner presented with "left upper arm pain" in her humerus and wrist. *Id.* On examination Dr. Santoni observed Petitioner had "allodynia[14] [in the] left humerus without rubor/calor/tumor" and a "homogeneous boggy prominence" in her left dorsal wrist. *Id.* at 77.

---

[10] Petitioner is from Senegal and her native language is Wolof. Formal and informal interpreter services were frequently used during her medical visits. It is noted on several occasions in the medical record that the language barrier created problems with communication or made Petitioner "an unreliable historian due to language barrier." Pet'r's Ex. 13 at 133.

[11] Bicipital tenosynovitis is "inflammation of a tendon sheath" in the biceps muscle. *Dorland's* at 1853.

[12] Subcoracoid bursitis is the "inflammation of a bursa, occasionally accompanied by a calcific deposit in the underlying tendon" that is "inferior to the coracoid process." *Dorland's* at 260, 1760.

[13] Impingement is the "advancement of one thing out of its expected place to where it may collide with something else." *Dorland's* at 911.

[14] Allodynia is "pain resulting from a non-noxious stimulus to normal skin." *Dorland's* at 51.

On October 8, 2016, Petitioner followed up with Dr. Dove and complained of pain and swelling in her left arm which she had "for about [one] year." Pet'r's Ex. 9 at 3. Petitioner reported to Dr. Dove that she had pain in both her left arm and left shoulder on examination. *Id.* He again noted bursitis of her left shoulder as the likely diagnosis and scheduled a follow-up for four weeks. *Id.* at 4.[15]

Petitioner followed up with HHC Orthopedics on November 1, 2016, and was seen by Dr. Adam Bernatsky. Pet'r's Ex. 4 at 57. Dr. Bernatsky noted that "[p]reviously [Petitioner] stated that she had shoulder pain which radiated to her arm[,] but now she complains of pain midway around her humerus. [Petitioner] state[d] that it radiates to her elbow and says there is swelling around her entire arm." *Id.* Petitioner reported again that the pain started approximately one year ago and "that it may have happened after a flu shot, as it was around the same time." *Id.* Petitioner had "active [range of motion] to 110 degrees and then pain start to radiate from shoulder into elbow." *Id.* at 58. Petitioner was instructed to follow-up in two weeks to have a consult with a specialist. *Id.*

Petitioner followed up with HHC Orthopedics again on November 22, 2016, and was seen by Dr. Reginald Manning. Pet'r's Ex. 4 at 55. She again reported a symptom onset of November 2015 after receiving a flu vaccine. *Id.* Petitioner also noted that her physical therapy sessions had not helped. *Id.* After reviewing Petitioner's prior MRI, Dr. Manning diagnosed her with "impingement syndrome of the left shoulder.[16]" Pet'r's Ex. 7 at 151. He discussed surgery with Petitioner via an interpreter and scheduled Petitioner to undergo a left subacromial decompression for January 13, 2017, pending clearance from her insurance and PCP. *Id.* at 54.

Petitioner returned to HHC on January 6, 2017, to discuss her medical clearance with Dr. Manning. Pet'r's Ex. 4 at 48. She brought her brother to use as a translator to better explain her symptoms and the surgery because Petitioner "want[ed] to know exactly what is the surgery about." *Id.* at 49. Dr. Manning noted Petitioner's complaints as "left upper mid-arm pain, she state[d] it started after she received a flu shot." *Id.* He further noted "her pain [was] in the muscle, and increase[d] when she lift[ed] her arm." *Id.* On examination Dr. Manning observed Petitioner had passive and active range of motion with no pain, and that "there [was] pain on biceps muscle to palpitation." *Id.* Dr. Manning cancelled the surgery and ordered X-rays of Petitioner's humerus "for further investigation of the arm pain." *Id.*

On January 13, 2017, Petitioner underwent an X-ray of her left humerus, which showed normal findings. Pet'r's Ex. 4 at 46. At this visit Petitioner reported prior swelling in her left arm that had since decreased and persistent pain that "sometimes goes to her forearm." *Id.* Petitioner denied any neck pain and had full range of motion in her neck with a normal cervical examinatio. *Id.* An MRI of her left arm was ordered to further investigate Petitioner's pain. *Id.* The MRI revealed mild degenerative change of the left glenohumeral joint but was "[o]therwise unremarkable." Pet'r's Ex. 7 at 260.

[15] No record of this follow-up was filed.

[16] Impingement syndrome is "a type of overuse injury with progressive pathologic changes resulting from mechanical impingement by the acromion, coracoacromial ligament, coracoid process, or acromioclavicular joint against the rotator cuff; changes may include reversible edema and hemorrhage, fibrosis, tendinitis, pain, bone spur formation, and tendon rupture." *Dorland's* at 1804.

On January 21, 2017, Petitioner presented to the HHC ED with complaints of "pain in [her] left upper arm and fever[17] for weeks." Pet'r's Ex. 4 at 43. Petitioner again associated her pain with the flu vaccine she received in her left shoulder. *Id.* The triage nurse assessed Petitioner as afebrile with no redness or warmth to left deltoid. *Id.* at 44. She was triaged to "Urgent Care/Fast Track."[18] *Id.*

Petitioner returned to HHC Orthopedics on February 14, 2017, with further complaints of "left arm pain for more than one year after she received an injection on her arm." Pet'r's Ex. 4 at 37. Petitioner refused further physical therapy because it "helped the swelling, but did nothing for the pain." *Id.* On examination, the PA noted mild swelling in the left arm and "palpitation of the arm [was] painful." *Id.* Petitioner agreed to surgery for a subacromial decompression and/or rotator cuff repair of her left shoulder and would follow up with Dr. Santoni and Dr. Manning for medical clearance and scheduling. *Id.* at 38. Petitioner followed up with HHC Orthopedics on February 28, 2017. *Id.* at 30. The PA noted Petitioner was suffering from "chronic left shoulder pain with MRI documented joint derangement" and presented with pain on palpitation of the deltoid, and scheduled her for surgery on March 10, 2017, pending financial clearance. *Id.* Petitioner initially arrived for her scheduled surgery; however, she was feeling unwell, and the procedure was postponed until her illness resolved. Pet'r's Ex. 7 at 179. Petitioner returned on March 28, 2017, where Dr. Manning diagnosed her with left shoulder impingement and rescheduled her surgery for April 14, 2017. *Id.* at 177.

On April 14, 2017, Petitioner arrived for her scheduled surgery; however, Petitioner "complained of pain to a different area on the left shoulder."[19] Pet'r's Ex. 4 at 15. Dr. Manning noted that Petitioner's shoulder pain was "no longer subacromial in location" and reported a "subcutaneous soft tissue mass over the lateral deltoid that [was] somewhat tender." Pet'r's Ex. 7 at 416. Dr. Manning further reported Petitioner was negative for impingement sign and Hawkin's sign. *Id.* His noted impression of Petitioner's symptoms was "possible lipoma left shoulder . . . no findings consistent with subacromial impingement today." *Id.* Dr. Manning decided to cancel Petitioner's surgery as "surgery on ACJ wouldn't be beneficial to area where pain and nodule are at this time." *Id.* at 15–16. Dr. Manning ordered a new MRI of Petitioner's shoulder the same day, which revealed:

> mild tendinosis of the supraspinatus and subscapularis tendons . . . small partial tear of the distal infraspinatus tendon with a sentinel cyst as described above distal tear . . . mild thickening of the axillary recess which could suggest the diagnosis of

[17] Petitioner's oral temperature at the ED was recorded as 98.4 °F. She recorded temperatures of 99.2 °F and 97.0 °F at her orthopedic visits on January 6, 2017, and January 13, 2017, respectively. Pet'r's Ex. 4 at 43.

[18] The Fast Track Center was established to service patients who presents with non-urgent complaints. Examples of conditions suitable for Fast Track Area are simple headaches, sore throats, ear infections, strains or sprains, and muscle aches. www.nyc.gov/html/hhc/harlem/downloads/pdf/newsletter-ed-fast-track.pdf

[19] Petitioner disputes this accounting of the medical record in her affidavit, stating the language barrier caused a miscommunication between her and Dr. Manning and that the pain had not changed locations. Pet'r's Supp. Aff. at ¶ 25.

> adhesive capsulitis[20] . . . mild degenerative change at the inferior glenoid with a small subchondral cyst and mild articular cartilage thinning . . . [and] mild AC joint arthrosis.

Id. at 18. Petitioner was instructed to follow up with Dr. Manning. *Id.* at 16.

Petitioner returned to Dr. Manning on May 16, 2017. Pet'r's Ex. 4 at 12. In his report he noted Petitioner had "[p]ain with [range of motion] to local area of upper arm near deltoid" and opined the pain was from a "possible soft tissue mass most likely lipoma. Due to local tenderness possible axillary nerve involvement from injection." *Id.* His ultimate impression was left shoulder impingement. *Id.*

On July 28, 2017, Petitioner presented to Dr. Santoni with complaints of "persistent pain left upper extremity." Pet'r's Ex. 6 at 381. Dr. Santoni's notes indicated "[s]he ma[de] it clear the problem is NOT the shoulder but between the shoulder and elbow. She points to humerus soft tissue." *Id.*[21] Dr. Santoni further noted that Petitioner was "able to abduct and [externally rotate her] shoulder without displaying any signs of pain at the subjective 'hot spot' – the humerus soft tissue." *Id.* at 386. Dr. Santoni continued that "[n]euro[logy] does not feel it is a brachial plexopathy or [thoracic outlet syndrome]." *Id.*[22]

Petitioner presented to neurologist Mohammed Sheikh on August 3, 2017, to follow up for her left shoulder pain. Pet'r's Ex. 6 at 270. Dr. Sheikh noted Petitioner's range of motion had "improved significantly" with rehab, diagnosed her with subacromial bursitis, and ordered an MRI of the left shoulder.[23] *Id.* at 270–71.

On August 22, 2017, Petitioner returned to Dr. Santoni and again complained of left shoulder pain. Pet'r's Ex. 6 at 389. Dr. Santoni noted Petitioner's pain was in the "left humerus[,] 'in the bone'" and that her left arm was swollen. *Id.*

On referral from Dr. Dove, Petitioner presented to neurologist Casilda Balmaceda on October 5, 2017. Pet'r's Ex. 10 at 8. Petitioner reported that her pain began following the November 2015 flu shot and described the pain as a "bad pain, deep." *Id.* Dr. Balmaceda noted

---

[20] Adhesive capsulitis is "adhesive inflammation between the joint capsule and the peripheral articular cartilage of the shoulder with obliteration of the subdeltoid bursa, characterized by shoulder pain of gradual onset, with increasing pain, stiffness, and limitation of motion." *Dorland's* at 281.

[21] It should be noted that no interpreter was available through the Cyracom service used by Dr. Santoni. However, Dr. Santoni noted in his report that Petitioner consented to proceed without an interpreter. Pet'r's Ex. 6 at 384.

[22] Dr. Santoni also noted Petitioner presented with "abnormal" psychiatric conditions and appeared "teary-eyed" at this appointment. Pet'r's Ex. 6 at 383. Several other medical records associate Petitioner's psychiatric condition with her frustration that treatment is not helping her symptoms, and her doctors suspect she suffers from major depressive disorder. Pet'r's Ex. 13 at 61, 270, 273, 279, 303, 309. Other medical records also question whether there is a psychological component to her chronic pain. *Id.* at 170.

[23] The only MRI mentioned in the record with a close temporal association to this appointment was an MRI of the left humerus conducted on August 14, 2017, which was unremarkable. No records of the MRI were filed and it is only mentioned briefly in a separate record for an orthopedic appointment on October 24, 2017. Pet'r's Ex. 6 at 289.

that Petitioner had pain in her deltoid since her flu shot, and stated "the pain [was] not a burning nor neuropathic pain." *Id.* at 9. Dr. Balmaceda further noted that "[t]here [was] limitation [in] the shoulder but this [was] not a primary shoulder pain" and ordered a computed tomography ("CT") scan of Petitioner's left upper arm. *Id.* The CT revealed "mild degenerative glenohumeral joint disease" with "subchondral cystic change in the inferior glenoid and marginal osteophytosis, as well as subtle joint space narrowing." Pet'r's Ex. 4 at 9.

Petitioner presented to Dr. David Ehrlich at HHC Orthopedics with continued complaints of left shoulder pain on October 24, 2017. Pet'r's Ex. 6 at 288. Petitioner again stated the onset of her symptoms was immediately following her November 2015 flu shot. *Id.* Dr. Ehrlich noted Petitioner had full range of motion in her left elbow and "tenderness to palpation of lateral arm" with no edema, palpable mass, or ecchymosis[24] detected. *Id.* at 289. Because of an unremarkable MRI to Petitioner's left humerus two months prior, Dr. Ehrlich decided surgical intervention was not necessary at this time. *Id.* Petitioner refused further referrals to pain management or to see Dr. Manning again later that month. *Id.* at 289–90.

On November 11, 2017, Petitioner presented to the HHC ED with complaints of pain in her right arm and right breast. Pet'r's Ex. 7 at 374. Petitioner reported that "the left arm was like this [and] then it stopped" and asked whether she needed surgery. *Id.* at 375. Petitioner reported the onset date of her right arm pain to be October 17, 2017, the same day she received a flu vaccine in her right shoulder.[25] *Id.*; Pet'r's Ex. 6 at 7. PA Max Ariel Schwartzman noted Petitioner's pain to be in the right deltoid area, though it did not involve the shoulder specifically. Pet'r's Ex. 7 at 378. He also noted a history of "left shoulder adhesive capsulitis, . . . left subacromial bursitis, . . . [and] inflammatory rheumatological condition." *Id.* PA Schwartzman opined about the possibility of rheumatoid arthritis or other "still to be classified inflammatory arthritis" due to Petitioner's medical history and scheduled an evaluation in the rheumatology clinic. *Id.* at 378–79.

Petitioner returned to Dr. Balmaceda with further complaints of left shoulder pain on December 6, 2017. Pet'r's Ex. 10 at 10. Petitioner reported the pain "feels like a [muscle] pain, [that] feels like a tightness." *Id.* Dr. Balmaceda's primary diagnosis was "[o]ther polyosteoarthritis" and noted "there [was] limitation [in] the shoulder but this [was] not a primary shoulder pain." *Id.* at 11. Dr. Balmaceda discussed the findings of Petitioners previous CT and ordered an MRI of both the left shoulder and left humerus for further investigation of the pain. *Id.* Petitioner completed the imaging on January 15, 2018. Pet'r's Ex. 4 at 7–8. The MRI of her left humerus was unremarkable. *Id.* at 7. The MRI of her left shoulder revealed "[s]upraspinatus, infraspinatus and subscapularis insertional tendinosis" as well as a "[s]mall glenohumeral effusion." *Id.* at 8.

On January 25, 2018, Petitioner presented to cardiologist Harseerat Rataul with complaints of bilateral shoulder pain. Pet'r's Ex. 6 at 256. Petitioner reported her "[r]ight shoulder started hurting in 2017 and left shoulder since 2015 after getting flu shot." *Id.* Dr. Rataul noted the pain

[24] Ecchymosis is "a small hemorrhagic spot, larger than a petechia, in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch." *Dorland's* at 582.

[25] Although Petitioner did begin to experience pain in her right arm following this vaccination, Petitioner is not claiming injuries from her right shoulder in the Program. Petitioner claim is solely limited to her left shoulder pain.

was "probably not primary neurological in origin. Most likely recurrent/chronic bursitis" and referred her to the pain clinic. *Id.* at 258.

Petitioner returned to Dr. Balmaceda on February 13, 2018, with complaints of pain in her left shoulder and right side of her neck. Pet'r's Ex. 10 at 13. Dr. Balmaceda noted the new right neck pain "may be related to the whole spasm" but continued to opine the pain was not neuropathic in nature. *Id.*

On March 20, 2018, Petitioner presented to Dr. Jeremy Mudd at New York Presbyterian Hospital ("NYPH"), who diagnosed her with chronic arm pain and cervical radiculopathy.[26] Pet'r's Ex. 13 at 75. At a return visit on March 22, 2018, Dr. Mudd further noted "subacromial bursitis of left shoulder joint" in Petitioner's acute diagnosis after speaking with Petitioner's niece for further clarification.[27] *Id.* at 77–80. Petitioner was referred to the shoulder clinic for further evaluation. *Id.* at 80.

Petitioner returned to NYPH on April 3, 2018, and presented to Dr. Christina Eckhardt with complaints of bilateral upper arm pain for two years, with worse pain on the left side. Pet'r's Ex. 13 at 86. The note from Dr. Eckhardt noted four ED visits from September 6, 2017, to January 11, 2018, where Petitioner complained of pain in one or both of her shoulders. *Id.* Dr. Eckhardt noted Petitioner had full active range of motion in the right shoulder and the left was limited to 90 degrees. *Id.* at 88. X-rays of both the left and right humerus were unremarkable. *Id.* at 87. Dr. Eckhardt's differential diagnosis was "musculoskeletal etiology like tendinosis or degenerative joint disease versus inflammatory etiology like [polymyalgia rheumatica][28] or myositis."[29] *Id.* at 89. Dr. Eckhardt prescribed Petitioner a two-week course of prednisone and advised to wait until after Petitioner's upcoming orthopedic appointment for further treatment. *Id.*

On April 10, 2018, Petitioner presented to Dr. Matthew Grosso at NYPH Orthopedics with complaints of bilateral shoulder pain. Pet'r's Ex. 11 at 8. Petitioner also reported "neck, back, and leg pain," as well as "occasional tingling down to her hands." *Id.* X-rays revealed "small rotator cuff excrescences" and a "subacromial spur" in both shoulders. Pet'r's Ex. 13 at 97. Dr. Grosso's assessment was "radiating bilateral arm pain. No concern for shoulder or [upper extremity] pathology." Pet'r's Ex. 11 at 8. Petitioner was referred to the spinal clinic to "rule out cervical spine pathology." *Id.*

The next day, Petitioner returned to Dr. Eckhardt to follow up on her bilateral shoulder pain and requested expedited appointments with the spine and rehab clinics. Pet'r's Ex. 13 at 96.

---

[26] Cervical radiculopathy is "radiculopathy of cervical nerve roots, often with neck or shoulder pain." *Dorland's* at 1547; Radiculopathy is "disease of the nerve roots, such as from inflammation or impingement by a tumor or a bony spur." *Id.*

[27] It appears Dr. Mudd was unable to gather all the relevant information from Petitioner due to a language barrier at the March 20, 2018 visit, as a note from the March 22, 2018 visit stated "[Petitioner] requested RN to speak to niece on the phone because she was unable to give her the information provided to her on the last encounter." Pet'r's Ex. 13 at 80.

[28] Polymyalgia rheumatica is "a syndrome in the elderly characterized by proximal joint and muscle pain and a high erythrocyte sedimentation rate." *Dorland's* at 1468.

[29] Myositis is the "inflammation of a voluntary muscle." *Dorland's* at 1208.

Dr. Eckhardt noted her differential diagnosis to be bilateral degenerative joint disease versus rotator cuff tendinosis based on prior imaging. *Id.* at 99. Dr. Eckhardt further noted a lower chance of myositis due to the lack of response from Petitioner's prednisone trial. *Id.* She referred Petitioner to pain management and made a note to expedite Petitioner's future appointments. *Id.*

On May 11, 2018, Petitioner presented to Dr. Asad Siddiqi at the Columbia University Medical Center ("CUMC") on referral from Dr. Balmaceda. Pet'r's Ex. 12 at 30. Petitioner reported her "right shoulder [had] been painful since October 2017. Left shoulder ha[d] been painful since 2015" and described the pain as "sharp and shooting." *Id.* Dr. Siddiqi noted Petitioner's cervical spine was normally aligned and had "moderate tenderness to palpation over paraspinals and traps" with normal range of motion and pain on terminal range. *Id.* at 31. He also reported a positive Spurling test. *Id.* When examining Petitioner's shoulders Dr. Siddiqi observed "[n]otable tenderness about the bilateral shoulder, left worse than right," and normal range of motion bilaterally. *Id.* He also noted negative supraspinatus isolation, Speeds, O'brien's, Crossarm adduction, Neer, Hawkins, and apprehension tests. *Id.* His ultimate impression was "[c]ervical stenosis[30] and bilateral radiculitis"[31] and ordered an MRI of the cervical spine. *Id.*

On May 29, 2018, Petitioner returned to Dr. Balmaceda following an earlier ED visit for left-sided neck pain. Pet'r's Ex. 10 at 14. Dr. Balmaceda noted Petitioner's MRI revealed degenerative changes in the cervical spine. *Id*.

Petitioner returned to NYPH on June 8, 2018, and was seen by Kenny Chantasi, D.O., with complaints of bilateral shoulder pain and mild neck pain. Pet'r's Ex. 13 at 109. Petitioner again reported the onset of her left shoulder pain following a vaccine. *Id.* Dr. Chantasi reported "[s]he does feel a pain radiating from the neck to the lateral shoulder to the elbow at times." *Id.* Dr. Chantasi reviewed Petitioner's MRI, which revealed "multilevel [degenerative disc disease], posterior longitudinal ligament ossification, severe canal stenosis at C5-6[,] . . . [and] moderate canal stenosis at C6-7 with mild [bilateral] neural foraminal narrowing." *Id.* An ultrasound of Petitioner's shoulders "showed normal tendons and some bursitis." *Id.* On examination Dr. Chantasi observed limited abduction in both upper extremities and "full [range of motion] without pain." *Id.* at 110. He also noted a positive Hawking's test on the left shoulder with "[m]ultiple impingement signs on the left." *Id.* Petitioner's Spurling's test was negative bilaterally. *Id.* Dr. Chantasi specifically noted "[m]ost of her pain [was] more [musculoskeletal] than radicular and not following dermatomal patter. Most [consistent with] impingement long lasting and radiating pain." *Id.* Dr. Chantasi diagnosed Petitioner with left shoulder impingement syndrome and gave her a subacromial bursa injection in her left shoulder, which provided "significant pain relief" afterwards. *Id.* at 110–11.

Petitioner returned to NYPH on July 24, 2018, and was seen by orthopedic surgeon Rami Alrabaa. Pet'r's Ex. 11 at 16. She complained of bilateral neck and shoulder pain, and reported her shoulder injection had provided no relief. *Id.* Dr. Alrabaa noted that given the bulging at C5-6 and C6-7, epidural injections at those locations were a possibility to relieve the pain. *Id.* at 17. He further noted surgery likely would not be beneficial due to the chronic nature of Petitioner's

[30] Stenosis is "an abnormal narrowing of a duct or canal." *Dorland's* at 1740.
[31] Radiculitis is the "inflammation of the root of a spinal nerve, especially of that portion of the root that lies between the spinal cord and the intervertebral canal." *Dorland's* at 1547.

conditions. *Id.* at 17; Pet'r's Ex. 13 at 142. That same day Petitioner presented to Dr. Prakriti Gaba to establish a new PCP, and complained of sharp and throbbing pain in her upper extremities. Pet'r's Ex. 13 at 142. Dr. Gaba noted "she ha[d] previously had a shoulder injection in shoulder joint without significant improvement." *Id.* Petitioner also refused vaccines at this appointment. *Id.* at 144.

On August 24, 2018, Petitioner returned to Dr. Chantasi to follow up with her shoulder pain. Pet'r's Ex. 13 at 163. Petitioner reported her pain was primary "in the lateral deltoid regions" and again attributed the onset to her prior vaccination. *Id.* Dr. Chantasi noted that the previous shoulder injection "did not help" and she had attended physical therapy about 10 times with no improvement in her left shoulder. *Id.* He observed that"[i]f anything, it is worse with [l]eft shoulder impingement swelling and tenderness." *Id.* He noted Petitioner was previously scheduled for surgery at HHC, "but for some reason, suddenly stopped it. Unclear about cessation of the surgery for left shoulder." *Id.* Petitioner again presented with a positive Hawking's test on her left shoulder. *Id.* at 164. Dr. Chantasi referred Petitioner to orthopedics for further treatment. *Id.*

Petitioner returned to Dr. Balmaceda on September 10, 2018 with complaints of bilateral shoulder pain. Pet'r's Ex. 10 at 16. Petitioner reported she had recently received an injection into her right deltoid and that had started her right shoulder pain. *Id.* Petitioner declined epidural injections. *Id.* On examination Dr. Balmaceda noted "severe left deltoid pain, left shoulder pain and tenderness," and swelling of the left deltoid and left shoulder. *Id.* at 17. Dr. Balmaceda further noted that it was "[unclear why] she got the [vaccine in] the right arm since the left arm developed pain after the injections." *Id.*

On September 18, 2018, Petitioner returned to NYPH Orthopedics and was seen by Dr. Ajay Padaki. Pet'r's Ex. 11 at 9. On examination Dr. Padaki reported Petitioner had positive Hawkins and O'Brien's signs. *Id.* Dr. Padaki noted Petitioner's examination was "concerning for [rotator cuff] tear [and] bicipital tendinosis that [] failed extensive [nonoperational treatment]." *Id.* Dr. Padaki ordered an MRI of Petitioner's left shoulder and instructed her to return following the imaging. *Id.* Later that same day, Petitioner presented to the NYPH walk in clinic ("WIC") with complaints of a headache she thought was related to her shoulder pain. Pet'r's Ex. 13 at 170. The attending physician noted the pain was "characteristic of tension vs related from bilateral shoulder pain radiation (pain seems to be originating from trapezius muscle)." *Id.*

Petitioner returned to Dr. Padaki to follow up on her MRI results on October 9, 2018. Pet'r's Ex. 11 at 10. The MRI revealed supra tendinosis without a tear in her left shoulder. *Id.* Petitioner refused further injections or physical therapy and was referred to pain management. *Id.* Petitioner returned to orthopedics on October 23, 2018, and presented with neck pain.[32] Pet'r's Ex. 13 at 212. Orthopedics diagnosed her with cervical stenosis and referred her to pain management for an epidural steroid injection. *Id.*

On November 29, 2018, Petitioner presented to Dr. Mudd and reported pain in her left shoulder for three years and pain in her right shoulder for one year. Pet'r's Ex. 13 at 212. She reported that the "pain in both shoulders started after 'bad injections' in her shoulders at Harlem

[32] No record of this visit was filed in this case. This visit in mentioned in an ambulatory care visit, dated November 29, 2018. Pet'r's Ex. 13 at 212.

Hospital" and that "subacromial corticosteroid injections in both shoulders" provided little relief. *Id.* On examination Dr. Mudd observed severe tenderness "on palpation of posterior and lateral deltoid bilaterally," and observed Petitioner had full range of motion but was limited by pain. *Id* at 214. He also noted cervical vertebral tenderness C4-T4. *Id.* He further noted Petitioner's prior MRI showed "cervical stenosis as likely cause of bilateral neuropathic [upper extremity] pain. *Id.* at 218.

Petitioner received the cervical epidural steroid injection at CUMC on December 7, 2018. Pet'r's Ex. 12 at 25. Petitioner then returned to Dr. Balmaceda on December 19, 2018, and reported tightness in the left side of her neck. Pet'r's Ex. 10 at 18. Petitioner further reported that the "cervical epidurals helped a bit." *Id.* Petitioner returned to CUMC on January 14, 2019, to follow up after her cervical epidural. Pet'r's Ex. 12 at 21. Petitioner reported her pain had resolved following the injection, but now presented with left trapezius/muscular aching sensation. *Id.* Petitioner reported that "[t]he pain [was] typically with lifting heavy objects and [was] not constant." *Id.* On examination, Petitioner had full range of motion in both shoulders and "left shoulder tenderness on palpation of trapezius muscle." *Id.* at 22. Petitioner was referred to physical therapy for cervical radiculopathy and left shoulder pain. *Id.* at 23. On February 8, 2019, Petitioner returned to NYPH and presented to Dr. Mudd with complaints of a cough and bilateral shoulder pain. Pet'r's Ex. 13 at 245. Petitioner reported that the "[p]ain in her shoulders [] improved briefly with steroid injection, [but] returned in two weeks." *Id.*

On February 25, 2019, Petitioner returned to CUMC to follow up on complaints of neck and bilateral shoulder pain. Pet'r's Ex. 12 at 13. Petitioner underwent an MRI of her left shoulder, which revealed "[m]ild rotator cuff tendinosis without rotator cuff tear . . . [s]ubacromial/subdeltoid bursitis . . . [and m]ild glenohumeral osteoarthrosis." *Id.* at 12. Petitioner was then seen by Dr. Leena Mathew, who noted Petitioner's pain had "substantially improved since [the] cervical [injection] but with continued left shoulder arthralgia most likely secondary to subacromial bursitis and rotator cuff tendinosis and osteoarthrosis." *Id.* at 13. Dr. Mathew discussed another injection of Petitioner's left shoulder, which was agreed to and administered the same day. *Id.*

On March 29, 2019, Petitioner returned to NYPH and presented to Dr. Mudd with further complaints of bilateral shoulder pain. Pet'r's Ex. 13 at 269. Petitioner reported that the cervical injection in January had briefly helped but had since worn off. *Id.* She further reported "the pain in her arm ha[d] been so bad that she [] mutilated her face from scratching." *Id.* On examination Dr. Mudd noted severe pain on "palpation of posterior and lateral left deltoid," and "full [range of motion] that was limited by pain." *Id.* at 270. Dr. Mudd advised Petitioner to continue with pain management and planned for an additional epidural injection. *Id.* at 273.

Petitioner presented to Dr. Mudd again on May 28, 2019, for continued pain in her left neck and shoulder. Pet'r's Ex. 13 at 303. Petitioner had previously been seen by orthopedics on April 2, 2019, and declined to pursue further physical therapy.[33] *Id.* Orthopedics referred Petitioner to pain management for another cervical injection. *Id.* Petitioner reported pain was worse with movement. *Id.* On examination Dr. Mudd reported "moderate to severe [pain] on palpation of posterior and lateral left deltoid," as well as cervical vertebral tenderness C4-T4 and mild

[33] There is no documentation in the record for this visit.

numbness of her left upper extremity. *Id.* at 305. Dr. Mudd further noted that an X-Ray of Petitioner's left shoulder on April 2, 2019, revealed "[m]ild left greater than right glenohumeral osteoarthritis without interval progression." *Id.* at 307. Dr. Mudd also noted an April 9, 2019 MRI of Petitioner's cervical spine, which revealed "degenerative disc disease from C5 through C7" and "mild degenerative productive changes related to bilateral neural foramina as above with greatest apparent foraminal narrowing at left C4." *Id.* at 309. Dr. Mudd recommended continued follow-ups with orthopedics and to plan on another injection in her cervical spine. *Id.* at 322.

No other relevant medical records were filed.

III. Affidavits

A. Petitioner's Initial Affidavit

On November 8, 2018, Petitioner filed a brief affidavit. Pet'r's Ex. 1. She stated that "[w]ithin [24] hours of receiving the vaccine, [she] began experiencing pain in [her] left shoulder and limitation of motion." *Id.* at ¶ 6. She stated that "[i]n or about September, 2016, the pain in [her] left shoulder began to radiate down [her] arm and to [her] wrist," which she reported to Dr. Santoni. *Id.* at ¶ 10. She stated she related her pain to her flu vaccination at her appointment with Dr. Manning on November 22, 2016. *Id.* at ¶ 11. Petitioner further stated that at the April 14, 2017 visit with Dr. Manning, she "complained of left shoulder pain and impingement which radiated down [her] arm to [her] wrist, which started after [her] flu injection." *Id.* at ¶ 13. She further stated that the chart "incorrectly note[d] that [she] complained of pain to a different area of [her] left shoulder," and that she could not explain the error other than that she speaks "little English and there may have been a problem with translation." *Id.* Petitioner does not know why her surgery was not rescheduled. *Id.* at ¶ 14.

B. Petitioner's First Supplemental Affidavit

Petitioner filed her first supplemental affidavit on August 13, 2019. ECF No. 19.[34] She stated that prior to her November 10, 2015 flu vaccination, she had received three prior flu vaccinations and a Tdap vaccination in her left shoulder without incident. *Id.* at ¶¶ 6–7. She stated that she first attempted to treat the pain with home remedies, but "those remedies were of limited effect, and the pain worsened . . . over the next month." *Id.* at ¶ 10. She stated that she did not seek care before her December 30, 2015 ED visit, because she "thought the pain would go away with the passing of time." *Id.* at ¶ 11. Petitioner further stated the flu vaccination she received in her right shoulder on October 17, 2017, "had no effect on [her] left shoulder." *Id.* at ¶ 31.

C. Petitioner's Second Supplemental Affidavit

Petitioner filed her second supplemental affidavit on February 24, 2020. ECF No. 26-1.[35] Petitioner stated that at the time of her injection she "was in a seated position." *Id.* at ¶ 4. She stated that "[t]o the best of [her] recollection, the injector was standing as he gave [her] the injection, because . . . he had to bend down as he injected the vaccine." *Id.* She stated that "[a]t no time was

[34] Petitioner did not label this affidavit with an exhibit number.
[35] Petitioner did not label this affidavit with an exhibit number.

[she] asked by the injector, or anyone else, to place [her] left arm in a certain position before, during or after the injection." *Id.* at ¶ 5.

IV. Expert Reports[36]

A. Expert Qualifications

1. Petitioner's Expert, Dr. Naveed Natanzi, D.O.

Dr. Natanzi is a board-certified specialist in physical medicine and rehabilitation who practices interventional sports and rehabilitation medicine. Pet'r's Ex. 14, Tab 1 at 1, ECF No. 40-2. He received his Doctorate of Osteopathy from Western University of Health Sciences and subsequently completed an internship at Downey Regional Medical Center and residencies at the University of California, Irvine. *Id.*at 1–2. He is currently a Staff Physician at the Veteran's Affairs Long Beach Healthcare System, and he runs the Regenerative Sports and Spine Institute in Sherman Oaks, California. *Id.* at 1. He "almost exclusively treat[s] musculoskeletal issues including but not limited to the shoulder joint," and on average treats or diagnoses "40-50 shoulder pathologies per month." Pet'r's Ex. 14 at 1, ECF No. 40-1.

2. Respondent's Expert, Dr. Paul Cagle, M.D.

Dr. Cagle is a board-certified orthopedic surgeon. Resp't's Ex. B at 1, ECF No. 28. He received his medical degree from Loyola University Chicago Stritch School of Medicine. Resp't's Ex. A at 1, ECF No. 28. He completed an orthopedic surgery residency at the University of Minnesota Academic Health Center and Medical School. *Id*. He also completed a Shoulder and Elbow Fellowship under Evan L. Flatow, M.D., at Mount Sinai Hospital and a Shoulder Fellowship under Gilles Walch, M.D., at Private Hospital Jean Mermoz/Centre Orthopaedic Santy. *Id.* He is currently an Assistant Professor and Associate Program Director of the Leni & Peter May Department of Orthopedics at the Icahn School of Medicine at Mount Sinai. *Id.* He is "involved in teaching and educating medical students, graduate students and orthopaedic surgical residents" on a daily basis. Resp't's Ex. B at 1. His "current practice focuses on the shoulder, representing approximately 95% or more of the patients and pathology" he treats. *Id.* He has published several articles related to shoulder pathologies and treatment. Resp't's Ex. A at 3–7.

B. Expert Opinions

1. Diagnosis

a. Dr. Natanzi's Initial Report

Dr. Natanzi opined that Petitioner's case was consistent with a vaccine-related shoulder injury and provided the following mechanism to explain her symptoms:

[36] Although Petitioner initially filed another expert report with her petition, she is proceeding with only the reports of Dr. Natanzi as per her brief. *See* Pet'r's Ex. 5, ECF No. 1.

> [i]nadvertent overpenetration of the vaccination needle resulting in [b]ursal and or rotator cuff penetration causing a rotator cuff injury resulting in immediate pain, limited range of motion, and discomfort. Vaccine interacts with naturally-occurring antibodies from a prior vaccination, resulting in an exaggerated, robust, and prolonged inflammatory response resulting in [r]otator cuff inflammation and tendinopathy.

Pet'r's Ex. 14 at 13. He further noted that "[t]he medical literature . . . describes dozens of cases of an immune-mediated inflammatory reaction as the result of a vaccine." *Id.* at 14 (citing Pet'r's Ex. 15, Tab 2[37]; Pet'r's Ex. 15, Tab 3[38]; Pet'r's Ex. 15, Tab 4[39]; Pet'r's Ex. 15, Tab 5[40]; Pet'r's Ex. 15, Tab 6[41]; Pet'r's Ex. 15, Tab 7[42]; Pet'r's Ex. 15, Tab 10[43]; Pet'r's Ex. 15, Tab 11[44]; Pet'r's Ex. 15, Tab 12[45]; Pet'r's Ex. 15, Tab 13[46]; Pet'r's Ex. 15, Tab 14[47]; Pet'r's Ex. 15, Tab 15[48]; Pet'r's Ex. 15, Tab 16[49]; Pet'r's Ex. 15, Tab 17[50]; Pet'r's Ex. 15, Tab 18[51]; Pet'r's Ex. 15, Tab 19[52]; Pet'r's Ex. 15, Tab 20; Pet'r's Ex. 15, Tab 21[53]; Pet'r's Ex. 15, Tab 22.[54] Barnes et al.

---

[37] S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049 (2010)
[38] Matthew G. Barnes et al., *A "Needling" Problem: Shoulder Injury Related to Vaccine Administration*, 25 J. AM. BD. FAM. MED. 919 (2012)
[39] Brian P. McColgan & Frank A. Borschke, *Pseudoseptic Arthritis After Accidental Intra-Articular Deposition of the Pneumococcal Polyvalent Vaccine: A Case Report*, 25 AM. J. EMERG'Y MED. 864 (2007). This is also labeled as Pet'r's Ex. 15, Tab 20.
[40] Zeina M. Saleh et al., *Onset of Frozen Shoulder Following Pneumococcal and Influenza Vaccinations*, 14 J. CHIROPRACTIC MED. 285 (2015)
[41] Gokean Okur et al., *Magnetic Resonance Imaging of Abnormal Shoulder Pain Following Influenza Vaccination*, 43 SKELETAL RADIOLOGY 1325 (2014)
[42] Gall B. Cross, et al., *Don't Aim Too High: Avoiding Shoulder Injury Related to Vaccine Administration*, 45 AUSTRALIAN FAMILY PHYSICIAN 303 (2016).
[43] Marko Bodor & Enoch Montalvo, *Vaccination-Related Shoulder Dysfunction*, 25 VACCINE 585 (2007).
[44] I. Degreef & Ph. Debeer, *Post-Vaccination Frozen Shoulder Syndrome. Report of 3 Cases*, 112 ACTA CHIRURGICA BELGICA 447 (2012).
[45] Christina Trollmo et al., *Intra-Articular Immunization Induces Strong Systemic Immune Response in Humans*, 82 CLINICAL & EXPERIMENTAL IMMUNOLOGY 384 (1990).
[46] Ian F. Cook, *An Evidence Based Protocol for the Prevention of Upper Arm Injury Related to Vaccine Administration (UAIRVA)*, 7 HUM. VACCINES 845 (2011).
[47] Christopher V. Macomb et al., *Treating SIRVA Early With Corticosteroid Injections: A Case Series*, 185 MIL. MED. 298 (2020).
[48] Soshi Uchida et al., *Subacromial Bursitis Following Human Papilloma Virus Vaccine Misinjection*, 31 VACCINE 27 (2012).
[49] L.H. Martín Arias et al., *Risk of Bursitis and Other Injuries and Dysfunctions of the Shoulder Following Vaccinations*, 35 VACCINE 4870 (2017).
[50] Alexandra Wright et al., *Influenza Vaccine-Related Subacromial/Subdeltoid Bursitis: A Case Report*, 13 J. RADIOLOGY CASE REP. 24 (2019).
[51] Sofia Szari et al., *Shoulder Injury Related to Vaccine Administration: A Rare Reaction*, 36 FED. PRAC. FOR HEALTH CARE PROF. VA, DoD, & PHS 380 (2019).
[52] Michael Shahbaz et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): An Occupational Case Report*, 67 WORKPLACE HEALTH & SAFETY 501 (2019).
[53] J.H. Salmon et al., *Bone Erosion and Subacromial Bursitis Caused by Diphtheria-Tetanus-Poliomyelitis Vaccine*, 33 VACCINE 6152 (2015).
[54] Ian F. Cook, *Subdeltoid/Subacromial Bursitis Associated with Influenza Vaccination*, 10 HUM. VACCINES & IMMUNOTHERAPEUTICS 605 (2014).

explained that SIRVA can result in a wide range of symptomology depending on the exact location of the vaccination site and patient's immunological reaction to the antigenic material. Pet'r's Ex. 15, Tab 3. The authors noted that these symptoms may present themselves "due to an inflammatory effect from vaccine administration into the subdeltoid bursa." *Id.* at 3.Atanasoff et al., in a study of 13 cases, identified rapid onset of pain and limited range of motion as common characteristics of the injury. Pet'r's Ex. 15, Tab 2 at 1. Thirty-nine percent of patients presented with fluid collections in the deltoid or overlying the rotator cuff tendons, as well as bursitis, tendonitis, and rotator cuff tears. *Id.* at 2. Additional studies have identified frozen shoulder, impingement syndrome, and adhesive capsulitis as possible symptoms associated with SIRVA. Pet'r's Ex. 15, Tab 6[55]; Pet'r's Ex. 15, Tab 11.[56] Notably, these studies also identified inconsistent results from Hawkins, O'Brien, and Neer tests across patients, with some presenting positive symptoms while others had negative presentations. *Id.* While corticosteroids are often used to treat SIRVA injuries, patients may require several treatments before resolution of their symptoms can be achieved. Pet'r's Ex. 15, Tab 15.[57]

Further, Shahbaz et al.[58] detailed a timeline of MRI imaging after suffering a SIRVA injury. Pet'r's Ex. 15, Tab 19. The patient's first MRI, performed one week after the injury, revealed moderate glenohumeral joint effusion and synovitis, fluid accumulation in the subscapularis recess, and moderate biceps' tenosynovitis. *Id.* at 3. Six weeks after the injury, a second MRI demonstrated near-complete resolution of the glenohumeral joint effusion, but "changes consistent with tenosynovitis of the extraarticular portion of the biceps' tendon remained." *Id.* A third MRI performed eight months after the injury revealed persistent mild tenosynovitis, interval accumulation of a large glenohumeral joint effusion, and infraspinatus tendinitis. *Id.* at 4.

In the present case, Dr. Natanzi relied on Petitioner's left shoulder MRI on July 16, 2016, which "revealed signs of rotator cuff tendinopathy and/or partial thickness rotator cuff tearing, which are commonly seen in the context of a SIRVA injury." Pet'r's Ex. 14 at 11 (citing Pet'r's Ex. 4 at 5–6; Pet'r's Ex. 15, Tab 2[59]; Pet'r's Ex. 15, Tab 3[60]; Pet'r's Ex. 15, Tab 4[61]; Pet'r's Ex. 15, Tab 5[62]; Pet'r's Ex. 15, Tab 6.[63] He opined that "subacromial bursitis may not have been seen in

---

[55] Gokean Okur et al., *Magnetic Resonance Imaging of Abnormal Shoulder Pain Following Influenza Vaccination*, 43 SKELETAL RADIOLOGY 1325 (2014).
[56] I. Degreef & Ph. Debeer, *Post-Vaccination Frozen Shoulder Syndrome. Report of 3 Cases*, 112 ACTA CHIRURGICA BELGICA 447 (2012).
[57] Uchida et al., *Subacromial Bursitis*, 31 VACCINE 27 (2012).
[58] Michael Shahbaz et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): An Occupational Case Report*, 67 WORKPLACE HEALTH & SAFETY 501 (2019).
[59] S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049 (2010)
[60] Matthew G. Barnes et al., *A "Needling" Problem: Shoulder Injury Related to Vaccine Administration*, 25 J. AM. BD. FAM. MED. 919 (2012).
[61] Brian P. McColgan & Frank A. Borschke, *Pseudoseptic Arthritis After Accidental Intra-Articular Deposition of the Pneumococcal Polyvalent Vaccine: A Case Report*, 25 AM. J. EMERG'Y MED. 864 (2007). This is also labeled as Pet'r's Ex. 15, Tab 20.
[62] Zeina M. Saleh et al., *Onset of Frozen Shoulder Following Pneumococcal and Influenza Vaccinations*, 14 J. CHIROPRACTIC MED. 285 (2015).
[63] Gokean Okur et al., *Magnetic Resonance Imaging of Abnormal Shoulder Pain Following Influenza Vaccination*, 43 SKELETAL RADIOLOGY 1325 (2014).

this case given the [eight]-month lapse of time between the MRI and the vaccination, during which an acute bursitis would have resorbed." *Id.* A subacromial bursa injection administered on June 8, 2018, provided approximately two months of relief, "further suggesting a shoulder-mediated source of pain (i.e. SIRVA)." *Id.* at 11–12 (citing Pet'r's Ex. 13 at 109–11; Pet'r's Ex. 12 at 21). "[M]ore specifically [a] rotator cuff-mediated pain [] is also suggested, given the fact that multiple orthopedic surgeons recommended a subacromial decompression which is performed to decompress an impinged or inflamed rotator cuff, again commonly occurring as the result of a SIRVA injury." *Id.* at 12.

Dr. Natanzi also noted Petitioner had no history of shoulder pain prior to the date of vaccination. Pet'r's Ex. 14 at 11. "In contrast, . . . during her first post-vaccination primary care visit with Dr. Santoni, [Petitioner] was found to have pain and reduced range of motion[64] in her left shoulder." *Id.* (citing Pet'r's Ex. 2 at 51–52). He further took note of Petitioner's reduced range of motion and weakness in her left shoulder at a physical therapy visit on May 19, 2016, and similar findings at visits with Dr. Emmanuel on November 1, 2016, and Dr. Manning on November 22, 2016. *Id.* (citing Pet'r's Ex. 4 at 54–55, 57; Pet'r's Ex. 8 at 17). He also noted Dr. Manning diagnosed Petitioner with impingement syndrome in her left shoulder on November 22, 2016, and May 16, 2017, "which is a hallmark clinical finding in SIRVA cases." *Id.* (citing Pet'r's Ex. 6 at 298).

Dr. Natanzi disagreed with the contention in Respondent's Rule 4(c) report that Petitioner's symptoms were caused by an alternative diagnosis of cervical radiculopathy. Pet'r's Ex. 14 at 12. He cited to several pieces of filed literature to contrast the symptomology with Petitioner's clinical presentation. *Id.* "Common clinical signs in cervical radiculopathy include one or more symptoms including but not limited to neck pain, limited range of motion, numbness along a dermatomal pattern, weakness in a myotomal pattern, depressed/asymmetric deep tendon reflexes and/or positive nerve root compression tests." *Id.* (citing Pet'r's Ex. 15, Tab 8).[65] Conversely, cervical radiculopathy is caused by compression of a cervical nerve root. Pet'r's Ex. 15, Tab 8 at 1. Caridi et al.[66] identifies arm pain and paresthesias in the dermatomal distribution of the affected nerve as the most common symptoms associated with cervical radiculopathy. *Id.* This can also include pain, numbness, and/or tingling in the upper extremity, weakness, or shocking pains. *Id.* Compression of the C3 and C4 vertebrae tend to result in vague neck and trapezius pain, while compression of the C5 vertebrae results in shoulder pain that radiates down to the elbow. *Id.* at 2. While Sembrano et al.[67] noted the presenting symptoms of shoulder and neck pathologies can overlap significantly, they also found that 94% of patients who presented with shoulder and/or arm pain were ultimately diagnosed with a shoulder pathology. Resp't's Ex. B, Tab 13 at 3.

Dr. Natanzi noted that "[o]n multiple initial physical examinations post-vaccination, [Petitioner] did not present with any of these symptoms. For example, on [March 22, 2016], Anne Kleinman, a neurologist, opined there was no neurologic involvement." *Id.* (citing Pet'r's Ex. 6 at

[64] Dr. Santoni's notes from this visit stated Petitioner had "preserved [range of motion]." Pet'r's Ex. 2 at 52.

[65] John M. Caridi et al., *Cervical Radiculopathy: A Review*, 7 MUSCULOSKELETAL J. HOSP. SPEC. SURGERY 265 (2011).

[66] John M. Caridi et al., *Cervical Radiculopathy: A Review*, 7 HOSP. SPECIAL SURGERY J. 265 (2011).

[67] Jonathan N. Sembrano et al., *Neck-Shoulder Crossover: How Often Do Neck and Shoulder Pathology Masquerade as Each Other?*, 42 AM. J. ORTHOPEDICS 76 (2013).

481). "Furthermore, a nerve conduction study [("NCS")] and electromyogram [("EMG")], which is diagnostic of any neuropathy or radiculopathy, was negative (normal) on [August 2, 2016]. *Id.* (citing Pet'r's Ex. 9 at 62).

Dr. Natanzi acknowledged "the improvement of some symptoms after a cervical epidural injection on [December 7, 2018]." Pet'r's Ex. 14 at 12. "As would be expected, the cervical epidural did help cervical symptoms but not her left shoulder symptoms. This is best exemplified by the ongoing complaints of left shoulder dysfunction and pain [Petitioner] expressed to Dr. Matthew (sic) on [January 14, 2019, and February 25, 2019]." *Id.* (citing Pet'r's Ex. 12 at 9). He noted the symptoms "were severe enough that she required a repeat shoulder cortisone injection" on February 25, 2019. *Id.*

Dr. Natanzi opined that Petitioner's "debility began initially with a [shoulder] injury, which over time caused overcompensation and strain in the neck, ultimately resulting in cervical mediated symptoms including radiculopathy." Pet'r's Ex. 14 at 12. He described the biomechanical mechanism as follows:

> [Petitioner's] left shoulder pain and reduced glenohumeral joint range of motion resulted in overuse, malpositioning, and imbalance in the scapulothoracic joint. In turn, muscles of the scapulothoracic joint that have attachments to the cervical spine (namely the levator scapulae and upper trapezius) exerted altered and atypical forces/strain onto the cervical spine resulting in cervical mediated signs, symptoms, and pathology.

Id. at 13 (citing Pet'r's Ex. 15, Tab 9).[68] He further noted the Health Resources & Services Administration's ("HRSA") criteria[69] for SIRVA diagnosis, which stated the following:

> i. No history of pain, inflammation, or dysfunction of the affected shoulder prior to intra-muscular vaccine administration that would explain the alleged symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection.
> ii. Pain occurs within the specified time frame, typically within 48 hours.
> iii. Pain and reduced range of motion are limited to the shoulder in which the intra-muscular vaccine was administered.
> iv. No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Id. Dr. Natanzi opined that Petitioner met all of the above linersted criteria for a SIRVA diagnosis. *Id.* at 14. In referencing the medical literature, Dr. Natanzi noted "[t]hese cases all include one or more of a variety of symptoms and diagnoses, including shoulder pain, decreased range of motion, adhesive capsulitis, rotator cuff tearing/tendinopathy, subacromial bursitis, clinical signs of

[68] F. Struyf et al., *Scapular Positioning and Movement in Unimpaired Shoulders, Shoulder Impingement Syndrome, and Glenohumeral Instability*, 21 SCANDINAVIAN J. MED. & SCI. SPORTS 352 (2011).
[69] No citation was given for this source. However, the criteria listed are the same as the qualifications and aids to interpretation ("QIAs") listed in the Vaccine Table for SIRVA. 42 C.F.R. § 100.3(c)(10).

impingement, limited range of motion, weakness, and bicipital tendinitis," many of which were present in Petitioner's clinical findings. *Id.*; *see also* Pet'r's Ex. 15, Tabs 2–7, 10–19, 21–22.

b. Dr. Cagle's Initial Report

Dr. Cagle began by noting that Petitioner's "MRI findings are consistent across multiple time points and frequently documented degenerative changes in the glenohumeral joint (shoulder joint)." Resp't's Ex. B at 5. "This is in stark contradiction [to] the SIRVA literature[, which] supports the presence of acute bursitis with subsequent MRI images demonstrating resolution of the bursitis." *Id.* (citing Resp't's Ex. B, Tab 2[70]; Resp't's Ex. B, Tab 3[71]; Resp't's Ex. B, Tab 4[72]; Resp't's Ex. B, Tab 5[73]; Resp't's Ex. B, Tab 6[74]; Resp't's Ex. B, Tab 7[75]; Resp't's Ex. B, Tab 8[76]). An increase[d] bursal fluid signal followed by a decrease is logical if the presumed mechanism is an acute inflammation. When the findings do not change over time, this is consider[ed] to be a chronic finding." *Id.* (citing Resp't's Ex. B, Tab 9[77]; Resp't's Ex. B, Tab 10[78]; Resp't's Ex. B, Tab 11[79]). Dr. Cagle also noted that "[c]hronic findings such as rotator cuff tendinosis can be incidentally found on MRI scans, and 50% of previously asymptomatic rotator cuffs can go on to be symptomatic." *Id.* at 5–6 (citing Resp't's Ex. B, Tab 12)[80] Dr. Cagle asserted that Petitioner's "MRI images show static age related change over time" and do not support a SIRVA or shoulder-mediated injury. *Id.* at 6.

Dr. Cagle continued by arguing Petitioner's symptoms resulted from her cervical radiculopathy, stating "it is clear that this was a cervical pathology from the very beginning." Resp't's Ex. B at 6. He noted that nonspecific findings on physical examinations and the fact that physical therapy did not help "alleviate subjective or objective findings" supported an association

---

[70] J. H. Salmon et al., *Bone Erosion and Subacromial Bursitis Caused by Diphtheria-Tetanus-Poliomyelitis Vaccine*, 33 VACCINE 6152 (2015).
[71] Matthew G. Barnes et al., *A "Needling" Problem: Shoulder Injury Related to Vaccine Administration*, 25 J. AM. BD. FAM. MED. 919 (2012).
[72] Patrick J. Messerschmitt et al., *Progressive Osteolysis and Surface Chondrolysis of Proximal Humerus Following Influenza Vaccination*, 35 ORTHOPEDICS 283 (2012).
[73] G. Kuether et al., *Atraumatic Osteonecrosis of the Humeral Head After Influenza A-(H1N1) v-2009 Vaccination*, 29 VACCINE 6830 (2011).
[74] Gokean Okur et al., *Magnetic Resonance Imaging of Abnormal Shoulder Pain Following Influenza Vaccination*, 43 SKELETAL RADIOLOGY 1325 (2014).
[75] Neeti A. Bathia, M.D., N.J. Med. School & Todd Stitik, M.D., "Influenza Vaccine Shoulder"-Vaccination-Related Traumatic Injury to the Infraspinatus: A Case Report, Poster Presentation at the 70th Ann. Meeting of the Am. Acad. of Physical Med. & Rehabilitation (Oct. 2009), *in* PM&R, Sept. 2009, at 118.
[76] Soshi Uchida et al., *Subacromial Bursitis Following Human Papilloma Virus Vaccine Misinjection*, 31 VACCINE 27 (2012).
[77] Jerry S. Sher et al., *Abnormal Findings on Magnetic Resonance Images of Asymptomatic Shoulders*, 77 J. BONE & JOINT SURGERY 10 (1995).
[78] Siegbert Tempelhof, *Age-Related Prevalence of Rotator Cuff Tears in Asymptomatic Shoulders*, 8 J. SHOULDER ELBOW SURGERY. 296 (1999).
[79] Hiroshi Minagawa et al., *Prevalence of Symptomatic and Asymptomatic Rotator Cuff Tears in the General Population: From Mass-Screening in One Village*, 10 J. ORTHOPAEDICS 8 (2013).
[80] Ken Yamaguchi et al., *Natural History of Asymptomatic Rotator Cuff Tears: A Longitudinal Analysis of Asymptomatic Tears Detected Sonographically*, 10 J. SHOULDER ELBOW SURGERY. 199 (2001).

with cervical radiculopathy. *Id.* He relied heavily on Petitioner's cancelled orthopedic surgeries, noting "the pain was atypical enough to cause her to have a shoulder surgery cancelled twice." *Id.* Dr. Cagle noted "[t]he reason for both cancellations was a documented belief that the pain was not coming from her shoulder and a shoulder surgery would not help her." *Id.* Dr. Cagle argued his theory was confirmed when Petitioner was "diagnosed with cervical stenosis and bilateral radiculitis" and "[a] subsequent cervical injection then provided relief" in 2018. *Id.* He cited to Sembrano et al.[81] as an example of neck pain masquerading as shoulder pain and posited that "identification of the correct pain generator is critical for effective treatment but that distinguishing between shoulder and cervical pain can be very difficult." *Id.* (citing Resp't's Ex. B, Tab 13). "The authors go on to suggest that [] this is such a common problem that approximately [one] out of 25 patients presenting for a shoulder evaluation actually have neck pathology causing the pain." *Id.* Dr. Cagle concluded that this neck-shoulder crossover matches the case of Petitioner "perfectly." *Id.*

Dr. Cagle further addressed Dr. Natanzi's usage of the HRSA criteria, specifically prong four. Resp't's Ex. B at 6. He stated that "point IV states that a patient cannot present with radiculopathy." *Id.* Because "there was a clear radiculopathy that when treated caused clinical improvements . . . this case does not meet SIRVA criteria." *Id.*

c. Dr. Natanzi's First Supplemental Report

In his first supplemental report, Dr. Natanzi reiterated the point in his initial report that an acute bursitis "would have most likely resorbed in the eight-month time laps between the MRI and the vaccination." Pet'r's Ex. 16 at 1. Dr. Natanzi also took issue with Dr. Cagle's interpretation of his description of the HRSA criteria, specifically prong four. Pet'r's Ex. 16 at 2. "Dr. Cagle erroneously writes that '[SIRVA patients] cannot present with radiculopathy.' The HRSA criteria . . . outline that for an injury to be considered SIRVA-related, no other condition or abnormality could explain the patient's symptoms." *Id.* (quoting Resp't's Ex. B at 6) (alterations in original). "In other words, the mere presence of a cervical radiculopathy does not negate a SIRVA injury." *Id.* Dr. Natanzi noted that that an individual "with an acute or chronic history of cervical radiculopathy . . . who is administered a vaccination incorrectly and suffers a SIRVA injury undoubtedly is deserved of SIRVA evaluation." *Id.* He contrasted this with an individual who presents for a shoulder claim after vaccination but shows no signs of shoulder impairment on MRI or physical examination, "but only shows signs of cervical radiculopathy causing shoulder pain," and admitted this would not qualify as a SIRVA injury. *Id.*

Dr. Natanzi then turned to Petitioner's case, and stated she "clearly and indisputably has shoulder mediated pain." Pet'r's Ex. 16 at 2. Dr. Natanzi reiterated that Petitioner's medical history detailed several shoulder-related symptoms in the days and months immediately following vaccination, including a diagnosis of impingement. *Id.* (citing Pet'r's Ex. 2 at 51–52; Pet'r's Ex. 4 at 54–55, 57; Pet'r's Ex. 6 at 298; Pet'r's Ex. 8 at 17). Dr. Natanzi also reiterated that Petitioner's symptoms improved following corticosteroid injections in her shoulder and that Petitioner had twice been scheduled for subacromial decompression surgery. *Id.* Dr. Natanzi argued that "[t]here are clearly two pathophysiological processes occurring simultaneously" which he identified as

[81] Jonathan N. Sembrano et al., *Neck-Shoulder Crossover: How Often Do Neck and Shoulder Pathology Masquerade as Each Other?*, 42 AM. J. ORTHOPEDICS 76 (2013).

"cervical radiculopathy and SIRVA-mediated rotator cuff tendinopathy and impingement." *Id.* at 3.

d. Dr. Cagle's First Supplemental Report

Dr. Cagle first addressed Dr. Natanzi's contention that an acute bursitis would have resolved by the time an MRI was conducted eight months later by arguing that Dr. Natanzi failed to provide "any type of supporting proof." Resp't's Ex. C at 1. He argued that "Dr. Natanzi is only offering his own opinion and has provided no validated support which would overturn a comparison to the available literature." *Id.* In comparison, Dr. Cagle noted he had "provided peer reviewed published papers demonstrating [his] statements to be reliable and persuasive," and used this assertion as the basis to hold his "opinion that the MRI findings are not supported by the reliable evidence as set forth in the published literature." *Id.*

Dr. Cagle next addressed Dr. Natanzi's biomechanical theory that the SIRVA injury ultimately resulted in the development of cervical radiculopathy. Resp't's Ex. C at 1. He addressed two issues with Dr. Natanzi's analysis. *Id.* First, Dr. Cagle reiterated his argument that the presence of cervical radiculopathy negated prong four of the HRSA criteria. *Id.* (citing Resp't's Ex. B, Tab 1). Second, Dr. Cagle asserted that Dr. Natanzi's reports contradicted each other, as "in the first report by Dr. Natanzi, he state[d] the cervical symptoms came after the SIRVA symptoms, but the second report[] suggest[ed] simultaneous symptoms." *Id.* at 1–2. Dr. Cagle argued "[t]here is no alterative mechanism present, no additional supporting data, or no additional elaboration." *Id.* "The onset timing of symptoms (radiculopathy) that can and do explain the ongoing pain are now proposed to have started at two different times, and if they occurred simultaneously, clearly the radicular symptoms were not caused by a SIRVA." *Id.*

e. Dr. Natanzi's Second Supplemental Report

Dr. Natanzi's second supplemental report focused on the timeline of Petitioner's medical history to support his theory of a SIRVA-mediated injury and addressed Dr. Cagle's contention that the theories proposed in his previous reports were conflicting. Pet'r's Ex. 17 at 1. He reiterated his initial biomechanical theory of a shoulder injury which resulted in cervical radiculopathy. *Id.* "This phenomenon is best exemplified in the medical record on [January 14, 2019,] in which Dr. Matthew (sic) described the 'resolution' of cervical symptoms after an epidural but ongoing shoulder-mediated symptoms." *Id.* (citing Pet'r's Ex. 12 at 21). He noted that "[t]his would be the exact outcome one would expect after a cervical epidural, which effectively treated the cervical component of pain but had no bearing on the SIRVA or shoulder component." *Id.*

Dr. Natanzi also reiterated that Petitioner did not present with any common clinical signs of cervical radiculopathy in multiple physical examinations post vaccination. Pet'r's Ex. 17 at 2. Dr. Natanzi argued "[in early 2016,] there were strong physical signs of a shoulder issue but no neck issue." *Id.* He supported this by reemphasizing Petitioner's negative neurologic examinations in March and August 2016. *Id.* (citing Pet'r's Ex. 6 at 481; Pet'r's Ex. 9 at 62).

Dr. Natanzi contrasted this with Dr. Mudd's physical examination of Petitioner on November 29, 2018, which found "[t]enderness at the shoulder and pain with range of motion,

which would be expected in an ongoing shoulder issue and [a] description of marked cervical paraspinal tenderness from C4 to T4, which is in line with what one would expect with the diagnosed cervical radiculopathy." Pet'r's Ex. 17 at 2 (citing Pet'r's Ex. 13 at 214). "As such, at this point (in November 2018), signs of both a cervical and shoulder issue were evident." *Id.* He concluded by opining that Petitioner "experienced a SIRVA injury in late 2015 which went untreated and resulted in compensation and a superimposing cervical radiculopathy that began in mid- to late 2018." *Id.*

f. Dr. Cagle's Second Supplemental Report

Dr. Cagle began his second supplement report by again asserting that Dr. Natanzi had presented a third timeline and injury mechanism, "that a SIRVA ultimately led to cervical radiculopathy," and stated Dr. Natanzi selectively quoted portions of the medical record. Resp't's Ex. D at 1. Dr. Cagle argued that Dr. Natanzi "provided no explanation as to why no shoulder pain was noted" at visits to a gastroenterologist and ophthalmologist on November 12, 2015, and November 13, 2015, or at the ED visit on December 30, 2015. *Id.* He continued that Dr. Natanzi provided no explanation as to why Petitioner had negative Hawkins and Empty Can tests while demonstrating preserved range of motion in her left shoulder on January 5, 2016. *Id.*

Dr. Cagle also critiqued Dr. Natanzi's argument that pain with shoulder abduction "is only expected with shoulder pathology." Resp't's Ex. D at 1. Dr. Cagle noted that no explanation was given "as to what isolated pain in shoulder abduction means or why other [] named physical exam maneuvers . . . were negative." *Id.* He argued that:

> Abduction of the shoulder requires a complex series of muscle motions involving the glenohumeral joint and the scapula. The scapula maintains the insertional points of many muscles that originate from the neck. Thus, the motion of the scapula involves motion of muscles that connect to the neck.

Id. at 1–2. Dr. Cagle stated that "[a] lack of neck tenderness is also not a test that completely rules out cervical pathology . . . ." *Id.* He continued by questioning why Dr. Natanzi did not provide explanations for why Petitioner's January 14, 2016 visit reported a nonspecific shoulder examination, "why surgery was cancelled, or why a cervical epidural managed to resolve the clinical picture." *Id.*

g. Dr. Natanzi's Third Supplemental Report

Dr. Natanzi's final supplemental report focused on further clarification of his theory and Petitioner's medical timeline in response to contentions raised by Dr. Cagle. Pet'r's Ex. 18 at 1. He reiterated his findings from his initial report referencing Petitioner's MRI on July 16, 2016, which revealed "signs of rotator cuff tendinopathy and/or partial thickness rotator cuff tearing, which are commonly seen in the context of a SIRVA injury." *Id.* (quoting Pet'r's Ex. 14 at 11 (citing Pet'r's Ex. 15, Tabs 2–6)).

With regard to Petitioner's cervical radiculopathy diagnosis, Dr. Natanzi explained that "[t]here is no reasonable way an injection to the shoulder can directly cause a neck problem." Pet'r's Ex. 18 at 1. However, he noted an injury similar to Petitioner's could occur "through a

biomechanical compensation theory," as discussed in his initial report. *Id.* "The theory that shoulder dysfunction, namely through irregularities in the scapulothoracic muscle movements, contributes to cervical pathology is also opined by Marko Bodor [] (one of the first authors to ever describe SIRVA) . . . ." *Id.* at 2 (citing Pet'r's Ex. 18, Tab 1 at 24).[82]

2. Temporal Relationship

a. Dr. Natanzi's Initial Report

Dr. Natanzi began by describing the difficulties of associating a patient's symptoms to SIRVA. Pet'r's Ex. 14 at 10. SIRVA is "a relatively uncommon phenomenon and is unfamiliar to most people, including most medical professionals." *Id.* "Most people are unaware that a vaccination can cause significant shoulder dysfunction and they often do not inherently associate adverse symptoms with a vaccination." *Id.* Dr. Natanzi opined "this is why [Petitioner] and her medical providers do not immediately and consistently correlate symptoms with the vaccination." *Id.*

"Patients commonly attribute their symptoms to an exaggerated version of typical soreness one would expect after a vaccination and do not make much of them." Pet'r's Ex. 14 at 10. "Patients frequently put off visiting their medical providers," and Taber et al.[83] found that "12.2% of patients experienced a low-perceived need to seek medical care often because they believed their symptoms would self-improve over time." *Id.* (citing Pet'r's Ex. 15, Tab 1 at 4). Dr. Natanzi opined that "[f]or these reasons, oftentimes in SIRVA cases, a clear correlation is not always made between vaccination and symptoms." *Id.* "This may explain why [Petitioner] did not formally complain to her medical providers until 50 days post-vaccination." *Id.*

Dr. Natanzi relied on Petitioner's reporting of "[two] months of pain" at her December 30, 2015 ED visit; Dr. Kwakugah's note on March 22, 2016, which "link[ed] symptom onset directly to the vaccination time period;" and Dr. Emmanuel's note on November 1, 2016, that Petitioner "had been dealing with shoulder pain since her flu shot." Pet'r's Ex. 14 at 11; *see also* Pet'r's Ex. 4 at 57; Pet'r's Ex. 6 at 478; Pet'r's Ex. 7 at 302. While Respondent noted in his Rule 4(c) report that Petitioner failed to report her symptoms during visits to a gastroenterologist and ophthalmologist in the three days immediately following the vaccination, Dr. Natanzi found it "atypical to complain of a musculoskeletal issue to a gastroenterologist or ophthalmologist." Pet'r's Ex. 14 at 11. Ultimately, "given the lack of any plausible alternative etiology for the acute development of shoulder pain in the pre-vaccination time period," Dr. Natanzi opined that Petitioner's symptoms began "immediately post-vaccination." *Id.*

b. Dr. Cagle's Initial Report

Dr. Cagle began by stating for an injury to qualify as SIRVA, "the pain needed to begin within 48 hours of vaccination." Resp't's Ex. B at 5 (citing Resp't's Ex. B, Tab 1). He argued Petitioner's eye doctor and gut doctor appointments constituted "robust documentation of

[82] MICHAEL T. ANDARY ET AL., AM. ASS'N ELECTRODIAGNOSTIC MED., PAINFUL SHOULDER (2004).
[83] Jennifer M. Taber et al., *Why do People Avoid Medical Care? A Qualitative Study Using National Data*, 30 J. GEN. INTERN. MED. 290 (2015).

[medical] visits without shoulder pain following the vaccination event on [November 10, 2015]." *Id.* Dr. Cagle noted that "[i]t could be argued that the purpose of these visits was not a musculoskeletal evaluation, and a musculoskeletal visit is necessary for proper documentation." *Id.* He relied on Petitioner's ED visit on December 30, 2015, where he noted "shoulder pain was reported, but the physical examination from this day demonstrated tenderness along the triceps not the shoulder. The note state[d] there is no pain to the elbow or shoulder." *Id.*

Dr. Cagle also pointed to Petitioner's visit with Dr. Santoni on January 5, 2016, where "[s]houlder pain was reported but a nonspecific shoulder exam[ination] was noted." Resp't's Ex. B at 5. "This included a negative physical exam[ination] for Neer and Hawkins maneuvers (test that assess for impingement/bursitis)." *Id.* He further noted Dr. Santoni reported a negative Empty Bucket test and preserved range of motion in Petitioner's left shoulder. *Id.* "[Petitioner] was seen and examined by four different providers and none of them provided a clear documentation of shoulder pain. In fact, negative shoulder physical examination maneuvers were noted in detail. Thus, the medical documentation does not support SIRVA." *Id.*

c. Dr. Natanzi's First Supplemental Report

In Dr. Natanzi's first supplemental report, he noted that Dr. Cagle "completely ignores Dr. Kwakugah's note of [March 22, 2016] and Dr. Emmanuel's note of [November 1, 2016], which link her shoulder pain to her flu shot." Pet'r's Ex. 16 at 1. Dr. Natanzi reiterated his argument that Taber et al. supports a theory of a patient who did not sense an immediate need for medical attention, thus delaying her reporting of symptoms. *Id.* (citing Pet'r's Ex. 15, Tab 1) Dr. Natanzi found Petitioner's medical record presented "a compelling picture of a patient who thought that she was experiencing expected shoulder soreness from a flu vaccine, only to bring it to her doctors' attention when the pain failed to remediate." *Id.* Dr. Natanzi did not specifically address the temporal relationship in his subsequent reports.

d. Dr. Cagle's Supplemental Reports

In response to Dr. Natanzi's contention that Petitioner did not initially report her symptoms due to a lack of understanding, Dr. Cagle argued that Taber et al. is "a general paper looking at broad reasons why people do not go to the doctor. This is not a paper about vaccines." Resp't's Ex. C at 1 (citing Pet'r's Ex. 15, Tab 1). He critiqued Dr. Natanzi's use of Taber et al. as a reference because it is not specific to vaccine injuries. *Id.* In his second supplemental report, Dr. Cagle reiterated his argument that Dr. Natanzi had provided insufficient support for his explanation of the delay in reporting shoulder pain. Resp't's Ex. D. at 1.

V. Legal Standards

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, 837 (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, 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 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 as to whether a 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.").

A. Factual Issues

A 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). Contemporaneous medical records, "in general, 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) (rejection 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 (2001) ("[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.").

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 v. Sec'y of the Dep't of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991)). Ultimately, a determination regarding a witness' 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.").

B. 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).

Petitioner claims she suffered a SIRVA Table injury and claims in the alternative, that her injury was caused-in-fact by a vaccination. Under the Vaccine Table Qualifications and Aids to Interpretation ("QAIs"), SIRVA is defined as "shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm." 42 C.F.R. § 100.3(c)(10). "These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction." *Id.* Thus, SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.) and is not a neurological injury. *Id.* "[A]bnormalities on neurological examination or [NCS/EMG] studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known)." *Id.*

A vaccine recipient shall only be considered to have suffered a SIRVA Table Injury if all of the following are met:

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination finds, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. §§ 100.3(c)(10)(i)–(iv).

To prove a shoulder injury that was caused-in-fact by vaccination, 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 the 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 weights in his 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 a 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.

VI. Analysis

A. Diagnosis

The parties dispute the nature of Petitioner's shoulder injury, including diagnosis. In cases where the diagnosis is contested, "special masters may find whether a preponderance of evidence supports any proposed diagnosis before evaluating whether a vaccine caused that illness." *Hibbard v. Sec'y of Health & Hum. Servs*, No. 07–446V, 2011 WL 1766033, at *6 (Fed. Cl. Spec. Mstr. April 12, 2011) (citing *Broekelschen v. Sec'y of Health & Hum. Servs.,* 618 F.3d 1339, 1345–46 (Fed. Cir. 2010)). For the following reasons, I find there is preponderant evidence to show Petitioner suffered from an injury with a shoulder mediated pathology which was not the result of Petitioner's later diagnosed cervical radiculopathy. In the immediate months following Petitioner's vaccination she reported her pain as being localized to the shoulder and presented with limited range of motion and pain in her left shoulder. *See* Pet'r's Ex. 2 at 51 (presenting to Dr. Santoni on January 5, 2016, with left shoulder pain on abduction and motion); Pet'r's Ex. 7 at 119 (presenting to PA Sanchez on February 9, 2016, with reduced range of motion and left shoulder pain). Dr. Santoni, Dr. Dove, and Dr. Kleinman all noted Petitioner experienced left shoulder and/or left upper arm pain with limited range of motion throughout her visits, and continued to opine that Petitioner's symptoms were related to a shoulder injury. *See* Pet'r's Ex. 6 at 381, 389 (Dr. Santoni noting Petitioner presented with left upper arm pain on September 29, 2016, July 28, 2017, and August 22, 2017); *see also* Pet'r's Ex. 9 at 4 (Dr. Dove noting Petitioner presented with left shoulder pain and bursitis on October 8, 2016); Pet'r's Ex. 6 at 478 (Dr. Kleinman noting Petitioner's left shoulder pain was not neurological in nature). Petitioner's physical therapy notes also detailed pain in her left shoulder and limited range of motion, which showed inconsistent improvement over the course of nine sessions in 2016. *See* Pet'r's Ex. 8 at 2–18.

Further, in March 2016, Dr. Kleinman opined there was "no neurologic involvement" to Petitioner's shoulder pain; and negative NCS/EMG studies support the opinion that Petitioner's pain was not a symptom of a neurologic injury such as cervical radiculopathy. Pet'r's Ex. 6 at 478. Dr. Balmaceda echoed this sentiment by concluding that Petitioner's pain was "not neuropathic in nature." Pet'r's Ex. 10 at 8.

It is also noteworthy that Petitioner's physicians continued to opine that Petitioner's symptoms were related to a shoulder injury even after her cervical radiculopathy diagnosis. Dr. Mudd, the physician who initially diagnosed Petitioner with cervical radiculopathy in March 2018, specifically listed "subacromial bursitis of the left shoulder joint" under Petitioner's acute diagnoses. Pet'r's Ex. 13 at 75. In June 2018, Dr. Chantasi observed bursitis and impingement in Petitioner's shoulder, which he found to be more consistent with a musculoskeletal injury. Further, at a later visit in August 2018, Dr. Chantasi specifically questioned why Petitioner's shoulder decompression surgery was cancelled given Petitioner's presentation and ongoing symptoms. Dr.

Balmaceda, a neurologist, also continued to opine that Petitioner's shoulder pain was not neuropathic in nature, and specifically noted it was unclear why Petitioner opted for vaccination in her right arm because "the left arm pain developed after the injections." Pet'r's Ex. 10 at 17. Petitioner continued to present with positive Hawkins and O'Brien's signs when she was seen by Dr. Padaki in September 2018, which he noted was indicative of persistent bicipital tendinosis and rotator cuff tear. Petitioner's physicians consistently note a shoulder-mediated pathology, even after her cervical radiculopathy diagnosis, and her presentation remained indicative of shoulder injury, e.g., bursitis and impingement. In total, the record contains persuasive evidence that Petitioner suffered from a shoulder injury, notwithstanding the development of cervical radiculopathy.

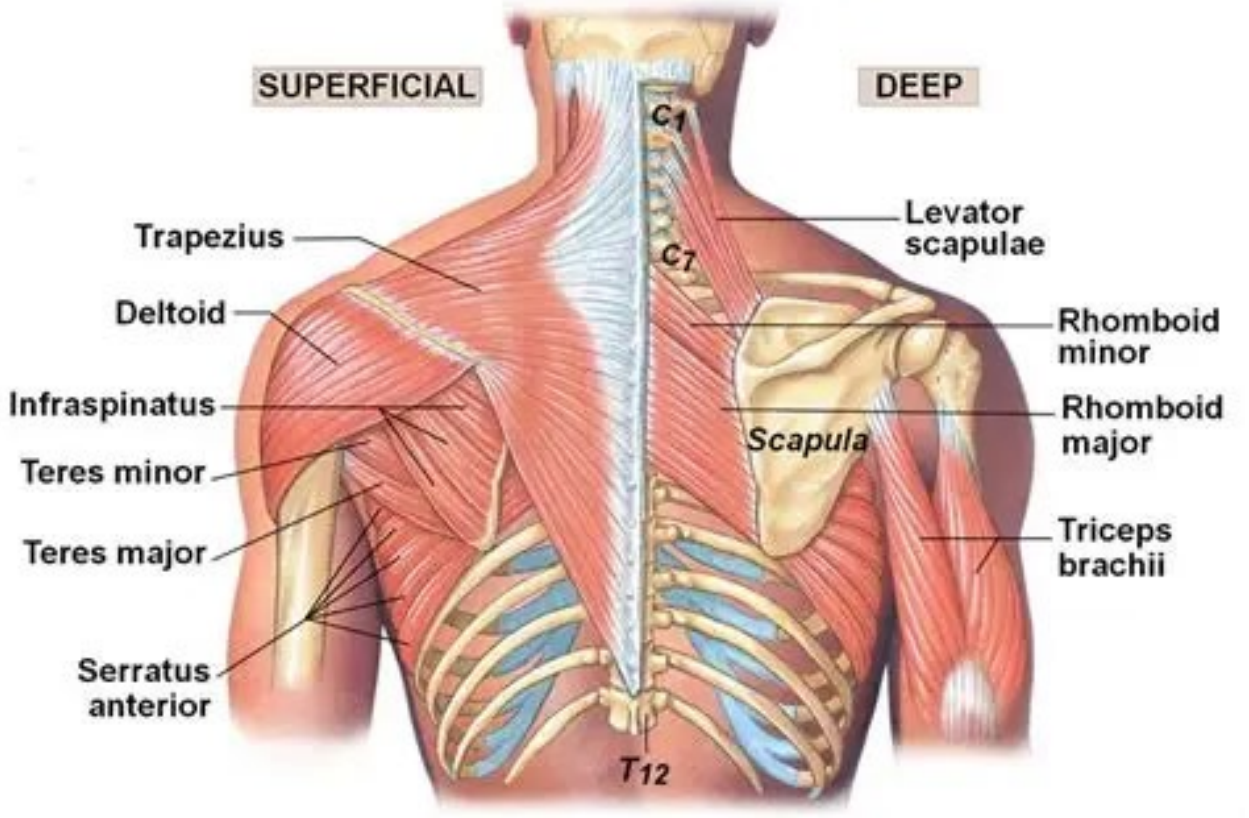
I also find the continuation of Petitioner's symptoms following her cervical epidural noteworthy, because as Dr. Natanzi noted, her neck pain improved, but her shoulder pain did not. A 2019 MRI, conducted after Petitioner's cervical epidural, also showed tendinosis and bursitis of the left shoulder. Following this imaging, Dr. Mathew specifically noted that because Petitioner's left shoulder pain had continued, her cervical radiculopathy was "likely secondary to subacromial bursitis and rotator cuff tendinosis and osteoarthrosis." Pet'r's Ex. 12 at 13. Yet another one of Petitioner's physicians opined that her shoulder pain was not primarily the result of her cervical radiculopathy, and instead the product of a shoulder-mediated pathology.

While Dr. Cagle relied on the fact that Petitioner's first MRI on July 16, 2016 (eight months post vaccination) did not reveal signs of an acute subacromial bursitis, he did not address that the MRI revealed subcoracoid bursitis and mild impingement. This is consistent with the theory proposed by Dr. Natanzi that an acute bursitis would have resorbed within the eight-month period between vaccination and the MRI, which is also supported by the Shahbaz et. al. case study.

Contrary to Respondent's contentions, Petitioner's medical record consistently details a shoulder-mediated pathology. Petitioner's treating physicians consistently note pain in the shoulder, and later MRIs of Petitioner's left shoulder conducted in April 2017, December 2017, and October 2018 consistently show supraspinatus and subscapularis tendinosis, in addition to signs of adhesive capsulitis. An ultrasound conducted in June 2018 also noted bursitis in Petitioner's left shoulder. Respondent relied heavily on Petitioner's January 2017 MRI of her left arm to argue there was no shoulder pathology, which was "unremarkable" aside from mild degenerative change to the glenohumeral joint. Pet'r's Ex. 7 at 260. However, an MRI of the left arm is not the same imaging and focus as an MRI of the left shoulder. While Petitioner's physicians focused on the left arm due to what appeared to be shifts in the location of Petitioner's pain, it is persuasive that imaging of Petitioner's left arm continued to be unremarkable, whereas consistent imaging of the left shoulder from 2016 to 2018 continued to show injuries related to Petitioner's left shoulder that are consistent with SIRVA.

Dr. Cagle also argued that the shifting and non-specific nature of Petitioner's shoulder pain supports a diagnosis of cervical radiculopathy instead of a shoulder injury. While Petitioner's medical record does indeed report a shift in the location of pain throughout Petitioner's medical history on certain occasions, I am not persuaded by Dr. Cagle's argument that this is indicative of a cervical pathology instead of a shoulder-mediated pathology. Petitioner is from Senegal and her native language is Wolof. On several occasions in the record, it is noted that Petitioner's doctors

had trouble communicating with her due to the language barrier and on several occasions no interpreter was present. These visits are also often the same visits where pain is reported as being in a different location than Petitioner's shoulder. Further, due to the difficulty of communication, many of the instances where Petitioner's pain is recorded as being not in her shoulder are documented through Petitioner pointing at the affected area. As shown below, there are a substantial number of muscles which connect at or extend into the shoulder and could easily be misunderstood by a treating physician when adding the complication of a language barrier.



2009 Pearson Education, Inc.

Petitioner's weight and limited range of motion in her shoulder are also factors that could affect her flexibility and any attempt to accurately point to a specific area of the body. Further, Petitioner's later treating physicians consistently relate her pain back to her shoulder, and Petitioner has documented MRI imaging to show injuries to her left shoulder. Given these factors, I am unpersuaded by Dr. Cagle's arguments that the shifting location of Petitioner's pain is indicative of a cervical radiculopathy instead of a shoulder-related injury.

Dr. Cagle further relied on Petitioner's two cancelled surgeries with Dr. Manning as indicative that there was no shoulder-mediated pathology. But Dr. Cagle did not discuss these decisions in light of the entire medical record. Dr. Manning noted that he cancelled one of her surgeries because it appeared that Petitioner's pain had shifted, and he no longer believed there was a shoulder-mediated pathology. However, in order to clarify the issue of pain location, Dr. Manning ordered a new MRI of Petitioner's shoulder. This revealed tendinosis and symptoms suggestive of adhesive capsulitis, and Dr. Manning reaffirmed his impingement diagnosis.

"[T]he opinions 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). An opinion by a treating physician that is not supported by a factual basis or other evidence is conclusory in nature. And a "treating physician's recognition of a temporal relationship does not advance the analysis of causation." *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at *26 (Fed. Cl. Spec. Mstr. July 30, 2012); *see also Robertson v. Sec'y of Health & Hum. Servs*, No. 18-554V, 2022 WL 17484980, at *17 (Fed. Cl. Spec. Mstr. Dec. 7, 2022) (finding treating physicians' statements of mere suspicion fall short of an opinion supporting vaccine causation); *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1347 (Fed. Cir. 2010) (concluding the special master did not err in affording little weight to the opinions of Petitioner's treating physicians where "none of the treating physicians concluded that the [] vaccine caused [Petitioner's condition]").

Here, I rely heavily on the statements of Petitioner's treating physicians as they are "in the best position" to determine Petitioner's injury and the cause of such injury. *See Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326; *Cucuras*, 993 F.2d at 1528 (noting contemporaneous medical records, "in general, warrant consideration as trustworthy evidence"). This is supported by later examinations in 2018, where Dr. Mudd specifically noted his confusion as to why Petitioner's shoulder surgery was cancelled twice given that Petitioner had a shoulder-mediated pathology. Accordingly, I am not persuaded by Dr. Cagle's arguments that there is no evidence of a shoulder pathology. Therefore, I find Petitioner has proven by preponderant evidence that she suffered from shoulder pain following her flu vaccination in November 2015.

B. Table Claim

1. Criterion One: Prior Condition

The first criterion for a SIRVA Table injury is that there can be "no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection." 42 C.F.R. § 100.3(c)(10)(i). Petitioner has no documented history in the record of left shoulder pain prior to the vaccination and there is no indication of any ongoing issue prior to vaccination. Respondent does not identify any relevant pre-existing shoulder injury, nor does Dr. Cagle dispute Dr. Natanzi's assertion that there is no history that would explain Petitioner's symptoms. Based upon a review of the record as a whole, including the medical records, affidavits, and expert reports, I find Petitioner did not experience issues with her left shoulder prior to vaccination that "would explain the alleged signs, symptoms, [and] examination findings . . . after vaccine injection." *Id.*

2. Criterion Two: Pain Onset

The specified timeframe on the Vaccine Injury Table for SIRVA is 48 hours post vaccination. 42 C.F.R. § 100.3(c)(10)(ii). Dr. Natanzi opined Petitioner's pain occurred within the specified timeframe because Petitioner consistently related her shoulder pain to her flu shot when speaking with her physicians and because there is no "plausible alternative etiology for the acute development of shoulder pain in the peri-vaccination time period." Pet'r's Ex. 14 at 14. Dr. Cagle

disagreed and argued that Petitioner failed to meet second criterion because she failed to report her pain at medical appointments within 48 hours after her vaccination. I agree with Dr. Natanzi and find that there is preponderant evidence that Petitioner's pain began within 48 hours of vaccination.

As noted by Dr. Natanzi, I find that Petitioner's consistent relation of her symptoms to her flu shot in the medical record to be highly persuasive, especially considering the numerous instances from 2016 to 2019 where Petitioner related her injury back to her flu shot. *See* Pet'r's Ex. 6 at 478 (noting Petitioner's pain began "after she took the flu shot"); *see also* Pet'r's Ex. 4 at 60 (complaining of pain since the flu shot); Pet'r's Ex. 4 at 55 (reporting pain onset as immediately after the flu shot); Pet'r's Ex. 4 at 43 (associating left shoulder pain with flu shot); Pet'r's Ex. 4 at 37 (reporting "left arm pain for more than one year after she received an injection on her arm").

Respondent asserts that Petitioner's failure to report her shoulder symptoms to a gut doctor and an eye doctor in the days immediately following vaccination should be fatal to her claim. I agree with Dr. Natanzi that it would be atypical for an individual to report musculoskeletal pain to doctors specializing in the digestive and visual systems. I find Dr. Natanzi presented a persuasive argument of an individual who experienced shoulder pain and attempted to treat her symptoms through home remedies until she realized more aggressive treatment was required.

Based on the contemporaneous medical records, affidavits, and expert reports, I find that Petitioner presented preponderant evidence that her shoulder pain began within 48 hours of Petitioner's November 10, 2015 flu vaccination, satisfying the second criterion. *See, e.g., Williams v. Sec'y of Health & Hum. Servs.*, No. 17-1046V, 2020 WL 3579763, at *5 (Fed. Cl. Spec. Mstr. Apr. 1, 2020) (finding Petitioner's onset of shoulder pain started within 48 hours of vaccination because the medical records consistently referred to onset "after" vaccination, "following" vaccination, "since" vaccination, and "very soon after" vaccination); *Humbert v. Sec'y of Health & Hum. Servs.*, No. 17-360V, 2023 WL 2565729, at *25 (Fed. Cl. Spec. Mstr. Mar. 20, 2023) (using affidavit testimony in addition to medical records and expert reports to find onset began within two days of vaccination).

3. Criterion Three: Scope of Pain and Limited Range of Motion

The third criterion requires Petitioner's pain and reduced range of motion to be limited to the shoulder. 42 C.F.R. § 100.3(c)(10)(iii). This criterion "is intended to ensure that SIRVA claims are limited to instances in which 'the condition is localized to the shoulder in which the vaccine was administered.'" *Durham v. Sec'y of Health & Hum. Servs.*, No. 17-1899V, 2023 WL 3196229, at *12 (Fed. Cl. Spec. Mstr. May 2, 2023) (quoting 82 Fed. Reg. 6294, 6269 (Jan. 19, 2017)). "[T]he gravamen of this requirement is to guard against compensating claims involving patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder." *Id.* (citing *Grossman v. Sec'y of Health & Hum. Servs.*, No. 18-13V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb 15, 2022)).

However, the third Table criterion "does not prevent a petitioner with simultaneous areas of pain from also meeting the Table SIRVA definition." *Rodgers v. Sec'y of Health & Hum. Servs.*, No. 18-0559V, 2021 WL 4772097, at *8–9 (Fed. Cl. Spec. Mstr. Sept. 8, 2021); *see also Werning v. Sec'y of Health & Hum. Servs.*, No. 18-0267V, 2020 WL 5051154, at *10 (Fed. CL. Spec. Mstr. July 27, 2020) (finding that Petitioner satisfied the third SIRVA criterion where there was a

complaint of radiated pain, but the Petitioner was "diagnosed and treated solely for pain and limited range of motion to her right shoulder"); *Cross v. Sec'y of Health & Hum. Servs.*, No. 19-65V, 2022 WL 3226776, at *8 (Fed. Cl. Spec. Mstr. May 25, 2022) (holding that "claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body").

Petitioner's brief argues that her cervical radiculopathy is separate and resulting from the shoulder injury but does not explain the radiating pain or shifting pain to her biceps, triceps, and arm. Although, as discussed above, I do not find that Petitioner's shifting shoulder pain is indicative of a cervical radiculopathy, I cannot ignore the significant reporting in the medical record detailing pain in areas other than Petitioner's shoulder when analyzing the third criterion for a Table SIRVA—requiring that Petitioner's pain be localized to her shoulder.

Dr. Natanzi did not directly address the third criterion in his reports, aside from stating "[i]n my opinion . . . [Petitioner's] presentation clearly meets all the [Table] criteria." Pet'r's Ex. 14 at 14. Dr. Cagle argued that Petitioner has not satisfied the third criterion because she was documented with triceps pain on December 30, 2015, and subsequent examinations did not reveal specific shoulder pain or limitation. Respondent's brief expands on this by arguing Petitioner's shifting pain proves her pain was not localized to her shoulder, and therefore she fails the third criterion. I agree with Respondent and find that Petitioner has not shown by preponderant evidence that her pain was localized to her shoulder.

Throughout Petitioner's medical record there are several instances where her pain is noted as being in areas other than her shoulder. *See* Pet'r's Ex. 7 at 297 (noting pain in the triceps); Pet'r's 8 at 18 (noting left arm swelling and shoulder pain); Pet'r's Ex. 2 at 76 (noting left upper arm pain in the left arm and wrist); Pet'r's Ex. 9 at 3 (noting pain and swelling in the left arm that radiates into the elbow); Pet'r's Ex. 4 at 46, 48 (noting pain in the biceps and forearm). As explained by Respondent, at different times Petitioner reported pain in her arm, biceps, triceps, and elbow, including radiating pain from the shoulder and into other areas of Petitioner's arm. Petitioner provides no argument, reasoning, or explanation as to these alternative locations of pain in the medical record. While I do believe that Petitioner's language barrier and other factors may have prevented proper treatment and diagnosis, as stated above, I cannot overlook the existence of significant reporting that Petitioner's pain was not localized to her shoulder in the medical record with regard to the third criterion. Accordingly, I find that Petitioner has failed to establish the third criterion by preponderant evidence.

4. Criterion Four: Other Condition or Abnormality

The fourth criterion requires that "[n]o other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." 42 C.F.R. § 100.3(c)(10)(iv). Under this specific language and the facts of this case, Petitioner bears the burden of "establishing that any clinical evidence of cervical radiculopathy that is present is not meaningful to the existence of [her] symptoms." *Durham*, 2023 WL 3196229, at *14. That is, she must "prove by preponderant evidence either (a) that her history is entirely free of, for example, clinical evidence of radiculopathy, or (b) if not, that the radiculopathy would not explain her symptoms." *Id.*

Because a cervical MRI revealed degenerative change at Petitioner's C4-C5 vertebra, the fourth SIRVA Table criterion turns on whether the cervical radiculopathy explains Petitioner's shoulder symptoms. Petitioner argues cervical radiculopathy cannot explain her shoulder symptoms, and that it occurred after her shoulder pain began as a result of her exerting atypical strain on her neck and shoulder. Respondent disagrees and argues that Petitioner's shoulder pain can be explained entirely by her cervical radiculopathy rather than by the flu vaccine.

Throughout Petitioner's clinical presentation, both shoulder and neck (cervical spine) issues were addressed. Petitioner's shoulder pain was frequently documented, including multiple X-rays, MRIs, physical examinations, and physical therapy. In late 2017 and early 2018, Petitioner began to complain of neck pain, leading her physicians to diagnose and begin treatment for her cervical radiculopathy.

However, as I discussed above, I find that the record provides preponderant evidence that Petitioner's shoulder pain was the result of a shoulder injury, and not her cervical radiculopathy diagnosis. Petitioner was not diagnosed with cervical radiculopathy until three years after the onset of her shoulder problems, which originated following her flu vaccine. Additionally, the physicians who diagnosed Petitioner with cervical radiculopathy continued to opine that her cervical issues were secondary to a shoulder-mediated pathology. This is further supported by Petitioner's consistent MRI imaging detailing tendinosis and bursitis. Accordingly, I find Petitioner has provided preponderant evidence to satisfy the fourth criterion.

In conclusion, while I find Petitioner has satisfied the first, second, and fourth Table criteria, I find Petitioner does not satisfy the third Table criterion. Because a petitioner is only considered to have suffered a SIRVA Table injury if all of the criteria are met, Petitioner's table claim must fail. *See* 42 C.F.R. § 100.3(c)(10).

C. Causation-In-Fact Claim

1. *Althen* Prong One

Under *Althen* prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. *Andreu*, 569 F.3d at 1375; *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"), *aff'd* 475 F. App'x 765 (Fed. Cir. 2012). 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 oftentimes 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 (Ct. Cl. 1980))).

The mechanism for a shoulder injury is well described by Dr. Natanzi and the medical literature filed in this case. In Atanasoff et al., the authors propose that the causal mechanism "is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Pet'r's Ex. 15, Tab 2 at 1. They found "rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response." *Id.* at 3. MRI findings supported the conclusion that shoulder impairments, such as rotator cuff tears, "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." *Id.* Similarly, Bodor and Montalvo proposed that a "vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response." Pet'r's Ex 15, Tab 10 at 1. They found multiple structures within the shoulder involved, which suggested "a primary inflammatory etiology rather than a mechanical overuse problem." *Id.* at 3.

Further, when proposing the addition of SIRVA to the Vaccine Table, Respondent discussed the mechanism by which this injury is caused. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45137 (July 29, 2015).

Respondent contends that Petitioner has failed to meet her burden of showing a medically recognized injury, as Petitioner's causation-in-fact claim asserts a SIRVA as the injury and "[R]espondent maintains that [P]etitioner may not pursue a causation-in-fact SIRVA claim." Resp't's Br. at 21. Respondent grounds this argument in SIRVA being "an injury defined by administrative rulemaking." *Id.* Respondent continues that Dr. Natanzi's mechanical theory should similarly fail because it refers to Petitioner's injury as a SIRVA, and not another specific shoulder injury such as bursitis or adhesive capsulitis. However, I find these arguments unpersuasive. This court has recognized that Petitioners may assert causation-in-fact claims for non-specific shoulder injuries, and that the mechanical mechanism of a SIRVA is a sufficient showing for the *medical theory* of a shoulder injury caused by a flu vaccine administered intramuscularly. *See Rance v. Sec'y of Health & Hum. Servs.*, No. 18-222V, 2023 WL 6532401 (Fed. Cl. Spec. Mstr. Sept. 11, 2023) (noting that Respondent's discussion of the SIRVA mechanism in the federal register was sufficient to support a medical theory under the first *Althen* prong for a shoulder injury). For the above reasons, I find Petitioner has provided by preponderant evidence a sound and reliable theory that the flu vaccine administered intramuscularly can cause a shoulder injury, and therefore, Petitioner has satisfied the first *Althen* prong.

2. *Althen* Prong Two

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 case, 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*, 400 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. *Id.* at 1325–26.

With regard to the second *Althen* prong, I find there is a preponderance of evidence in the record to support a logical sequence of cause and effect showing the November 10, 2015 flu vaccination caused Petitioner's left shoulder pain. *See Althen*, 418 F.3d at 1278. As noted previously, Petitioner presented with no prior complaints of left shoulder pain prior to her November 10, 2015 vaccination. Petitioner then began to experience left shoulder pain and limited range of motion, to include bursitis and impingement of the left shoulder, consistent with a shoulder injury associated with vaccine administration. Consistent MRI imaging documented shoulder bursitis and tendonitis, and Petitioner's treating physicians consistently related Petitioner's injuries to a shoulder-mediated pathology, even after her cervical radiculopathy diagnosis. These symptoms experienced by Petitioner are consistent with the biological mechanism proposed by Dr. Natanzi of an inadvertent overpenetration resulting in prolong inflammation due to the injection of an antigen. Accordingly, I find there is preponderant evidence consistent with the mechanism to show a logical sequence of cause and effect that the flu vaccine caused Petitioner's shoulder injury and satisfies the second *Althen* prong.

3. *Althen* Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been defined as a "medically acceptable temporal relationship." *Id.* Petitioner must offer "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder'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; *see Pafford*, 451, F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. *See, e.g., Veryzer*, 100 Fed. CL. At 356. (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury").

As stated above, I find preponderant evidence that the onset of Petitioner's left shoulder pain occurred within 48 hours of the vaccination on November 10, 2015. This timing is consistent with a proximate temporal relationship between vaccination and injury. *See Althen*, 418 F.3d at 1278. Thus, Petitioner has satisfied the third *Althen* prong.

D. Alternative Causation

Because I conclude that Petitioner has established a prima facie case, Petitioner is entitled to compensation unless Respondent can put forth preponderant evidence "that [Petitioner's] injury was in fact caused by factors unrelated to the vaccine." *Whitecotton v. Sec'y of Health & Hum. Servs.*, 17 F.3d 374, 376 (Fed. Cir. 1994), *rev'd on other grounds sub nom.*, *Shalala v. Whitecotton*, 514 U.S. 268 (1995); *see also Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the analysis related to the diagnosis and the Fourth Table criterion, I found Respondent failed to establish it more likely than not that Petitioner's shoulder injury was caused by a source other than her vaccination, including cervical radiculopathy. Thus, Respondent did not prove by a preponderance of the evidence that Petitioner's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

VII. Conclusion

For the reasons discussed above, I find that (1) Petitioner did not satisfy the SIRVA Table criteria, but (2) Petitioner has established by preponderant evidence that her flu vaccine caused her shoulder injury. Therefore, Petitioner is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Herbrina D. S. Young
Herbrina D. S. Young
Special Master