In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-0027V
UNPUBLISHED

MELISSA BISHOP, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: November 20, 2020 Special Processing Unit (SPU); Ruling on Entitlement; Causation-In-Fact; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Shealene Priscilla Mancuso, Muller Brazil, LLP, Dresher, PA, for petitioner.

Traci R. Patton, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On January 4, 2018, Melissa Bishop filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered left shoulder injuries related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine received on December 1, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

I. Relevant Procedural History

On January 4, 2018, Petitioner filed her petition and medical records (ECF No. 1). Petitioner filed additional medical records on April 5, 2018 (ECF No. 9). On December 7,

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

2018, Respondent filed his Rule 4(c) Report asserting that Petitioner had failed to establish entitlement to compensation for either a Table SIRVA claim or a non-Table, causation-in-fact version of the same claim (ECF No. 20).

Petitioner subsequently filed Exhibits 13-18 containing additional evidence, including an expert report and affidavits (ECF Nos. 22, 23, 27-28). Respondent then filed an expert report, Exhibit A (ECF No. 29). On September 20, 2019, a Finding of Fact was issued determining that the onset of Petitioner's shoulder injury likely occurred within 48 hours of vaccination. Finding of Fact, issued Sept. 20, 2019 (ECF No. 32).

On December 18, 2019, Respondent filed an Amended Rule 4(c) Report (ECF No. 37). In it, Respondent acknowledged the onset finding, and further advised that he would no longer defend the matter. Respondent's Amended Rule 4(c) Report, at *2. Respondent added that he "reserves his right to a potential appeal of this factual ruling and maintains that a finding of entitlement to compensation cannot be sustained if the Findings of Fact are vacated or overturned on appeal." *Id*. at *2, n.1. Respondent accordingly requested "a ruling based on the existing record regarding petitioner's entitlement to compensation." *Id*.

On April 21, 2020, Petitioner filed a status report indicating that on that date, Petitioner had forwarded a demand to Respondent (ECF No. 38). On June 22, 2020, the court directed Petitioner to file a status report with an update on the parties' discussions, including whether Petitioner had received a response to her demand (Non PDF Scheduling Order, issued June 22, 2020). On July 14, 2020, Petitioner filed additional medical records as Exhibit 19 (ECF No. 39). On July 29, 2020, Petitioner filed a status report stating that the parties had conferred on July 23 and 24, 2020 (ECF No. 40). Petitioner reported that Respondent stated he expected to respond to Petitioner's demand within ten days of the issuance of a decision on entitlement. *Id*. Accordingly, issuance of such a decision will help move the matter toward resolution.

II. Relevant Factual History

A. Pre-Vaccination Medical Records

Prior to the vaccination at issue in this case, Petitioner's medical history documented several health conditions, including fibromyalgia, hypertension, back pain, migraine, anemia, and gastroesophageal reflux. Ex. 7 at 4; Exs. 10, 12. In particular, on November 23, 2009, Petitioner was seen by Dr. Richard Brandon for back pain and knee swelling, and also reported pain in her upper back, shoulders, and lower back. Ex. 12 at 1. Dr. Brandon assessed her with "[d]iffuse musculoskeletal pain-probable fibromyalgia." *Id*.

A few months later, on January 19, 2010, Petitioner saw Dr. Brandon for a follow up. Among other concerns, she reported "pain in her chest that radiated to her left shoulder" occurring in conjunction with an episode of extreme anxiety. Ex. 12 at 2. On March 16, 2010, Petitioner returned to Dr. Brandon complaining of fibromyalgia, knee

pain, low back pain, migraines, and "some muscle pain in her neck and shoulder girdle area." *Id*.

B. December 1, 2016 Flu Vaccine and Post-Vaccination Medical Records

On December 1, 2016, Petitioner, then age 44, received the flu vaccine that is at issue in this claim. Ex. 1 at 1. The vaccine was administered intramuscularly in Petitioner's left deltoid. *Id*. She received the flu vaccine during an appointment with Dr. Sam Sadeghi, who was then her primary care physician. Ex. 7 at 96-101. During this appointment, Petitioner reported back pain, which was a chronic problem, but no other musculoskeletal issues. *Id*. at 99.

Just over a month later, in January 2017, Petitioner was seen by Nurse Practitioner ("NP") Dewayne Steffey. Ex. 2 at 16-18. The record indicated that she was a new patient and was previously a patient of Dr. Sherri Rajoo and Dr. Sam Sadeghi. *Id*. at 17. Petitioner reported having migraines and low back pain since her teens, being diagnosed with fibromyalgia in 2007, and that she had "a lot of joint pain which comes and goes." *Id*. On examination, NP Steffey observed "joint pain with rom [range of motion] pain with palpation lumbar spine." *Id*. The record includes a pain medication, Norco, in the medication list. *Id*. at 18.

On February 9, 2017, Petitioner was seen by NP Steffey for a follow up appointment. Ex. 2 at 11-14. The record of the visit states that she "continues to complain of multiple myalgias. She now has the other complaints." *Id*. at 14. The musculoskeletal examination notes were identical to the prior visit: "joint pain with rom pain with palpation lumbar spine." *Id*.

On March 9, 2017, Petitioner returned to NP Steffey. Ex. 2 at 10-13. She complained about her "left arm triceps where she had flu shot. She never had pain in it prior to the shot. She received shot 12-1-2016." *Id*. at 11. The musculoskeletal examination notes were identical to the two prior visits: "joint pain with rom pain with palpation lumbar spine." *Id*. In addition, the neurological examination section documented "limited rom left ac [acromioclavicular, i.e. shoulder] joint." *Id*. Petitioner was given a Medrol dose pak. *Id*. at 12. On March 28, 2017, Petitioner's left shoulder was x-rayed due to "[l]eft shoulder pain after flu shot." Ex. 3 at 1. Mild calcifications and minimal joint spurs were seen, with no fracture or dislocation. *Id*.

On April 6, 2017, Petitioner followed up with NP Steffey. Ex. 3 at 7-9. She reported "significant worsening pain related to pain in her back and generalized joint pain . . . . She is also having difficulty with lifting her left arm since she had a flu shot last December. The arm is painful and cannot be lifted very high." *Id*. at 8. On examination, her left shoulder joint was found to be unable to flex past 45 degrees, and Petitioner stated that she was unable to shave her underarm or fasten her bra. *Id*. An MRI and physical therapy were recommended for her shoulder. *Id*.

On April 14, 2017, Petitioner underwent an MRI of her left shoulder. Exs. 4 at 1; 2 at 25. The findings indicated that "[m]inimal fluid is seen in the shoulder joint and subacromial subdeltoid bursa . . . . Findings suggest adhesive capsulitis . . . . There is minimal tendinopathy of the supraspinatus tendon centrally." *Id*. On May 4, 2017, Petitioner returned to NP Steffey, continuing to report difficulty lifting her left arm since her flu shot in December and complaining of "pain in the left arm over the triceps." Ex. 2 at 5. The MRI was noted to reveal adhesive capsulitis. *Id*. Petitioner was referred to an orthopedist and for physical therapy. *Id*.

On May 23, 2017, Petitioner was seen by Dr. Linda Pearson for back pain. Ex. 8 at 2. Petitioner reported that she had a frozen left shoulder and that "she had the flu injection in December 2016 and had complications since then with the left shoulder and arm," although her primary issue was her back pain. *Id*. In the history section of the record under back pain, the record adds "[a]ssociated symptoms include headaches and tingling (left hand)." *Id*. at 3. On the same page, four paragraphs below, the paragraph about Petitioner's left shoulder pain notes that she "[r]eports her left fingers go numb along the finger tips and pain goes down from her left shoulder to her arm. Denies any issues with her left shoulder before the flu shot." *Id*.

On examination, Petitioner's left shoulder was noted to have abnormal range of motion in active and passive abduction, extension, and forward flexion. Ex. 8. at 11. Dr. Pearson was unable to assess her left shoulder strength due to limited range of motion. *Id*. Petitioner had positive impingement signs and tenderness in the acromion, acromioclavicular joint, and deltoid. *Id*. She was assessed with "more recent left shoulder adhesive capsulitis as well after a flu shot." *Id*. at 14. Dr. Pearson noted that Petitioner was scheduled to start physical therapy and be seen by an orthopedist for her shoulder problem. *Id*. at 16.

On May 24, 2017, Petitioner was seen at Results Physiotherapy for an initial evaluation of her shoulder. Ex. 5 at 35. The record stated:

> PATIENT IS A 44 YEAR OLD FEMALE WHO PRESENTS WITH A 5 MONTH HISTORY OF CONSTANT LEFT SHOULDER PAIN AND STIFFNESS OF VARYING INTENSITIES FOLLOWING HER FLU SHOT IN DECEMBER. PATIENT IS LIMITED WITH ANY SHOULDER MOVEMENTS WHICH IS LIMITING HER WITH HER ABILITY TO [PERFORM] HER NORMAL DAILY ACTIVITIES.

Ex. 5 at 35. Petitioner reported a pain level of 7/10 at the time of the appointment, ranging from 4/10 to 9/10. *Id*. at 35. The pain was noted to radiate from her shoulder to her wrist/hand and fingers and thumb. *Id*. The mechanism of injury was recorded as "FLU SHOT Stair Climbing."[3] *Id*. The Date of Injury stated "Month(s) Ago 5." *Id*.

On examination, Petitioner demonstrated reduced range of motion in all planes. Ex. 5 at 36. Her active range of motion was 25% of normal and limited by pain. *Id*. It was

[3] The reference to stair climbing is not explained further.

recommended that Petitioner attend physical therapy three times a week for four weeks. *Id*. at 38. A patient detail report signed by Petitioner on May 24, 2017, the date of her initial physical therapy evaluation, listed a date of injury of "12-1-2016." *Id*. at 90. A patient medical history from the same date listed the problem as having begun on 12/1/16. *Id*. at 102. In response to a question about her expectations of physical therapy, Petitioner wrote "To get my shoulder back to normal, the way it was before I got a flu shot." *Id*. at 103. She reported that "more or less anything the more I do aggravates my shoulder; my fingers are getting to where they are getting numb now." *Id*.

Petitioner attended an additional 15 physical therapy sessions between May 25 and June 30, 2017. Ex. 5 at 41-88. By June 1, 2017, her active range of motion had improved to 50%. *Id*. at 48. The physical therapist noted that Petitioner complained of pain going down from her left shoulder into the wrist. *Id*. at 49. On June 14, 2017, her left shoulder active range of motion had improved to 75% and passive range of motion was 90% in flexion and scaption and 50% in external rotation. *Id*. at 69. At her June 28, 2017 session, Petitioner reported that over the weekend she experienced a loud "pop" in her left shoulder and her range of motion improved thereafter. *Id*. at 85. At her June 30, 2017 session, Petitioner's left shoulder active range of motion was recorded as within normal limits. *Id*. at 87. She was assessed as having progressed well with strengthening and stabilization, and ready to continue on her own with a home exercise program. *Id*. at 88.

On June 1, 2017, Petitioner returned to NP Steffey. Ex. 2 at 1-3. She reported that she had been to pain management and that "[h]er pain in the arm has no[t] changed much with pain along her triceps . . . . She still does not have much motion in left arm. She states physical therapy has been painful as expected. She is to see orthopedist in a couple of weeks." *Id*. at 2.

On June 6, 2017, Petitioner was seen by orthopedist Dr. Jeffrey France. Ex. 6 at 2. Dr. France noted that Petitioner "had an injection in her left shoulder for flu in December 2016. It hurt and she kind of held it still and it has gotten stiff." *Id*. She had an MRI, which confirms some adhesive capsulitis and she is stiff with abduction, external rotation, forward flexion." *Id*. On examination, Dr. France found that Petitioner's left shoulder had "greatly decreased abduction, external rotation." *Id*. Dr. France assessed Petitioner with left frozen shoulder and adhesive capsulitis. *Id*. He concluded that "[t]he important thing is to get motion started. I think the shot probably just hurt and then she held it still and it got significantly stiff and inflamed. Hopefully, we can reverse all this with motion." *Id*. He noted that she was already in physical therapy and that if that was unsuccessful, a closed manipulation (surgical procedure) may be needed. *Id*.

On June 27, 2017, Petitioner returned to Dr. Pearson for a follow up concerning her back pain. Ex. 8 at 29. Her left shoulder range of motion was assessed as 100 degrees in active abduction and 70 degrees in forward flexion. *Id*. at 33. Dr. Pearson noted a "[g]reat improvement with range of motion." *Id*. at 34. Dr. Pearson determined that no procedures were needed given her significant improvement with physical therapy. *Id*. at 35.

On July 11, 2017, Petitioner returned to Dr. France. Ex. 6 at 1. She reported that her shoulder was doing much better with good motion, strength, and stability, and that she had worked hard to reestablish motion. *Id*. On examination, her left shoulder had "good extension, flexion, stability." *Id*. Dr. France indicated that he would see Petitioner as needed, and that both Petitioner and he were pleased with her progress in physical therapy. *Id*.

On July 13, 2017, Petitioner had medial branch blocks placed to help with her back pain. Ex. 8 at 61. Petitioner was seen for back pain by NP Brenda Friend, on July 26, August 24, and October 19, 2017. *Id*. at 37-56. There is no indication in the record that Petitioner's left shoulder was discussed or examined. *Id*.

On January 18, 2018, Petitioner was seen by NP Friend. Ex. 19 at 223. The record noted that she had done physical therapy resulting in improved range of motion. *Id*. She continued to have tenderness in the posterior left upper extremity and shoulder region, but that her orthopedist, Dr. France, did not recommend any further treatment. *Id*. At Petitioner's February 15, 2018 appointment, Dr. Pearson noted that Petitioner's left shoulder pain was "stable – worse with weather but tolerable. Doing her exercises." *Id*. at 244.

On September 11, 2018, Petitioner returned to Dr. France complaining of left shoulder pain. Ex. 11 at 1. She reported that the pain radiated down into her lateral bicep to the level of her elbow. *Id*. at 2. On examination, she exhibited tenderness of the supraspinatus, infraspinatus, subacromial bursa, subdeltoid bursa, and lateral cuff insertion, as well as subjective tenderness of the lateral acromion. *Id*. at 3. On examination, Dr. France found positive impingement signs, recording "Neer's test positive, Hawkin's test positive, and cross chest maneuver (impingement) positive." *Id*. Her range of motion was noted to be normal. *Id*. The record stated that she had "done well with her range of motion and strengthening today seems to be just impingement." *Id*. Dr. France administered a steroid injection into her subacromial space. *Id*.

On September 12, 2018, Petitioner was seen by NP Rebekah Ragan. Ex. 19 at 369. Petitioner reported "increased L shoulder pain. She states this started after a flu shot. She saw orthopedics for this yesterday and they gave her a steroid injection. She states they also ordered an xray of this advised that if injection does not help she will need surgery." *Id*.

On October 23, 2018, Petitioner returned to Dr. France. Ex. 11 at 6. On examination, he found her range of motion in her left shoulder to be "limited and painful." *Id*. at 7. She again displayed positive impingement signs as well as positive results on the O'Brien's test, Speed's test, Yergason's test, and subscapularis lift off test, and the empty can sign was positive. *Id*. Dr. France noted:

> [H]er left shoulder pain seems to be a combination of adhesive capsulitis and sub acromial impingement. she has been doing home PT for a long time without any success and her exam and HPI are concerning for

> something more going on than can be fixed with a CSI [corticosteroid injection] so we will get an MRI to further assess.

Ex. 11 at 7.

On November 7, 2018, Petitioner was seen by NP Ragan. Ex. 19 at 390. She reported "increased L shoulder pain s/t rotator cuff tear." *Id*. A November 1, 2018 MRI was noted as pending. *Id*.

A second left shoulder MRI was performed. Ex. 11 at 11. The record is undated but has a fax date of November 19, 2018. *Id*. The MRI showed "[n]o appreciable fluid in subacromial/subdeltoid bursa . . . . Infraspinatus tendinosis with a small intrasubstance tear of the posterior fibers at the insertion" as well as mild degenerative changes. *Id*.

On November 20, 2018, Petitioner returned to Dr. France to review her MRI results. Ex. 11 at 8. On examination, her left shoulder range of motion was "full but slightly painful, specifically with abduction." *Id*. at 10. She continued to exhibit positive impingement signs. *Id*. Dr. France noted that the MRI showed findings of impingement and a partial thickness rotator cuff lesion. *Id*. In light of Petitioner's "good but painful function of the shoulder," he recommended conservative treatment including physical therapy, injection therapy, and anti-inflammatory medication. *Id*. If that was not successful, surgical options could be discussed. *Id*. Petitioner indicated that she wanted to do the exercises on her own rather than returning to formal physical therapy. *Id*.

On February 4, 2019, Petitioner returned to Dr. Pearson for back pain. Ex. 19 at 449. Petitioner reported that she was still working on her exercises to keep her left shoulder mobile, and that she experienced increased pain after her exercises. *Id*. On examination, her left shoulder range of motion was found to be abnormal and she exhibited tenderness, positive impingement signs, and positive results on the cross arm test. *Id*. at 452. Dr. Pearson noted that strengthening, and not surgery, had been recommended for her left shoulder. *Id*. at 454.

On February 27, 2020, Petitioner was seen by NP Rebekah Weaver for back pain. Ex. 19 at 640. She also reported "increase intermittent in the left shoulder pain; reports she was given a flu shot wrong about 4 yrs ago." *Id*. Petitioner reported that "colder weather exacerbates her left shoulder pain which she reports began after flu shot 4 years ago." *Id*. at 644.

On April 23, 2020 and May 21, 2020, Petitioner was seen by video by NP Shawna Smith for back pain and shoulder pain. *Id*. at 667-68, 690. She reported an increase in left shoulder pain, and that her pain increased with rainy weather. *Id*. at 668. She reported a severity level of 6/10 and that the problem had been waxing and waning and was associated with limited range of motion and stiffness, but no joint swelling, numbness, or tingling. *Id*. at 669, 690.

C. Expert Reports

1. Petitioner's Expert Report

Petitioner provided an expert report from Naveed Natanzi, D.O., a board-certified specialist in physical medicine and rehabilitation with fellowship training in interventional sports and spine medicine. Ex. 14 at 1. Dr. Natanzi stated that he was trained by Marko Bodor, M.D., the first medical professional to describe SIRVA in literature from 2006. *Id*.

In his expert report, Dr. Natanzi summarized the records he had reviewed and relevant medical literature. Ex. 14 at 1-7. He found no evidence that Petitioner had a native left shoulder dysfunction prior to vaccination. *Id*. at 1-2. He noted that her pre-vaccination medical history included "complaints of vague myofascial pain but no native shoulder pathology" or dysfunction. *Id*. Following the December 1, 2016 flu shot, however, her records repeatedly indicated that she reported pain in her left shoulder since her flu shot. *Id*. at 2-4.

Dr. Natanzi opined that Petitioner's left shoulder pain was "a direct result of the influenza vaccine she received on 12/1/16." Ex. 14 at 1. He noted that Petitioner described atypical severe pain in her left arm immediately after vaccination. *Id*. at 8. Petitioner reported that when the vaccine was administered, Petitioner was seated with her left arm in a resting, non-abducted position by her side, and the injector was standing. *Id*.

Dr. Natanzi acknowledged Petitioner's "long history of fibromyalgia (FM) with chronic diffuse body aches stemming back to 2009-2010" that included "diffuse myofascial pains in the upper back, lower back, and shoulders." Ex. 14 at 8. However, he explained that fibromyalgia is "markedly different in clinical presentation than symptoms related to a structural shoulder injury." *Id*. FM symptoms are diffuse and throughout the body, while Petitioner's shoulder pains were focal and isolated. *Id*. He added that it would be "extremely unlikely to see left shoulder adhesive capsulitis with FM alone . . . . [while] in the context of SIRVA, adhesive capsulitis is a very common finding." *Id*.

Dr. Natanzi discussed Petitioner's limitations, and stated that "[t]he inability to perform behind the back movements such as putting on and off a bra are further suggestive of rotator cuff dysfunction, and again generally unlikely in the context of FM alone." Ex. 14 at 8. He added:

> In summary, although it is likely that Ms. Bishop experienced a heightened response to the dysfunction associated with vaccine overpenetration as a result of underlying FM, this does not change the fact that the vaccine did over-penetrate causing SIRVA. In other words, had a vaccination been properly administered, as in previous vaccinations (i.e. 11/18/15), it is extremely unlikely that these symptoms develop despite the presence of FM. As such, I opine that the presence of FM does not negate the fact that Ms. Bishop was in fact injured by her vaccination.

Id. at 8-9.

Dr. Natanzi acknowledged that Petitioner's history included chronic pain and multiple doctor visits, but found convincing that there were "never complaints of structural left shoulder dysfunction until post-vaccination" and that the first record of shoulder dysfunction was on March 9, 2017, when Petitioner reported left shoulder pain since December 1, 2016. Ex. 14 at 9. He described that record as "limited and poorly described" but noted that it documented joint pain and range of motion pain. *Id*. He added that Petitioner averred that she mentioned her shoulder symptoms to the nurse practitioner on February 9, 2017 "which may be referred to in the again incomplete note where it was written, 'she now has the other complaints.' " *Id*. He concluded:

> Given the lack of structural left shoulder dysfunction preceding the vaccination, coupled with the lack of any other injury or accident to explain the shoulder symptoms, all in conjunction with Ms. Bishop's affidavit outlining immediate onset of symptoms, I opine to a reasonable degree of medical certainty that Ms. Bishop's symptoms developed immediately after the vaccination. As such, this clinical scenario falls well in line within the generally accepted timeframe of symptoms in SIRVA cases (pain within 48 hours).

Id.

Dr. Natanzi then addressed the "tingling" noted as a symptom of pre-existing chronic back pain. Ex. 14 at 9. He stated that "there is no neuro-anatomic association where any low back dysfunction would present with upper extremity symptoms, namely [tingling]. Assuming that Ms. Bishop was experiencing tingling and the note erroneously listed it under the low back paragraph, the presence of isolated tingling is extremely non-specific and would certainly have no bearing on this claim." *Id*.

With respect to the records indicating that Petitioner's pain extended to her fingers and thumb, Dr. Natanzi stated:

> Radiating pains associated with tingling are common findings in cases of SIRVA. In fact, altered sensation in the ipsilateral [same side] limb after SIRVA was recorded by Atanasoff et al. in four patients out of a cohort of thirteen. Similarly, Okur et al. describe a cool, numb, and heavy sensation with radiating pains along the affected limb in a SIRVA patient immediately after vaccination. As such, in light of no history of other diagnoses (i.e., cervical radiculopathy, peripheral mononeuropathy, etc.) to suggest otherwise, I believe the hand symptoms experienced by Ms. Bishop were directly related to SIRVA."

Id. at 9-10.

Dr. Natanzi then reviewed the temporal course of events in this case and found that they "are consistent with SIRVA." Ex. 14 at 11. He described the sequence of events

as inadvertent over-penetration of the vaccination needle, resulting in bursal, capsular, and/or tendinous penetration, causing immediate sharp radiating pain, numbness, and discomfort associated with limited range of motion on the day of vaccination. *Id*. This resulted in the vaccine interacting with antibodies from prior vaccination and an exaggerated robust and prolonged inflammatory response. Ultimately, he opined that this sequence of events resulted in inflammation of the joint capsule and development of impingement, adhesive capsulitis, and reduced range of motion. *Id*.

Dr. Natanzi stated that for the reasons set forth in his report, he did not believe that Petitioner's fibromyalgia was a condition or abnormality that would explain Petitioner's symptoms. Ex. 14 at 11. Dr. Natanzi concluded:

> Ms. Bishop's symptoms closely mimic those of the SIRVA cases described in medical literature. Given the outlined temporal relationship of symptoms to the vaccine, evidence of improper vaccination technique, and the absence of any pre-vaccination shoulder dysfunction, it is more likely than not that the influenza vaccination on 12/1/16 caused Ms. Bishop's left shoulder dysfunction . . . . I see nothing in this case to preclude a SIRVA diagnosis.

Id. at 12.

2. Respondent's Expert Report

Respondent provided an expert report from Paul J. Cagle, M.D., Assistant Professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. Ex. A at 1. Dr. Cagle states that he is a Board Certified Orthopaedic Surgeon with fellowship training in shoulder surgery. *Id*. He is a member of the American Shoulder and Elbow Surgeons, the American Academy of Orthopaedic Surgeons, and the American Orthopaedic Association. *Id*. He states that his current practice focuses on shoulder problems, which represent approximately 95% or more of the patients and pathology he treats. *Id*.

Dr. Cagle's curriculum vitae ("CV") shows that he earned his medical degree at Loyola University Stritch School of Medicine. Ex. B at 1. He then did an orthopaedic residency at the University of Minnesota, followed by a Shoulder and Elbow Fellowship at Mount Sinai in New York and a Shoulder Fellowship at a private hospital in Lyon, France. *Id*. His CV lists grant funding, a patent, honors and publications, presentations, research, and other professional activities. *Id*. at 2-17.

In his expert report, Dr. Cagle focused on the two medical appointments between the December 1, 2016 vaccination and the March 9, 2017 record showing that Petitioner reported shoulder pain. Ex. A at 2. He noted that Petitioner was seen on January 10, 2017 and February 9, 2017, and that "[t]hese two visits demonstrate a pattern of diffuse muscle and joint pain involving multiple areas of her body." *Id*. The first record of shoulder pain, on March 9, 2017, indicated that Petitioner reported pain in her left triceps. *Id*. He noted

that the April 14, 2017 MRI showed minimal fluid in the shoulder joint and subacromial subdeltoid bursa. *Id*.

Dr. Cagle then discussed the proposed mechanism of injury. He noted that current Centers for Disease Control and Prevention guidelines would call for a 1-inch needle for Petitioner. Ex. A at 3. He added that studies have found this to be a safe needle length, and thus "it can be presumed that . . . the risk of 'overpenetration' was quite low." *Id*.

Dr. Cagle then noted that Petitioner's medical records do not reflect any report of shoulder pain until over three months after vaccination. Ex. A at 3. In the interim, Petitioner was seen and treated twice for pain in her muscular skeletal system, noted as back pain and joint pain. *Id*. As Dr. Cagle noted:

> This finding is of significance. Had she been evaluated for a completely unrelated event, it could be conceivable that new onset shoulder pain would not have been discussed, but as she was presenting for treatment of back and joint pain, pains in the muscular skeletal system were clearly assessed and discussed during the visit. Thus for over 3 months, there was no mention or record of shoulder pain, even though Ms. Bishop had two visits for joint and back pain. Shortly after Ms. Bishop reported her shoulder pain, an MRI was performed and showed minimal fluid in the shoulder joint and subacromial subdeltoid bursa. This is again of significance as an injection into either the capsule or the bursa capable of causing adhesive capsulitis would cause inflammation and a fluid response. A fluid reaction to an influenza injection has been documented in the literature and a lack of fluid response on the MRI from 4/14/2017 speaks against a claim of acute reaction from the vaccination.

Id. at 4.

Dr. Cagle then critiqued Dr. Natanzi's report by asserting that Dr. Natanzi "incorrectly assessed or [did] not read" Ex. 14.10, a medical journal report by Arias et al.,[4] and, as a result, miscalculated the number of SIRVA cases reported in the literature. Ex. A at 4. Dr. Cagle added that there is "no documentation at all of the technique utilized for the vaccination, this [that an improper technique was used for the vaccination at issue] is only speculative and I do not understand where the assertion is being derived from." *Id*. at 5. Dr. Cagle otherwise had "concerns about relying on [statements in Petitioner's affidavit] as they do not coincide with the lack of reported shoulder pain demonstrated in the medical records." *Id*. Dr. Cagle concluded that there was no definitive evidence of inappropriate vaccination technique, no documentation of appropriate timing of onset of symptoms, and thus "it is highly unlikely that the influenza vaccination which occurred on 12/1/2016 and any subsequent shoulder pain or injury experienced by Marie Bishop are correlated." *Id*.

[4] L.H. Martin Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations*, 35 Vaccine 4870 (2017), filed as Petitioner's Exhibit 14.10, Respondent's Exhibit A15.

D. Affidavit Evidence

Petitioner has filed an affidavit explaining the administration of the December 1, 2016 flu vaccine, the symptoms she experienced thereafter, and her subsequent seeking of medical care. Ex. 13. She was seated on the exam table while the nurse who administered the vaccine was standing. *Id*. at ¶ 2. The nurse "jabbed [the needle] into my upper left arm . . . . [and] it burned and hurt. Immediately following vaccination, I felt pain in my left shoulder. The pain and burning continued to hurt after she administered the shot. It was the worst pain that I have ever had when receiving a flu vaccine . . . . When I first received my injection, my range of motion was affected. . . . Later on that night my left arm and shoulder [were] still sore." *Id*.

Petitioner further explained that the pain continued through December 2016 and January 2017. Ex. 13 at ¶ 3. This pain was intermittent, and thus she did not think much of it. *Id*. However, over time, the condition progressed to where she could no longer lift her arm in front of her or over her head. *Id*. She explained that she did an internet search of her symptoms in February or March 2017, and found a person describing symptoms similar to hers that resulted from a flu vaccine. *Id*. at ¶ 5. Until then, she had not realized that the flu vaccine could cause this kind of injury. *Id*.

Regarding her January 10, 2017 appointment, Petitioner stated that she was a new patient, and was trying to focus on remembering what to discuss/mention, while NP Steffey had a lot of questions. *Id*. at ¶ 8. As a result, and due to her desire to end the appointment quickly, she neglected to mention her shoulder/arm pain at this time. *Id*. At the February 9, 2017 appointment, however, Petitioner recalled saying something to NP Steffey about her arm at the end of the appointment. *Id*. at ¶ 9. In response, Petitioner recalls, NP Steffey told her that if her arm was still hurting at her next appointment, he would order x-rays, which he in fact did after the March 9, 2017 appointment. *Id*.

Petitioner has also submitted an affidavit from her husband, David Bishop. Ex. 16. He avers that he took her to the December 1, 2016 appointment at which she received the flu shot. *Id*. at ¶ 2. He stated that he waited for her in the lobby and that when she came out, she told him that "the shot they gave her didn't feel like the other Flu shots she had gotten before. She told me that it hurt and burned immediately when the nurse had given it to her, and she had felt pain in her left shoulder afterwards." *Id*. In particular:

> She took her bandaid off when she got home and it was up high toward the back of her arm in the back of her shoulder. She was very sore and she began to swell after a few days and it got harder for her to raise her arm up in front of her even above her head. I was there when she took her bandaid off. I remember she wouldn't let me take it off because she was in so much pain.

Id. at ¶ 4. Mr. Bishop adds that "I would have to help my wife for awhile with getting her bra on." *Id*. at ¶ 5. He explained that the pain continued through Christmas and "she had a hard time doing some things with her arm such as picking up plates." *Id*. at ¶ 7.

In addition, Petitioner submitted an affidavit from her mother in law, Leala Bishop. Ex. 17. This affidavit averred that Petitioner "never complained about pain in her shoulder until she had the flu vaccination in December of 2016." *Id*. at ¶ 2. However, around Christmas of 2016, "I remember her telling me of the flu shot and how her arm had swollen as the days went by . . . . I remember her arm hurting her and seeing her having difficulty in putting her arm around to the front of her and to the side, she was in pain . . . . she couldn't hardly raise her arm." *Id*. at ¶ 3. As this affiant explained:

> She had told me over several different times about when she went and got the vaccine shot and the pain afterwards. She had talked about it had burned and hurt afterwards . . . . she would hold her shoulder when she would come over to visit and complain of pain . . . Melissa would complain or favor her left shoulder . . . . She can only put her arm/hand, not very far in the back of her back . . . . She still has pain.

Id. at ¶¶ 4-6.

Petitioner's mother, Paula Trent, also submitted an affidavit. Ex. 18. She averred that "my daughter has never had a prior injury to her left arm/shoulder ever before December 1, 2016." *Id*. at ¶ 2. After the December 1, 2016 vaccination, however, Ms. Trent stated:

> 3. . . . I remember her complaining to me the day she received her vaccination on December 1, 2016, that when she went to the doctor that she got a Flu shot earlier that day and that when the nurse gave it to her it felt different . . . .
> 4. I remember a few days went by that when I had talked to her again she had told me it was swollen . . . . and it was kind of hard to put her arm in front of her and to the side of her, and she could barely extend her arm outward.
> 5. I had talked to her again about a week following the vaccination and her pain had not gotten any better. It had gotten harder for her to put her arm up in front of her and above her head. She couldn't get plates out of the cabinet . . . .
> 6. At Christmas that year, I remember as we gathered for family time that my daughter was holding her left arm and rubbing her shoulder a lot. I remember asking her what was wrong and she had reminded me of the Flu shot she had got and I couldn't believe that she was still hurting from that. I had told her she might should get it looked at. But my daughter, as I know, my daughter puts off going to the doctor until the last minute, she is that much like her dad.
> 7. I remember seeing her range of motion in her left shoulder continue to go down into March 2017.

Id. at ¶¶ 3-7.

III. Ruling on Entitlement

In this case, Respondent has represented that he no longer intends to defend this case, but does not otherwise concede that Petitioner is entitled to compensation. In similar circumstances, special masters have determined that it is appropriate to proceed to decide entitlement. *See,* e.g., *Davis v. Sec'y of Health & Human Servs.*, No. 09-295V, 2010 WL 3790178, at *3 (Fed. Cl. Spec. Mstr. Sept. 8, 2010) (noting that "respondent does not concede liability in this case [but] has stated . . . that respondent will not expend any further resources to defend this case" and proceeding to rule on entitlement).

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1). Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.* In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[5] a petitioner must establish that she suffered an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C). In this case, the claim is analyzed as an off-Table, or causation in fact, claim based on the allegations of the Petition. Petition at ¶ 14.

A petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351. The Federal Circuit has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface,* 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Federal Circuit subsequently reiterated these requirements in a three-pronged test. *See Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required:

[5] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E). These requirements are not contested in this case and I find that the medical records and other evidence establish that they are met.

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Althen,* 418 F.3d at 1280.

Although the first and second prongs of *Althen* appear to be similar, these analyses involve different inquiries. *See Doe 93 v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 553, 566-67 (2011). The first prong focuses on general causation - whether the administered vaccine *can* cause the particular injury suffered by the petitioner; while the second prong focuses on specific causation - whether the administered vaccine *did* cause the injury. *Pafford v. Sec'y of Health & Human Servs.,* 451 F.3d 1352, 1355-56 (Fed. Cir. 2006).

In this matter, I find preponderant evidence exists with respect to all three *Althen* prongs, thus entitling Petitioner to an award of damages. I discuss the bases for my conclusion below.

A. Althen Prong One

Even though this case is a non-table claim, I take judicial notice of the fact that Respondent has added SIRVA after receipt of an intramuscularly administered seasonal flu vaccine to the Table.[6] Thus, in proposing the Table addition of SIRVA, Respondent discussed the scientific evidence regarding the means by which this injury is caused – and in so doing specifically referenced two articles also offered in connection with both expert reports in this case. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45136-37 (July 29, 2015); S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Petitioner's Exhibit 14.5 and Respondent's Exhibit A4 (ECF Nos. 23-7 and 29-5) ("Atanasoff"); M. Bodor and E. Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Petitioner's Exhibit 14.2 and Respondent's Exhibit A4 (ECF Nos. 23-4, 29-12) ("Bodor").

[6] Although claimants may not rely expressly on the Table elements of a claim comparable to a non-Table claim to meet their burden of proof, the fact that the Table has been amended to add a claim naturally suggests the existence of reliable scientific or medical evidence in support of the "can cause" prong. *See Doe 21 v. Sec'y of Health & Human Servs.,* 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds,* 527 Fed. Appx. 875 (Fed. Cir. 2013).

These articles provide persuasive and reliable support for the conclusion that the flu vaccine could cause a SIRVA injury. The mechanism set forth in Atanasoff is described as "the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Atanasoff, Ex. 14.5 at 1. As its authors indicated, this results in an inflammatory response which may be prolonged due to pre-existing antibody in the synovial tissue from an earlier, naturally-occurring infection or vaccination. *Id.* at 3. They also observed that bursitis and greater fluid in the bursa were two of the findings often seen in MRI studies of vaccine injured shoulders. Atanasoff further mentioned that many of the patients they studied may have had prior conditions such as rotator cuff tears which only became symptomatic following the improper vaccine injection. To distinguish this type of vaccine-related shoulder injury from conditions caused by a mechanical injury or overuse, the authors pointed to "the rapid onset of pain with limited range of motion following vaccination" which was seen in the patients they studied. *Id.* Bodor provides additional support for this proposed mechanism.

This scientific/medical evidence comprises preponderant evidence supporting the conclusion that the seasonal flu vaccine, when administered intramuscularly but improperly injected in the synovial space, can cause an inflammatory response resulting in shoulder injury. Petitioner has therefore satisfied the first *Althen* prong.

B. Althen Prong Two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu v. Sec'y of Health & Human Servs.,* 569 F.3d 1367, 1375-77 (Fed. Cir. 2009)); *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1326 (Fed. Cir. 2006)*; Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" an injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("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).

In his expert report, Dr. Natanzi opined that the following sequence of events, consistent with SIRVA, explained Petitioner's injury. He theorized that inadvertent over-penetration of the vaccination needle resulted in bursal, capsular and/or tendinous penetration, causing Petitioner to experience immediate sharp radiating pain, numbness, and discomfort associated with limited range of motion on the day of vaccination. Then, he suggested, the vaccine interacted with naturally occurring antibodies from a prior vaccination, resulting in an exaggerated robust and prolonged inflammatory response.

This, he proposed, resulted in inflammation of the joint capsule and development of impingement, adhesive capsulitis, and reduced range of motion. Ex. 14 at 11.

The medical records contain evidence corroborating Petitioner's contention that the flu vaccine caused Petitioner's shoulder injury in the manner described by Dr. Natanzi. At the appointment when Petitioner received the vaccine, she reported back pain but no other musculoskeletal issues. Ex. 7 at 99. Shortly thereafter, however, she developed pain within 48 hours that persisted and worsened over time. After three months, Petitioner sought care for her shoulder pain and reduced range of motion. Her symptoms persisted, and an MRI showed fluid in her shoulder joint and subacromial subdeltoid bursa, as well as tendinopathy.

Dr. Cagle focuses on the MRI noting "minimal" fluid, and finds this significant. Ex. A at 4. He argues that an injection capable of causing adhesive capsulitis would cause inflammation and a fluid response, and that "a lack of fluid response on the MRI from 4/14/2017 speaks against a claim of acute reaction from the vaccination." *Id*. Dr. Cagle seems to wrongly interpret "minimal fluid" to mean no fluid at all. He inaccurately discusses the April 2017 MRI as showing a lack of fluid response; instead, the MRI *does* show a fluid response, which Dr. Cagle agrees would be present with an injection that led to adhesive capsulitis.

I find that the preponderance of the evidence demonstrates that Petitioner's December 1, 2016 flu vaccine likely caused her left shoulder injury.

C. Althen Prong Three

The third *Althen* prong "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs*., 539. F.3d 1347, 1352 (Fed. Cir. 2008).

On September 20, 2019, a fact ruling was issued finding that the onset of Petitioner's left shoulder pain occurred within 48 hours of vaccination, which is the required timing for a Table SIRVA.[7] This fact finding is also sufficient to satisfy the third

[7] Respondent's amended Rule 4(c) Report asserts in a footnote that the September 20, 2019 fact ruling acknowledged that expert reports were filed but did not address the experts' opinions regarding onset. Respondent's Amended Rule 4(c) Report, at *8, n.3.

While the onset ruling did not expressly discuss the experts' opinions on onset, I have reviewed those opinions and find that they do not cast doubt on the onset ruling. I acknowledge that Dr. Cagle emphasized the significance of the fact that the January 10 and February 9, 2017 appointments involved Petitioner's muscular skeletal system but not her shoulder injury. However, I note that Petitioner did report non-specific

Althen prong here, since that timeframe has been shown by the evidence offered by Petitioner to be medically acceptable.

IV. Conclusion

Having reviewed the affidavits, medical records, expert reports, and documentation in this case, I find that Petitioner has provided preponderant evidence to establish that the flu vaccine she received on December 1, 2016, likely caused her to suffer pain and reduced range of motion in her left shoulder. Petitioner is therefore entitled to compensation under the Vaccine Act. A damages order will be issued setting the next deadline in this case.

IT IS SO ORDERED.

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

"joint pain" at these visits. Dr. Cagle implies that the lack of specifically-identified shoulder pain means that Petitioner did not have shoulder pain at the time of those appointments. However, Petitioner explained that she did not discuss her shoulder pain with her care provider at the January appointment because the appointment was long and she was tired, and that she did mention it at the end of the February appointment. I find Petitioner's explanation to be consistent with the medical records. Moreover, I note that at the time of the January and February 2017 appointments, Petitioner was taking prescription pain medication which, even if not prescribed for her shoulder pain, likely alleviated that pain at least somewhat. Finally, Petitioner explained that the pain following vaccination initially was intermittent and thus she did not think much of it, but she became concerned when it worsened over time. In addition, she explained that she was unaware that a flu vaccine could cause a shoulder injury until February or March of 2017.

Reviewing the record as a whole, I find that a preponderance of the evidence supports the finding that the onset of Petitioner's shoulder pain began within 48 hours of vaccination. Therefore, I affirm the September 20, 2019 fact ruling.