In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: March 17, 2025

VICTORIA MARCUS,	*	
	*	No. 19-812V
Petitioner,	*	
v.	*	Special Master Gowen
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Leah V. Durant, Law Office of Leah V. Durant, PLLC, Washington, D.C., for petitioner.
Jennifer L. Reynaud, U.S. Dept. of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On June 3, 2019, Victoria Marcus ("petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program.[2] Petition (ECF No. 1). Petitioner alleges that she suffered a left shoulder injury as a result of receiving an influenza ("flu") vaccination on November 10, 2017. *Id.* After a review of the record, including medical records, affidavits, expert reports and accompanying medical literature, for the reasons set forth below, I find by preponderant evidence that petitioner is entitled to compensation.

I. Procedural History

Petitioner filed her claim on June 3, 2019, alleging she had sustained a left shoulder injury related to vaccine administration ("SIRVA") caused by the intradermal vaccine she received on November 10, 2017. Petition. Petitioner filed medical records to support her claim on June 14, 2019. Petitioner's Exhibits ("Pet'r Exs.") 1-7 (ECF No. 7).

[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

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On November 19, 2020, respondent filed a Rule 4(c) report recommending against compensation, stating that petitioner cannot demonstrate a Table SIRVA injury because the vaccine she received was administered intradermally and that she had not filed a report from an expert to support her cause-in-fact claim. Respondent's ("Resp't") Report (ECF No. 24).

Petitioner filed an expert report from orthopedic surgeon, Dr. Uma Srikumaran[3] on September 15, 2021. Pet'r Ex. 10 (ECF No. 29). Respondent filed an expert report from orthopedist, Dr. Julie Bishop.[4] Resp't Ex. B (ECF No. 30). I held a Rule 5 status conference on January 10, 2024, recommending that the parties seek to resolve this case informally. *See* Scheduling Order (ECF No. 32). On May 17, 2024, respondent filed a status report stating that it is his position that "this case is not appropriate for settlement," and requested a schedule be set for briefing entitlement. Resp't Status Rept. (ECF No. 37). On July 17, 2024, petitioner filed the instant motion for a ruling on the record. Pet'r Motion ("Mot.") ECF No. 39. Respondent filed a response on October 24, 2024, and petitioner filed a reply on November 8, 2024. Resp't Resp. (ECF No. 42); Pet'r Reply (ECF No. 43).

This matter is now ripe for adjudication.

II. Background

a. Summary of Medical Records

Petitioner was the director of a salon spa when she received the intradermal flu vaccine in her left deltoid on November 10, 2017. Pet'r Ex. 1 (ECF No. 7). Her past medical history included pain in the left hip, thrombocythemia, and hypertension. *See* Pet'r Ex. 2 at 23, 28. At

[3] Dr. Srikumaran serves as an associate professor in the Shoulder Division at the Johns Hopkins School of Medicine and serves as the Shoulder Fellowship Director and Chair of Orthopaedic Surgery for the Howard County General Hospital. Pet. Ex. 11 at 1. He also serves as the Medical Director of the Johns Hopkins Musculoskeletal Service Line in Columbia, Maryland. *Id*. Each year Dr. Srikumaran sees approximately 2500-3000 patients for shoulder issues and performs 400-500 shoulder surgeries annually. *Id*. He has treated approximately ten to twelve patients with shoulder dysfunction after vaccination in the past five years. (Id.) Dr. Srikumaran received his medical degree from Johns Hopkins School of Medicine in 2005. *Id*. He completed his orthopaedic residency at Johns Hopkins Hospital and completed a shoulder surgery fellowship at Massachusetts General Hospital. *Id*. Dr. Srikumaran is board certified in orthopaedic surgery. *Id*. at 10. He peer-reviews journal articles for several orthopaedic journals including The Journal of Bone & Joint Surgery, Orthopedics, Clinical Orthopedics and Related Research, and The Journal of Shoulder and Elbow Surgery. *Id*. 1-2. Dr. Srikumaran was selected to serve on the Shoulder and Elbow Content Committee for the American Academy of Orthopaedic Surgery. *Id.*

[4] Dr. Julie Y. Bishop is a board-certified Orthopaedic Surgeon and specializes in shoulder surgery. Resp't Ex. C at 1; Resp't Ex. B at 1. She currently is a Professor of Orthopaedics at the Ohio State University, Wexner Medical Center and is the Chief of Division of Shoulder Surgery at the same institution. Resp't Ex. C at 2. Dr. Bishop received her medical degree from Cornell University Medical College in 1997 and did a General Surgery Internship at the George Washington University in Washington, D.C., followed by an Orthopaedic Residency at the same institution. *Id.* at 1. After her residency, Dr. Bishop went to Mt. Sinai Hospital in New York, New York for a Shoulder Surgery Fellowship. *Id.* at 2. She is currently licensed to practice medicine in the State of Ohio, but was previously licensed in Washington, D.C. and New York State. *Id.* at 2. In 2019, Dr. Bishop was awarded OSU Orthpaedic Educator of the Year. *Id.* at 3. She has been a lead author and co-author on numerous medical articles focused on shoulder-related issues and treatments. *Id.* at 9-10. Dr. Bishop stated that she has treated multiple SIRVA patients. Resp't Ex. B at 1. She is accepted as an orhopaedic expert.

her most recent general health examination, petitioner reported that she was exercising regularly, including walking, lifting, circuit training and cardio, and helping with her grandchildren. *Id.* at 23. Petitioner had also sought treatment at Shady Grove Orthopaedics for "right thumb and wrist pain," right knee pain, and pain in her left hip. *See generally* Pet'r Ex. 5.

On January 31, 2018, petitioner had an appointment with orthopedist, Dr. Mark A. Peterson at Shady Grove Orthopaedics. Pet'r Ex. 5 at 15. Under "History of Present Illness," the record provides, "[Petitioner] is a 59 y/o female here c/o left shoulder pain. She describes a few months of pain and stiffness in her shoulder. She denies any injury or trauma." *Id.* The physical examination of petitioner's left shoulder showed "50 degrees of external rotation at side (90 degrees on the right side), -20 degrees of external rotation at 90, 90 degrees of abduction…and internal rotation to L5 (T12 on right side). Pain at extremes of motion. Intact strength." *Id.* at 15. Dr. Peterson diagnosed petitioner with adhesive capsulitis of the left shoulder and gave her a steroid injection. *Id.* He also referred her to physical therapy.

Petitioner had her initial physical therapy appointment on February 20, 2018. Pet'r Ex. 3 at 13. The "Date of Injury" was recorded as November 11, 2017. *Id.* Under "History of Injury/Recent Aggravation," the record states, "shoulder pain started after getting the flu shot in LUE(11/11/2017); restriction in ROM follows, x-rays for adhesive capsulitis, got steroid [injection]." *Id.* Petitioner reported that the steroid injection she got "three weeks ago" helped a lot with range of motion," and she was taking over-the-counter medication as necessary for pain. *Id.* Her abduction was 150 degrees, external rotation was 95 degrees, internal rotation at 42 degrees, and she had positive empty can and drop arm tests and positive for pain. *Id.* The examination also noted "weakness of the left scapula." *Id.* Physical therapy was recommended twice a week for 6-8 weeks. *Id.*

Petitioner participated in 10 physical therapy sessions, with her last being on April 10, 2018. At the March 20, 2018 appointment, petitioner reported that her symptoms were getting better, but that she was having difficulty zipping up her skirts when reaching behind her. Pet'r Ex. 3 at 8. On March 24, 2018, petitioner reported having significant tightness and pain in her left cervical region that was radiating into her left shoulder. *Id.* at 7. At the next PT appointment, on March 27, 2018, petitioner explained that she was having difficulty sleeping, as she was trying not to "roll onto her left shoulder." *Id.* at 6. The "Assessment" section of this record states, "left shoulder sore and painful during abduction range of motion." *Id.*

Petitioner returned to Dr. Peterson on April 4, 2018. Pet'r Ex. 5 at 17. The reason for the appointment was "follow-up left shoulder and left hip." *Id.* Under the "History of Present Illness: Left Shoulder," the record states, "I saw her 2 months ago for pain and stiffness in this shoulder, diagnosed as adhesive capsulitis. She received an intraarticular corticosteroid injection and was referred to PT. She has made some improvements since then." *Id.* The exam of petitioner's left shoulder showed that her external rotation was 45 degrees, abduction 85 degrees, and her internal rotation was to L5. *Id.* Dr. Peterson again diagnosed petitioner with left shoulder adhesive capsulitis and administered another corticosteroid injection to her left shoulder. *Id.* at 17-18.

Petitioner returned to physical therapy two days later, on April 6, 2018. Pet'r Ex. 3 at 4. The record states that petitioner's pain level decreased due to the second steroid injection, but her left shoulder's range of motion was still restricted in all directions. *Id.* Under "Assessment" it noted that petitioner had "no significant change in range of motion." *Id.*

On June 15, 2018, petitioner returned to Dr. Peterson for a follow-up appointment. Pet'r Ex. 5 at 19. He noted that she had two steroid injections and had been attending physical therapy, but her shoulder "remains stiff and painful." *Id.* The examination showed petitioner had 40 degrees of external rotation at her side, abduction was 90 degrees, -20 degrees of external rotation at 90 degrees. *Id.* Dr. Peterson explained to petitioner that because of her persistent symptoms, "she will likely have to consider surgery, which would include an arthroscopic lysis of adhesions." *Id.* He diagnosed petitioner with left shoulder adhesive capsulitis and ordered an MRI. *Id.*

Petitioner had an MRI of her left shoulder on June 21, 2018. Pet'r Ex. 6 at 4. The MRI found "mild supraspinatus tendinosis without tear; mild-to-moderate proximal biceps head tendinosis with additional thinning indicative of a chronic partial-thickness tear; and mild-to-moderate acromioclavicular osteoarthritis with mild subchondral osseous stress edema in the distal clavicle." *Id.*

Petitioner went to Progressive Spinal and Sports Rehabilitation for physical therapy on July 12, 2018 for "adhesive capsulitis." Pet'r Ex. 4 at 7. The record indicates that petitioner's symptoms appeared in "Oct. 2017." *Id.* at 7. The initial evaluation showed petitioner had tightness and tenderness in her left infraspinatus, left supraspinatus, left brachialis, and left subscapularis. *Id.* at 12. Petitioner had "marked pain and limited [range of motion] with Neer's and Hawkin's test on her [left] side; mild with pain and weakness with supraspinatus press test on left side; and trapezius tightness with stretch response present with shoulder depression test." *Id.* Her range of motion was recorded as flexion 100 degrees, external rotation to L4, and abduction to 120 degrees. *Id.* It was recommended that petitioner have physical therapy twice a week for six to eight weeks. *Id.* She attended two more physical therapy sessions on July 17 and 19, 2018.

On August 20, 2018, petitioner reported to her PCP that she was "still dealing with the pain and decreased range of motion" in her left shoulder due to frozen shoulder. Pet'r Ex. 2 at 8. Under History of Present Illness, it stated that petitioner has "left frozen shoulder following flu shot; 2 injections, PT." *Id.* Although petitioner's review of symptoms and physical exam were normal, she was diagnosed with "Adhesive capsulitis of left shoulder." *Id.* at 10.

Petitioner had an appointment with Dr. Peterson on January 15, 2019 for a review of the MRI of her left shoulder. Pet'r Ex. 5 at 21. Dr. Peterson noted that he saw her seven months ago and that she was "frustrated at her lack of progress," *Id.* In this record, he wrote, "She returns today reporting no real changes in her symptoms since I saw her. She reports that her symptoms began the day after receiving the flu vaccine on 11/10/2017, followed by progressively worsening symptoms." *Id.* The examination of the left shoulder showed some improvement in abduction to 150 degrees, tight external rotation at 90 degrees, -25 degrees of external rotation at side and her internal rotation to L5 remained as it had been. *Id.* He wrote, "MRI of the left

shoulder is consistent with adhesive capsulitis." *Id.* Dr. Peterson diagnosed petitioner with adhesive capsulitis of the left shoulder and encouraged her to continue a stretching program to increase range of motion. *Id.*

On April 9, 2019, petitioner had an appointment with Dr. Peterson for a follow-up regarding left shoulder pain. Pet'r Ex. 7 at 1. He noted that he had "followed her over the past 14 month for adhesive capsulitis of this shoulder," and that "she returns today reporting that she has not had any real improvement from when I last saw her." *Id.* In this same record, Dr. Peterson wrote, "she reports that her symptoms began the day after receiving a flu vaccine on 11/10/2017." *Id.*

Petitioner had a follow-up appointment with Dr. Peterson on August 9, 2019 for her left shoulder. Pet'r Ex. 30 at 1. Dr. Peterson wrote that the last time he saw the petitioner, he recommended a Home Exercise Program ("HEP"). *Id.* Petitioner reported that she had no significant improvement. *Id.* Petitioner had an external rotation of 80 degrees (compared to 90 on the right side), internal rotation to L4 (T12 on the right side, abduction to 150 degrees (full on her right side), and external rotation to 90 degrees. *Id.* Dr. Peterson again diagnosed petitioner with left adhesive capsulitis, but noted it had "improved." *Id.* He wrote, "I discussed the diagnosis and treatment options with the patient. She seems to have made some improvement and has nearly symmetrical motion to the right shoulder. A continued HEP was encouraged." *Id.*

There are no additional medical records past this appointment relating to her left shoulder in the record.

b. Petitioner's Affidavit

Petitioner stated that the flu vaccine she received was administered by a technician at her PCP's office. Pet'r Affidavit ("Aff.") ¶ 1. She stated, "Later that day, I began experiencing a burning and aching sensation that traveled from the sight of the injection down to my wrist. I had never experienced this type of pain in the past, but I still contributed it to the injection." *Id.* She took over the counter medical to "help with the pain and just figured I would work through it and it would eventually go away." *Id.* She stated that, "…as the days went on it became more and more difficult to raise my arm." *Id.* Petitioner explained that while she was getting decorations down for the holidays, "…when I reached up, I practically passed out from the pain. I lowered my arm quickly and the pain diminished enough for me to stop crying!" *Id.* She stated that it "became increasingly more difficult for me to do things, such as: lifting, zipping up clothes from the back, putting my arm behind me whatever reason." *Id.* "After making it through a painful holiday season, [petitioner] decided it was time to visit [her] orthopedic surgeon, Dr. Mark Petersen." *Id.*

She stated that she received the cortisone injection on January 31, 2018, as indicated in her medical records and began to participate in physical therapy. *Id.* at ¶ 2. After participating in physical therapy until the end of April, she had a follow-up appointment with Dr. Petersen, who gave her another steroid injection. *Id.* Petitioner stated that the steroid injections provided

"some relief for a day or two, but as soon as the anesthetic from the injection wore off, the pain was back." *Id.*

When she returned to Dr. Petersen for a follow-up appointment, he discussed surgery as a possible solution when petitioner had no change in her condition. *Id.* at ¶ 4. Instead, petitioner had a referral for massage therapy thinking it could be of some help, as she also began to experience some general back pain. *Id.* Petitioner stopped the massage after a few sessions because "the pain during the sessions was intolerable." *Id.* at ¶ 5.

Explaining the lack of treatment between August 2018 and January 2019, petitioner stated that she had taken a break from therapy because she was told, "that sometimes it's a good idea to take a break yet continue to do the stretching and exercises at home as much as I could tolerate." *Id.* at ¶ 6. She stated that she was told, "sometimes the shoulder will actually go through a 'thawing process.' " *Id.* Petitioner took a break from her treatment because she had used all of her accrued sick time and she could not afford to stop working. *Id.*

Petitioner stated that her left shoulder pain has created "a multitude of challenges that most certainly have an effect on my life and daily living." *Id.* at ¶ 7. She stated that "sometimes the pain is so intense when I attempt to reach out and/or across I find myself doubled over in pain." *Id.* Petitioner gave an example of a time when she tried to catch her one-year-old grandson from falling, she reached out to catch him and "nearly passed out from the pain." *Id.* "My reaction was enough to scare him, sending him crying to his Mommy." *Id.* Petitioner also stated that her sleep is "constantly compromised and interrupted," and if she accidently rolls on her left side, she wakes up with intense pain. *Id.* at 8. This disruption can cause her to lose an hour of sleep, limiting her to getting only 4-6 hours of sleep each night. *Id.*

Petitioner's shoulder pain has also affected her exercise regimen. *Id.* at ¶ 9. She focuses on weight training, but with her arm pain, she can "no longer lift any amount of weight higher than the height of my head without pain." *Id.* Petitioner has "always prided [herself] on staying physically fit," but now she is "watching her left arm begin to atrophy." *Id.*

Additionally, her left shoulder pain has affected other areas of daily living. *Id.* at ¶ 10. It takes her longer to get ready for work; she cannot reach behind her to zip or fasten clothes behind her back; and has limited her ability to stock shelves at work. *Id.* at ¶ 10-11.

Petitioner states that she is continuing her daily stretching and exercises, in hopes that her left shoulder will recover, but she is concerned that this is a permanent disability. *Id.* at ¶ 12.

c. Petitioner's Expert's Opinion on Vaccine Causation: Dr. Uma Srikumaran

Petitioner submitted an expert report from orthopaedic surgeon, Dr. Uma Srikumran, to support her claim. Pet'r Ex. 10. Dr. Srikumaran reviewed petitioner's medical history in his report and wrote, "[petitioner] does not have a documented history of any prior issue or medical care specifically relating to her left shoulder," and that it is his opinion that the intradermal vaccine she received on November 10, 2017 was the cause of her left shoulder pain and dysfunction. *Id.* at 9.

Dr. Srikumaran first addressed the onset of petitioner's left shoulder pain. *Id.* at 7. It is his opinion that petitioner's pain began within 48 hours of her vaccination. *Id.* at 6. He stated, "Though [petitioner] does not seek medical attention until approximately three months following the vaccination, it is my experience that there are many reasons for when patients seek care which are supported in the scientific literature." *Id.* He stated that it was his experience that "the vast majority of patients do not have their pain (outside of acute traumas/emergency room situations) evaluated within 48-hours [of onset]." *Id.* "Most people are hopeful things will improve with time and basic measure and try several over-the-counter remedies for many weeks or months before seeking professional evaluation." *Id.* Dr. Srikumaran stated that "petitioner consistently and reliably reported that her shoulder pain began the day after receiving the vaccine, on November 11, 2017, to varied medical providers." *Id.* Referencing petitioner's first appointment with Dr. Peterson in January 2018, he noted that petitioner reported that her left shoulder pain was present for "a few months," which correlates with the timing of her vaccination. *Id.* Additionally, Dr. Srikumaran noted that petitioner reported that the onset of her left shoulder pain began "after getting a flu shot," to her physical therapist, and then continued such reporting to different providers. *Id.*

Dr. Srikumaran also opined that petitioner's onset of pain and dysfunction is consistent with the initiation of inflammation to the vaccine antigen, which spreads to the surrounding structures of the shoulder, leading to pain and reduced range of motion. *Id.* at 8-9. He stated that the vaccination did not cause petitioner's "chronic, degenerative conditions found on her MRI," but instead the vaccine "was the likely trigger that instigated inflammation in the bursal tissue leading to exam findings consistent with bursitis and tendonitis." *Id.* at 8. Dr. Srikumaran stated that most people petitioner's age likely have imaging findings of chronic degenerative conditions such as frayed or partially torn ligaments and tendons and arthritic joints, however, the majority of these conditions are asymptomatic. *Id.* at 9. The Atansoff et al. article, which Dr. Srikumaran referenced to support this proposition states:

> In general, chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions, including impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis, and adhesive capsulitis. In many cases, these conditions may cause no symptoms until provoked by trauma or other events. Riley et al. reviewed a series of shoulder ultrasounds and MRI studies obtained in asymptomatic persons past middle age and found partial or complete rotator cuff tears in 39% of those individuals. Therefore, some of the MRI findings in our case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination associated synovial inflammation.

Pet'r Ex. 12 at 3.[5]

He opined that the limited range of motion that petitioner demonstrated by January 2018, at her first appointment with Dr. Peterson, was consistent with an injury or insult affecting the

[5] Atanasoff, S. et al., *Shoulder Injury Related to Vaccine Administration (SIRVA),* 28 Vaccine 8049-8052 (2010). [Pet'r Ex. 12].

subacromial space or bursa. Pet'r Ex. 10 at 8. He explained that "an initial injury causes disuse of the arm along with diffuse inflammation which in turn causes the joint capsule to stiffen," leading to a diagnosis of adhesive capsulitis. *Id.* Dr. Srikumaran also observed that there was no other event identified in the medical records, such as a fall or traumatic event that provides an alternate explanation for her shoulder pain. *Id.*

He also opined that the intradermal vaccine could cause a shoulder injury related to vaccine injury ("SIRVA"), and that those injuries are not limited to intramuscular injections. Pet'r Ex. 10 at 5. Acknowledging that an intradermal injection is meant to enter the dermal layer, he stated, "technique can lead to a deeper-injection location." *Id.* at 9. He opined that "a needle can reach a further depth than its length by pressing firmly into the tissue," and that "it is quite feasible, and even likely in at least some portion of cases, that some injectors may inadvertently push harder than is recommended or appropriate." *Id.* This would explain how an intradermal vaccine's antigen is pushed further than the targeted dermal layer. *Id.* While the Laurent et al. article Dr. Srikumran refenced found that "A 1.5 mm needle inserted perpendicularly into the skin surface would have ensured the appropriate delivery of vaccine into the dermis….especially at the deltoid," it also found that the average skin thickness of women is 1.89 mm at the deltoid, but he observed, "The study does not test the actual depth to which the needle is capable of penetrating with normal or firm pressure." *See* Pet'r Ex. 23 at 5[6]; Pet'r Ex. 10 at 10;

Additionally, "inflammation often does not simply localize to a small defined area, rather it often occurs in a generalized area," and "inflammation in the muscle can affect the surrounding structures, including the bursa and rotator cuff tendon, leading to bursitis and tendonitis." *Id.* at 10. Dr. Srikumaran compared the length of an intradermal needle, which is 1.5 mm, to that of a bee stinger and wrote, "as anyone that has sustained a bee sting can attest," the "inflammatory response…does not restrict itself to areas as small as millimeters or centimeters." *Id.*

Dr. Srikumaran referenced both the Bodor and Atanasoff articles to support his theory that the intradermal vaccine can cause shoulder pain and dysfunction, even though the two articles discuss shoulder injuries after intramuscular vaccination. Pet'r Ex. 10 at 10. Both Atanasoff and Bodor opine that a shoulder injury after vaccination is caused by an inflammatory reaction to the vaccine when it is injected near or into the synovial tissue of the shoulder. *Id.* Atanasoff explains, "…the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon." Pet'r Ex. 12 at 3. Bodor also endorses an inflammatory response to the vaccine injected into shoulder structures. Pet'r Ex' 15 at 2.[7] Bodor describes two cases of patients with post-vaccination shoulder pain and dysfunction, who previously had no issues, but after vaccination one developed adhesive capsulitis and the other developed bicipital tendonitis and subacromial bursitis. *Id.* at 1-2. Bodor wrote that in "both cases the problem involved multiple shoulder structures-the subacromial space, the bicipital tendon and the glenohumeral joint-requiring multiple injections for all pain to

[6] Laurent, A., *Echographic Measurement of Skin Thickness in Adults by High Frequency Ultrasound to Assess the Appropriate Microneedle Length for Intradermal Delivery of Vaccines,* 25 Vaccine 6423-430 (2007). [Pet'r Ex. 23].
[7] Bodor, M. & Montalvo, M., *Vaccination-Related Shoulder Dysfunction,* 25 Vaccine 585-87. [Pet'r Ex 15].

resolve, consistent with a primary inflammatory etiology rather than a mechanical overuse problem." *Id.* at 3.

Dr. Srikumaran opined that the onset of petitioner's symptoms, beginning the day after vaccination, in addition to there being no traumatic event or other injury, and her treatment course are all consistent with a post-vaccination shoulder injury. Pet'r Ex. 10 at 7, 11.

d. Respondent's Expert's Opinion on Vaccine Causation: Dr. Julie Bishop

Respondent's expert, orthopaedic surgeon, Dr. Julie Bishop opined that petitioner's shoulder pain and dysfunction, leading to a diagnosis of adhesive capsulitis was not caused by the intradermal vaccine administered on November 10, 2017. Resp't Ex. B at 8.

Dr. Bishop argued that the intradermal vaccination cannot be the cause of a post-vaccination shoulder injury because the microneedle intradermal delivery system cannot reach the muscle layer or the subacromial space and cause a robust inflammatory response, suggested by Dr. Srikumaran. Resp't Ex. B. at 6. She explained that intradermal vaccine targets "Langerhans cells," which stimulates a greater immune response than the intramuscular injection. *Id.* at 4. Dr. Bishop stated that because of the skin cells targeted by the vaccine, intradermal vaccine can cause "a heightened local reaction compared to intramuscular injections," but those reactions resolve after 2 days without local sequelae. *Id.* at 5. The "Fluzone Intradermal Facts at a Glance" fact sheet explained, "In clinical trials, the most common solicited injection-site reactions reported in participants given the intradermal vaccine were erythema (redness) (>75%), swelling (>50%), induration (>50%), pain (>50%), and pruritis (itching) (>40%)." Resp't Ex. A at 1.

Even though Dr. Bishop acknowledged a "heightened local skin reaction" compared to intramuscular injections, she suggested the 1.5 mm needle could not penetrate past the skin and into structures further than intended. Resp't Ex. B at 5. She wrote, "given that skin thickness is very consistent and skin thickness in women is greater than 1.5mm in all cases, it is virtually impossible for the needle to even reach the muscle of the one being vaccinated, let alone penetrate the depth of the muscle in the shoulder (the deltoid) and reach the subacromial space." *Id.* Dr. Bishop disagreed with Dr. Srikumaran's assertion that the inflammatory response to the intradermal vaccine could spread past a localized area and further into the structures of the shoulder. *Id.* at 6. She stated that the "the basis for the theory of SIRVA is that the inflammatory response is induced by inadvertent injection in the SA space/bursa. However, the theory does not support that proper administration of the vaccine antigen in the proper deltoid muscle location triggers this immune mediated inflammatory reaction." *Id.* Dr. Bishop also asserted that because the intradermal vaccine is "dose sparing" and uses "even less vaccine antigen than normally seen in an IM administration," that "one could reasonably conclude this would lead to an even less robust immune-mediated inflammatory response if somehow (which is truly not possible) the vaccine was administered to the subacromial space." *Id.*

Dr. Bishop argues that petitioner's pain did not begin within 48-hours after she received the November 10, 2017 vaccination. Resp't Ex. B at 6. Dr. Bishop argues that petitioner's first medical appointment for her shoulder was three months later and at the appointment, petitioner

did not attribute the onset of her pain or shoulder issue to the flu vaccine. *Id.* at 6. Dr. Bishop stated, "It would be very unusual for a patient to omit that her pain started immediately after receiving the vaccination." *Id.* She also asserts that petitioner did not relate her left shoulder pain to the vaccination at the next two appointments to Dr. Peterson, contradicting Dr. Srikumaran's opinion that petitioner "reliably reported that her shoulder pain began the day after receiving the vaccination." *Id.* (quoting Pet'r Ex. 10).

Finally, Dr. Bishop argued that petitioner's diagnosis of adhesive capsulitis and the degenerative changes found on the MRI explain the left shoulder pain and dysfunction. Dr. Bishop agrees that petitioner's diagnosis was adhesive capsulitis, however, she stated that adhesive capsulitis does not need "an alternative mechanism or trigger" to occur. *Id.* at 7. She explained, "Adhesive capsulitis is an inflammation of the capsule, which leads to pain and gradual contraction of the capsule and stiffness." *Id.* She wrote, "As I have treated many patients with adhesive capsulitis, often patients spend significant time trying to determine what "caused" their frozen shoulder to occur and many do try to correlate (when they remember) the gradual onset of symptoms to an event in their lives." *Id.* Dr. Bishop wrote that when petitioner first presented to Dr. Peterson for treatment in January 2018, she denied any "injury or trauma," which "clearly confirms that one cannot reliably state her onset of pain was at the time of her vaccination." *Id.* Dr. Bishop also stated that, "[w]hen petitioner presented to Progressive Spinal and Sports rehabilitation on July 12, 2018, she noted that the onset of her pain was in October 2017. This is not consistent with pain starting immediately after her November 10, 2017 vaccination, and further supports that her pain had an insidious onset, like any typical frozen shoulder." *Id.*

III. Legal Standard for Adjudication

a. Finding of Fact

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391

(1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

b. Causation

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

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991). 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). 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).

To receive compensation through the Program, petitioner must prove either (1) that [he] suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a

vaccine that she received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); *Capizzano v. Sec'y of Health & Hum. Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that he suffered a Table Injury, he must prove that a vaccine he received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and her injury ("*Althen* Prong Three"). § 13(a)(1); *Althen*, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The 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). Recently, in *Kottenstette,* the Federal Circuit reiterated that proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Kottenstette v. Sec'y of Health & Hum. Servs.,* -- Fed.Appx.—(Fed. Cir. June 15, 2021) (citing *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 549 (Fed. Cir. 1994). Causation "can be found in vaccine cases….without detailed medical and scientific exposition of the biological mechanisms." *Knudsen,* 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1325 (Fed. Cir. 2010).

Petitioner cannot establish entitlement to compensation based solely on his 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 undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs 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 petitioner's favor).

In Vaccine Act cases, expert testimony may be evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo*, 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Vaccine Program cases, the *Daubert* analysis has been used in the weighing of the scientific evidence actually proffered and heard rather than as a tool for the pre-trial exclusion of expert testimony. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (Fed. Cl. 2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"), *aff'd*, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to determine the persuasiveness and/or reliability of expert testimony in

Vaccine Program cases has routinely been upheld. *See, e.g.*, *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742–45 (2009). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly,* 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Close calls regarding causation must be resolved in favor of the petitioner. *Althen,* 418 F.3d at 1280 (holding that Congress created a system in which "close calls regarding causation are resolved in favor of injured claimants"); *Knudsen*, 35 F.3d at 551 ("If the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded.").

IV. Analysis

a. Onset of Petitioner's Symptoms

In this case, respondent argues that petitioner has not established that her left shoulder pain began within 48-hours after she received the November 10, 2017 intradermal flu vaccine. Resp't Br. at 8, 13. More specifically, respondent asserts that petitioner "did not report her shoulder pain to a medical provider for nearly three months," and when petitioner sought treatment, "she did not mention to him that her pain began when she received the flu vaccine." *Id.* at 8. Respondent states, "It does not appear that [petitioner and Dr. Peterson] discussed this potential temporal relationship until a year later, after a seven-month gap in treatment." *Id.* Importantly, petitioner quite specifically reported to her physical therapist at her first appointment in February 2018 that the date of injury was November 11, 2017 and the shoulder pain began after receiving the flu shot in the left upper extremity. Pet Ex. 3 at 13.

Petitioner argues she consistently related the pain in her left shoulder beginning the day after she received the vaccination. Pet'r Br. at 11. Petitioner acknowledged that the record from the first appointment with her orthopedist does not specifically reference the flu vaccination, but petitioner does report that her left shoulder pain and stiffness had been ongoing for a "few months." *Id.* Petitioner asserts that the reference to "a few months" is consistent with the onset of her left shoulder pain beginning the day after she received the flu vaccine. *Id.*

Further, Dr. Srikumaran explained that delaying treatment in non-trauma orthopedic cases such as SIRVAs is common, as patients have various reasons for delaying treatment, including hoping the pain will resolve, insurance issues and other reasons. *Id.* at 12. He concluded that it appeared that Ms. Marcus hoped the pain would go away as stated in her affidavit, that she specifically mentioned the date of vaccination and the vaccination as the cause when providing the history to her physical therapist, and that her her history of pain for a couple months given to Dr. Peterson was not at all inconsistent with the onset occurring two and a half months before.

Petitioner has demonstrated by preponderant evidence that her left shoulder pain began one-day after she received the November 10, 2017 intradermal vaccine. Petitioner's medical records, Dr. Srikumaran's opinion, and petitioner's affidavit support this finding.

While petitioner's first medical appointment for her left shoulder did not occur until two and a half months after vaccination, as has been held in multiple cases delaying treatment for a shoulder injury post-vaccination is not *per se* dispositive as to whether onset of the pain occurred within the time specified for a post-vaccination shoulder injury. *See Larson v. Sec'y of Health & Hum. Servs.*, No. 19-462, 2023 WL 6223898 (Fed. Cl. Spec. Mstr. Aug. 28, 2023); *Tenneson v. Sec'y of Health & Hum. Servs.,* No. 16-1664V, 2018 WL 3083140, at *5 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *rev. denied*, 142 Fed. Cl. 329 (2019) (finding onset of shoulder pain within 48-hours despite delaying treatment for nearly six months); *Wyfells v. Sec'y of Health & Hum. Servs.*, No. 18-1874, 2021 WL 798834, at *4 (Fed. Cl. Spec. Mstr. Jan. 26, 2021) (finding an onset of pain within 48-hours despite petitioner not seeking treatment for her left shoulder injury for approximately three months); *Lang v. Sec'y of Health & Hum. Servs.,* No. 17-995V, 2020 WL 7873272, at *11 (Fed. Cl. Spec. Mstr. Dec. 11, 2020); *Yost v. Sec'y of Health & Hum. Servs.*, No. 18-288V, 2021 WL 2326403, at *12 (Fed. Cl. Spec. Mstr. May 6, 2021) (finding onset of pain within 48-hours despite a four-month lapse between the vaccination and first medical appointment).

Petitioner's explanation of using over-the-counter medication and thinking the pain would eventually go away is a common fact pattern seen in SIRVA cases. *Lesher v. Sec'y of Health & Hum. Servs.*, No. 17-1076V, 2020 WL 4522381, at *6 (Fed. Cl. Spec. Mstr. July 2, 2020) ("It is common for a SIRVA petitioner to delay treatment, thinking his/her injury would resolve on its own, and not otherwise realizing the potential significance of immediate post-vaccination pain."); *see also Smallwood v. Sec'y of Health & Hum. Servs.*, No. 18-291V, 2020 WL 2954958 (Fed. Cl. Spec. Mstr. Apr. 29, 2020); *Rodriquez v. Sec'y of Health & Hum. Servs.,* No. 21-876V, 2024 WL 3425761, at *4 (Fed. Cl. Spec. Mstr. June 10, 2024) ("It has also been repeatedly observed that SIRVA petitioners often delay treatment, thinking that an injury will resolve on its own."). Additionally, Dr. Srikumaran credibly explained, "The vast majority of patients do not have their [musculoskeletal] pain evaluated within 48-hours (outside of acute traumas/emergency room situations). Most people are hopeful things will improve with time and basic measures, and try several over-the-counter remedies for many weeks or months before seeking professional evaluation (particularly when they expect there is to be some pain as after any vaccination)." Pet'r Ex. 10 at 7.

Further, when petitioner did seek treatment with her orthopedist, Dr. Peterson, she reported that her pain and stiffness in her left shoulder had been ongoing for "a few months." Pet'r Ex. 5 at 15. The description of "a few months" since the onset of her pain, although imprecise, coincides with the onset of pain shortly after the vaccination given on November 10, 2017. She was more precise when reporting her history when she had her first physical therapy evaluation the following month. She attributed the onset of her left shoulder pain to the flu shot that she received on November 10, 2017. The record states, "…pain started after getting the flu shot in left [upper extremity]." Pet'r Ex. 3 at 13. Later with her primary care physician, under "History of Present Illness," petitioner reported she had "left frozen shoulder following flu shot;

2 injections, PT and still dealing with the pain and decreased range of motion." Pet'r Ex. 2 at 8. While the medical records from Dr. Peterson do not associate the onset of petitioner's left shoulder pain and dysfunction to the flu shot until the appointment on August 9, 2019, she reported to other providers in intervening appointments and the history given to him was not inconsistent.

Respondent's expert, Dr. Bishop, argued that "It would be very unusual for a patient to omit that her pain started immediately after receiving the vaccination. She said she was clearly asked this question by Dr. Peterson, and she clearly said there was no trauma or inciting even leading to the onset of her pain." Resp't Ex. B at 6. However, the records from Dr. Peterson never established that petitioner was asked directly if her pain was caused by a vaccination, but instead she was asked more generally if there was a trauma. I have concluded that this question was likely interpreted by petitioner to refer to a more common usage of the word trauma to mean a fall, a car crash or other accident as the inciting event. Therefore, petitioner's response to Dr. Peterson regarding a traumatic event should not be understood to exclude a vaccination but rather to exclude only the more common usages of the term trauma.

Thus, petitioner has preponderantly demonstrated that the onset of her left shoulder pain and dysfunction began one-day after receiving the flu shot on November 10, 2017.

b. Causation Analysis

i. *Althen* prong one

Under *Althen* prong one, the causation theory must relate to the injury alleged. The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. It must only be "legally probable, not medically or scientifically certain." *Id.* At 549. However, the theory still must be based on a "sound and reliable medical or scientific explanation." *Id.* At 548. The Federal Circuit explained in *Althen* that "while [that petitioner's claim] involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, *a sequence hitherto unproven in medicine*, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body." Althen,* 418 F.3d at 1280 (emphasis added).

For the reasons set forth below, I find that petitioner has provided preponderant evidence of a sound and reliable theory for how the intradermal influenza vaccine can cause shoulder pain and dysfunction.

As both experts explained, the administrator of the vaccine used the intradermal delivery system with a 1.5 mm needle that was intended to deliver the antigen into the intradermal space in the skin. Pet'r Ex. 10 at 9; Resp't Ex. B at 4. According to an article by Kim,[8] "the skin contains high concentrations of antigen-presenting cells, and is thus a site capable of inducing

[8] Kim, Y.C. et al., *Delivery Systems for Intradermal Vaccination,* 351 Topics in Microbiology and Immunol. 77-112 (2012). [Resp't Ex. B, Tab 7].

potent immune responses." Resp't Ex. B, Tab 7 at 3-4. An article by Lambert[9] explains, "The skin generates both innate (antigen non-specific response without immunological memory) and adaptive immune responses (antigen specific response with immunological memory)….The key groups of immune cells involved in the skin's innate immune response are dendritic leukocytes: Langerhans cells in the epidermis and dermal dendritic cells in the dermis." Resp't Ex. B, Tab 5 at 4. Dr. Bishop stated, "…because the [intradermal] vaccines target the epidermal Langerhans cells, this stimulates a greater immune response than the [intramuscular injection]." Resp't Ex. B at 4.

The experts agree that the intradermal flu vaccine can cause an inflammatory reaction. Resp't Ex. B at 4-5; Pet'r Ex. 10 at 9-10. They disagree that the intradermal vaccine, with the 1.5 mm needle and microinjection system can cause the type of inflammatory reaction that would lead to shoulder pain and dysfunction.

Dr. Srikumaran opined that the intradermal flu vaccine caused an inflammatory response to the vaccine antigen and the inflammatory response spread to the structures of the shoulder, resulting in pain and dysfunction. Pet'r Ex. 10 at 9. Further, he opined that while the intradermal injector was intended not to deliver antigen beyond the dermis, the needle may penetrate further than the intended target by inadvertently being pressed firmly into the tissue of the arm. *Id.* He also opined that the inflammation caused by the vaccine may not remain localized to a small area, but once triggered can spread into the muscle and surrounding structures of the shoulder. *Id.* It is the inflammation that initiates pain in a previously asymptomatic person who may have underlying degenerative shoulder condition, leading to adhesive capsulitis. *Id.*

Dr. Bishop, however, opined that the needle used in the intradermal vaccine cannot penetrate further than the skin and reach the muscle or even penetrate the subacromial space. Resp't Ex. B at 5. She asserted that the skin thickness of, on average 1.5 to 3.0 mm thick, prevents the deposition of antigen further than the intended target. *Id.* Dr. Bishop argued that a post-vaccination shoulder injury can only occur as a result of the contents of the vaccine being deposited directly into the subacromial space or bursa. Resp't Ex. A at 6. I find this argument unpersuasive.

I have found Dr. Srikumaran's theory of causation as sound and reliable in other shoulder pain and dysfunction cases post-intradermal flu vaccination, forming the basis for petitioners to be entitled to compensation. *See Lagle v. Sec'y of Health & Hum. Servs.*, No. 16-1053V, 2022 WL 2299003, at *28 (Fed. Cl. May 25, 2022) (Finding that an intradermal vaccination initiated an immune-mediated inflammatory response in and around the structures of petitioner's right shoulder); *Allen v. Sec'y of Health & Hum. Servs.*, No. 15-1278V, 2022 WL 2255042, at *19 (Fed. Cl. June 2, 2022) (Finding that an intradermal vaccination caused a robust local inflammatory response, resulting in pain protective behaviors, and ultimately adhesive capsulitis); *Galante v. Sec'y of Health & Hum. Servs.*, No. 18-1933V, 2022 WL 17852427, at *24 (Fed. Cl. Nov. 30, 2022) (Finding that an intradermal vaccination initiated an inflammatory response in and around the structures of his left shoulder, sufficient to induce pain and shoulder

[9] Lambert, P. & Laurent, P., *Intradermal Vaccine Delivery: Will new delivery systems transform vaccine administration?* 26 Vaccine 3197-3208 (2008). [Resp't Ex. B, Tab 5].

dysfunction); *Larson v. Sec'y of Health & Hum. Servs.,* No. 19-462V, 2023 WL 6223898, at *19 (Fed. Cl. Spec. Mstr. Aug. 28, 2023) (Finding that an intradermal flu vaccine can cause an inflammatory response which spreads to other structures of the shoulder initiating pain and leading to decreased mobility). In several of these cases, such as *Lagle*, a full hearing was held where Dr. Srikumaran testified about his explanation for the spread of shoulder pain caused by the inflammatory response to the antigen after excessive pressure was likely used with the intradermal injector. *See Lagle v. Sec'y of Health & Hum. Servs.*, 2022 WL 2299003, *13-14. As Dr. Srikumaran opined in this case, "it is quite feasible, and even likely in at least some portion of cases, that some injectors may inadvertently push harder than is recommended or appropriate." Pet'r Ex. 10 at 9. The Lambert article explains that the microneedle injector was being developed as a "*new vaccine delivery platform,"* and was being trialed for influenza delivery. Resp't Ex. B, Tab 5 at 7. The same article explains that how the new microneedle injector delivery system being developed was different from "[t]he standard intradermal injection technique." *Id.* at 6. It was also a different delivery system than standard intramuscular vaccines, which could result in confusion or misadministration, as the microneedle was relatively new technology.

However, I am not basing my opinion solely on past decisions. *See Hanlon v. Sec'y of Health & Hum Servs.*, 40 Fed. Cl. 625, 630 (1998), *aff'd* 191 F.3d 1344 (Fed. Cir. 1999) ("Special masters are neither bound by their own decisions…"). Dr. Srikumaran's theory of vaccine causation is also supported by the medical literature filed in this case. The Kim article states, "[intradermal] immunizations caused more local inflammatory-like reactions than intramuscular immunizations," and the Lambert article also acknowledged that local adverse events post-intradermal vaccination were equivalent to those post-intramuscular vaccination, but edema and redness at the injection site was reported more frequently after intradermal vaccination. Resp't Ex. B, Tab 5 at 7. Additionally, the "Fluzone Intradermal: Facts at A Glance," sheet, submitted by respondent, indicated that the most common "solicited injection-site reactions reported in participants given the intradermal vaccine were: erythema (redness) (>75%); swelling (>50%); induration (hardness) (>50%); pain (>50%), and pruritus (itching) (>40%)." Resp't Ex. A at 1. Additionally, the fact sheet indicates that reports of pain post-vaccination in those that received the intradermal vaccine was similar to those that received the intramuscular vaccination. *Id.* at 2.

Even though Atanasoff discusses shoulder injuries after intramuscular vaccinations, as the intradermal injector had not been in use at the time of his article,[10] the article also supports Dr. Srikumaran's theory that the vaccine can cause an inflammatory response, leading to pain and dysfunction in degenerated shoulder structures which were previously asymptomatic. Atanasoff indicated that "the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff. We believe that this type of phenomenon is not due to a specific vaccine but results from injection of a vaccine antigen to which a person has previously been sensitized as a result of previous naturally occurring infection or past

[10] The intradermal injector had been introduced for use with the flu vaccine fairly shortly before its use in this case and the others that I have heard. It has since been removed from the market.

vaccination. This concept is consistent with the vaccines which were given in this case series, namely influenza…." Pet'r Ex. 12 at 3.

These articles and the fact sheet demonstrate that the flu vaccine delivered by the intradermal injection system can and does produce an inflammatory response that generates both local and systemic adverse events, consistent with Dr. Srikumaran's theory and I have found that his explanation of the likely mechanics of a painful shoulder injury post vaccination with the intradermal injector can cause the painful, inflammatory response that the petitioner experienced to be sound and reliable.

I find that Dr. Srikumaran's theory explaining how the flu vaccine delivered by an intradermal injector can cause an inflammatory response which spreads to other closely situated structures of the shoulder, leading to pain and dysfunction in the shoulder to be sound and reliable. Therefore, petitioner has demonstrated *Althen* prong one by preponderant evidence.

ii. *Althen* Prong Two

Under *Althen* prong two, petitioner must prove "a logical sequence of cause and effect showing that the vaccination was the reason for [his or her] injury." *Althen*, 418 F.3d at 1278. This prong is sometimes referred to as the "did it cause" test; i.e. in this particular case, did the vaccine(s) cause the alleged injury. *Broekelschen*, 618 F. 3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Temporal association alone is not evidence of causation. *See Grant v. Sec'y of Health & Hum. Servs.,* 9556 F.2d 1144, 1148 (Fed. Cir. 1992). This sequence of cause and effect is usually supported by facts derived from petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148.

Petitioner's onset of acute and persistent pain, decreased shoulder mobility, and treatment course are well explained by Dr. Srikumaran's theory as explained under prong one. He has also provided a logical explanation for vaccine caused pain even though the antigen was delivered by the intradermal injector.

Prior to the vaccination petitioner received on November 10, 2017, she did not experience any pain or dysfunction in her left shoulder. She had been treated for other orthopedic issues, such as left hip pain, right hand and wrist pain, and right knee pain. *See* Pet'r Ex. 5 at 7-14. On November 10, 2017, petitioner received the flu vaccine delivered by the intradermal injector. In her affidavit, she stated that that a technician in her doctor's office administered the injection in her upper arm and later that day began to experience burning and aching in her left arm that traveled from the site of the injection down to her wrist. Pet'r Aff. at ¶ 1. She stated that she took some over-the-counter medication to help with the pain and attempted to work through it. *Id.* As the days went by, she found it more and more difficult to raise her arm and once she was through the holiday season, she made an appointment with her orthopedist. *Id.*

On January 31, 2018, petitioner presented to her orthopedist, Dr. Peterson complaining of left shoulder pain and stiffness that had been ongoing for "a few months." *Id.* at 15. After an examination, he diagnosed adhesive capsulitis, administered a steroid injection, and gave her orders for physical therapy. *Id.* at 14-15. Petitioner participated in physical therapy from February 20, 2018 through April 10, 2018. *See generally* Pet'r Ex. 3. Her initial physical therapy evaluation showed that petitioner had positive drop arm and empty can tests, and decreased range of motion of her left shoulder compared to her right. *Id.* at 13. On April 3, 2018, petitioner had a follow-up appointment with Dr. Peterson, during which she still demonstrated decreased range of motion in her left shoulder. Pet'r Ex. 5 at 17. Petitioner received a second steroid injection. *Id.* After completing physical therapy, petitioner had a third appointment with Dr. Peterson on June 15, 2018, where she reported that her shoulder remained stiff and painful. *Id.* at 19. She continued to have decreased left shoulder mobility and Dr. Peterson's assessment remained "adhesive capsulitis." *Id.* At this appointment, he advised petitioner that "In light of her persistent symptoms, I believe that she will likely have to consider surgery, which would include an arthroscopic lysis of adhesions." *Id.* Dr. Peterson ordered an MRI of petitioner's left shoulder and requested she return after the MRI.

The MRI, done on June 21, 2018 showed that petitioner had "thickening of the interior joint capsule along with mild synovitis in the axillary recess," which were consistent with adhesive capsulitis. Pet'r Ex. 4 at 5. Further, the MRI showed that petitioner had degenerative changes to her shoulder, including mild-to-moderate proximal biceps long head tendinosis with additional thinning indicative of a chronic partial thickness tear; mild-to-moderate acromioclavicular osteoarthritis with mild subchondral osseous stress edema in the distal clavicle; and mild glenohumeral osteoarthritis with glenoid labral degeneration. *Id.* After the MRI, petitioner went to Progressive Spinal and Sports Rehabilitation for additional physical therapy, but she had to stop after three appointments because "the pain was so intolerable" and she felt that it was "doing more harm than good." Pet'r Ex. 4; *see also* Pet'r Aff. at ¶ 5.

Petitioner explained that she had temporarily stopped physical therapy due to the pain and she had used all of her medical leave. Pet'r Aff. at ¶ 6. When she returned to Dr. Peterson on January 15, 2019, Dr. Peterson stated that her MRI was "consistent with adhesive capsulitis." Pet'r Ex. 5 at 21. Petitioner reported she still had pain and stiffness in her left shoulder. *Id.* Dr. Peterson encouraged petitioner to continue home exercises to increase her range of motion. *Id.* at 21. The last filed record from Dr. Peterson was from an appointment on August 9, 2019, when he observed that she had improved her shoulder function and mobility due to the home exercise program. Pet'r Ex. 30 at 1. However, in her affidavit, petitioner indicated that her shoulder injury still causes her discomfort when sleeping, has limited her ability to weight train with her left upper extremity which has made it difficult for her to perform some tasks at work, such as stocking high shelves, and interrupts her activities of daily living. Pet'r Aff. at ¶¶ 9-12.

The medical literature filed in this case explained that onset of pain after an intradermal vaccination is a common adverse effect. The Fluzone Fact sheet describes pain after the intradermal vaccination as one of the "most common" local side effects that can occur. Resp't Ex. A at 2. Additionally, the articles and the fact sheet also acknowledge that inflammatory reactions, including swelling and redness do occur at the site of injection and that "injection-site reactions were more frequent with participants given the intradermal vaccine compared to the

intramuscular vaccine." *Id.* at 2. Petitioner consistently reported to medical professionals, her left shoulder pain began within one day after she received the November 10, 2017 intradermal flu vaccine.

Dr. Srikumaran opined that the pain initiated by the intradermal flu vaccine caused her to limit use of her arm which then led her to develop adhesive capsulitis, for which she was diagnosed and treated by Dr. Peterson. Pet'r Ex. 10 at 8 She also received two courses of physical therapy. He noted that "an initial injury causes disuse of the arm along with diffuse inflammation which in turn causes the joint capsule to stiffen." *Id.*

Dr. Srikumaran observed that petitioner's MRI findings were consistent with long-standing degenerative changes, but those changes were not symptomatic until after the vaccination. *Id.* Dr. Bishop agreed that petitioner's MRI showed "age related degenerative changes," but that petitioner's adhesive capsulitis followed a normal course where there is no specific "trigger," but that pain and dysfunction is more gradual. Resp't Ex. B at 7.

I do not find Dr. Bishop's explanation persuasive because petitioner's course is consistent with an inflammatory response to a vaccine in the shoulder region, resulting in adhesive capsulitis as a result of pain limited non-use over time. The Bodor article described the case of an elderly woman who developed adhesive capsulitis after receiving a vaccine. Pet'r Ex. 15 at 1. The case report explained that the 71-year-old woman experienced onset of pain two days after receiving a vaccination, leading to difficulty moving her left arm over a five-month period. *Id.* The woman received corticosteroid injections into her left shoulder for pain relief. *Id.* at 2. While the patient described in the Bodor article received an intramuscular vaccination, the mechanism of injury was described as a "primary inflammatory etiology rather than a mechanical overuse problem," which is the theory Dr. Srikumaran posited was the cause of petitioner's adhesive capsulitis in this case.

Additionally, Atanasoff explained that some SIRVA patients may have positive MRI findings that include bursitis, tenonitis, rotator cuff tears, or osteoarthritis but posited that these findings may have pre-dated the vaccination and became symptomatic as a result of synovial inflammation. *See* Pet'r Ex. 12 at 3. In this case, petitioner's MRI showed signs of glenohumeral and acromioclavicular osteoarthritis and a "chronic partial-thickness tear" of the biceps long head, which were not likely caused by the vaccination, and both experts agree are considered chronic, degenerative conditions. *See* Pet'r Ex. 4 at 4-5; Pet'r Ex. 10 at 8 ("The MRI in this case demonstrates findings consistent with arthritis…tendinosis, and degradation of the labrum. These are chronic degenerative conditions."); Resp't Ex. B at 7 (describing petitioner's MRI findings as "consistent with age-related degenerative changes," and the SLAP tear and tendinosis of the biceps tendons as "very common, age-related changes.). Dr. Srikumaran did not attribute the underlying structural damage in her shoulder to the vaccination but recognized that she had no history of pain in the shoulder until the inflammatory response to the vaccine caused her shoulder to become symptomatic. *See* Pet'r Ex. 10 at 11. As noted above, Atanasoff made the same observation: "the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff.

Finally, petitioner's medical history and treatment course is similar to the other intradermal flu-shoulder injury cases resolved in this Court, including *Lagle* and *Allen.* For example, in both *Lagle* and *Allen,* the petitioners also experienced pain shortly following an intradermal flu vaccination, demonstrated symptoms consistent with adhesive capsulitis over time, received steroid injections, and participated in physical therapy with limited success in improving shoulder function. *See Lagle v. Sec'y of Health & Hum. Servs.,* 2022 WL 2299003, at *4, 32 (Fed. Cl. Spec. Mstr. May 25, 2022); *Allen v. Sec'y of Health & Hum. Servs.,* 2022 WL 2255042, at *4-5, 8 (Fed. Cl. Spec. Mstr. June 2, 2022).

Accordingly, I find that petitioner has demonstrated *Althen* prong two by preponderant evidence.

iii. *Althen* prong three

Under *Althen* Prong Three, petitioner must establish a "medically acceptable temporal relationship" between the vaccination and the injury alleged. *Althen,* 418 F.3d at 1281. That term has been equated to the phrase, "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one). *Id.* at 1352.

In her affidavit, petitioner stated that her pain began the same day she received the intradermal flu vaccination and that the pain "traveled from the site of the injection down to her wrist." Pet'r Aff. at ¶ 1. She explained that she believed the pain would go away and took over-the-counter medication. *Id.* However, her pain continued, and it became "more and more difficult" for her to raise her arm. *Id.* Dr. Srikumaran opined that the onset of pain later the same day as the vaccination, and her progressively worsening shoulder mobility is consistent with an inflammatory reaction to an already sensitized shoulder. Pet'r Ex. 10 at 11. Dr. Bishop opined that petitioner's shoulder pain and dysfunction was not temporally associated with the vaccination, based mostly on the medical records of Dr. Peterson. Resp't Ex. B at 6. As explained above, even though Dr. Peterson's records do not mention the flu shot in conjunction with the petitioner's left shoulder pain and dysfunction she received in November 2017 until one year after he started treating her for that condition, petitioner did consistently associate the onset of her shoulder injury to the November 10, 2017, vaccine to other health care providers including her physical therapist and family doctor in other appointments. Further, her explanation of the time of onset to Dr Peterson was consistent with the timing of the vaccination even if the injection was not specifically mentioned in Dr. Peterson's records.

Additionally, the Fluzone Intradermal Fact Sheet explained that injection-site adverse reactions, which include pain, pruritis, erythema, swelling, and induration may occur within 7 days of vaccination. Resp' Ex. A. As I have found as a fact above that the petitioner's pain began within one day of the injection, she has satisfied prong three.

Conclusion

In accordance with the above, petitioner has established by preponderant evidence that she is entitled to compensation, demonstrating that the intradermal flu vaccine administered on November 10, 2017, was the cause-in-fact of her left shoulder pain and dysfunction. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master