In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-1397V

JOHN AGATE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: August 7, 2024

Brian L. Cinelli, Schiffmacher Cinelli Adoff, LLP, PC, Buffalo, NY, for Petitioner.

Emilie Williams, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On September 13, 2018, John Agate 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 alleged that as a result of an influenza ("flu") vaccine he received on September 15, 2015, he suffered a shoulder injury related to vaccine administration ("SIRVA") as defined by the Vaccine Injury Table (the "Table"). Petition (ECF No. 1) at Preamble. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[1]Because this decision 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 this Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[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).

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

For the reasons discussed below, I find that Petitioner is not entitled to compensation, and therefore, the Petition is dismissed.

I. Relevant Procedural History

The claim was initiated in the fall of 2018, and the relevant medical records were filed thereafter. ECF Nos. 1-16. Approximately one year later, on August 1, 2019, Respondent filed a status report stating that he had reviewed the case and was not interested in settlement. ECF No. 24.

On September 30, 2020, Respondent filed his Rule 4(c) Report contesting entitlement based on the argument that Petitioner had failed to demonstrate that his shoulder pain began within 48 hours of vaccination, that Petitioner's treating physicians identified other causes of his shoulder pain, including a "straightforward impingement syndrome" and saw no connection to the flu shot, and that Petitioner could not otherwise establish a causation-in-fact claim. Respondent's Report at 8-10. ECF No. 25.

I ordered Petitioner to file additional evidence to address the issue of onset. ECF No. 26. In response, Petitioner filed a supplemental affidavit and an additional record from Rite Aid corporation that contained a note from the pharmacy that stated that Petitioner had complained about arm pain on October 27, 2015. Ex. 23. After reviewing the additional evidence, I ordered the parties to consider informal resolution of the case, but they were unsuccessful. ECF Nos. 34, 46.

A status conference was held on February 4, 2022. Petitioner requested the opportunity to present additional testimony from his treating physicians. Respondent also requested the opportunity to respond if Petitioner presented expert testimony. The parties were ordered to confer and to report back on how they wished to proceed within 30 days. ECF No. 47.

On March 7, 2022, the parties filed a joint status report stating that they had elected to proceed with briefing the issues of entitlement and damages for my consideration. ECF No. 48. The parties have now filed their respective briefs and this case is ready for adjudication. Petitioner's Motion for Ruling on the Record and Brief in Support of Damages ("Mot."), ECF No. 52-53; Respondent's Response ("Opp."), ECF No. 56-57; Petitioner's Reply ("Reply"), ECF No. 60.

II. Relevant Medical History

1. Medical Records

Mr. Agate (age 41), a sales manager and mortgage banker, received a flu vaccine in his right shoulder on September 15, 2015, at a Rite Aid pharmacy located in Williamsville, New York. Ex. 2 at 1-2. His medical history included chronic back pain that worsened after a motor vehicle accident in 2010, left-side neck and left shoulder pain, acid reflux and abdominal pain. *See e.g.*, Ex. 4 at 3-28. He had no history of right shoulder pain or injury.

On October 6, 2015, there is a note from Petitioner's massage therapist, Stephanie Tasulitis from Invision Health, that Mr. Agate complained of a "left side labral tear and right shoulder/deltoid tension." Ex. 24 at 106. There is no other mention of right shoulder pain during this visit.

On October 27, 2015, Mr. Agate returned to Rite Aid to complain about his shoulder pain following the flu vaccination. Ex. 22 at 1. Petitioner stated that he was informed that the pain was "perfectly normal" and that it should subside on its own. *Id*. The Rite Aid record documenting this visit states, "[s]topped in 10/27/15 to talk about pain from flu shot – recommended ice/Motrin and to follow up … Pain has been subsiding and almost gone he said." Ex. 23 at 2. Based on this representation, Mr. Agate stated that he did not seek further medical attention at this time. Ex. 1 at 2.

One day later, on October 28, 2015 (now approximately six weeks after vaccination), Mr. Agate was seen by a spinal surgeon for back pain that had been present since 2010. Ex. 4 at 34. Petitioner's past medical history was reviewed which included a notation for a positive right labral tear on the shoulder. There is no other mention of right shoulder pain at this visit. *Id*.

On October 31, 2015, Mr. Agate saw massage therapist Stephanie Jaczewski, and reported increased neck and upper back pain, as well as right shoulder pain. Ex. 24 at 108. Almost a week later, on November 6, 2015, he saw his primary care provider ("PCP") and complained of lower back pain, with his diagnoses including anxiety disorder, insomnia, cervicalgia, and lower back pain. Ex. 4 at 38. He returned to his neurosurgeon for low back pain with radiation into his right leg on December 2, 2015, but no shoulder pain is mentioned in these records. *Id.* at 40. And he saw the neurosurgeon again in mid-January 2016, after a repeat lumbar spine MRI. Ex. 4 at 43. The findings of the MRI had not changed, and surgery was again recommended. *Id.* No other issues were mentioned. *Id.*

Several months later, in May 2016, Mr. Agate went to his PCP for complaints of lower back pain, and his diagnoses at this visit included right shoulder pain (although there was no discussion or examination conducted for shoulder pain at this time). Ex. 4 at 49. No history or examination was documented, but an x-ray was ordered, and Mr. Agate was referred to physical therapy for his lower back pain. *Id.*

Later that same month, Petitioner was evaluated by another neurosurgeon for his lower back pain, and the surgeon noted that Petitioner "has been having ongoing neck and back pain since [the 2010 motor vehicle] accident and reports the lumbar pain is the worst complaint." Ex. 4 at 52. Under the section of the report for this visit labeled "Musculo," the neurosurgeon recorded that Mr. Agate "[r]eports neck pain, lower back pain, left shoulder pain and left arm pain." *Id.* at 54. On examination, Mr. Agate exhibited normal strength in both upper extremities, and experienced no reported pain with range of motion of either shoulder. *Id*. The neurosurgeon reiterated that the cause of Petitioner's lower back pain was his motor vehicle accident in 2010 and recommended surgical intervention. *Id.* Petitioner obtained additional related evaluations in July and August 2016 – and although surgery was recommended for the ongoing lower back pain, no mention was made of shoulder pain at these visits. *Id.* at 57-64.

On August 16, 2016, Mr. Agate attended his first appointment with a new orthopedist. *See* Ex. 6 at 1. The record from this visit states that Petitioner was experiencing persistent, disabling pain in his right shoulder which he rated at a 9/10, and that "[h]e developed pain in his right shoulder after receiving a flu shot into his right shoulder at CVS [sic] 1 year ago." *Id.* On examination, Petitioner exhibited full passive range of motion and full strength except for mild weakness for the supraspinatus muscle on the right side. *Id.* Certain orthopedic tests performed on his right shoulder, such as the Hawkins and Jobe tests, were positive for findings of impingement. The orthopedist scheduled an MRI for Mr. Agate's shoulder. *Id*. at p. 2.

On September 2, 2016, Mr. Agate underwent a right shoulder MRI for complaints of "deltoid muscle pain at site of flu shot injection. Limited range of motion." Ex. 4 at 66. The MRI impression stated:

1. Mild to moderate AC joint degenerative change is present with mass effect on the supraspinatus tendon, mild bursal edema.
2. There is a posterior inferior labral tear between the 3:00-6:00 positions with suggestion of an inferior para labral cyst measuring 5 mm at the 6:00 position.
3. There are also findings suspicious for a SLAP type II tear which could be confirmed with MRI arthrography if clinically indicated. Questionable SLAP tear extends to roughly the 3:00 position.
4. Rotator cuff is intact.

Id.

On September 15, 2016, Mr. Agate was evaluated by another orthopedist for right shoulder pain after the flu vaccine. Ex. 4 at 67. Mr. Agate reported that "1 year ago he received a flu shot. Since then he has had a discomfort and pain in the shoulder both with activity and as well as at rest. He feels as though he is limited with certain movements as well as overhead lifting." *Id*. Mr. Agate reported discomfort and pain in the shoulder with activity and while at rest. *Id.* On examination, Petitioner's right shoulder exhibited weakness with resisted abduction bilaterally and positive apprehension test bilaterally and some discomfort with external rotation. *Id.* Surgery was discussed, but Mr. Agate opted to proceed with conservative management. *Id*. at 68.

On September 21, 2016, Mr. Agate went to Registered Physician Assistant James C. O'May with complaints of right shoulder pain since receiving a flu shot one year prior. Ex. 4 at 69. On examination, Petitioner displayed full passive range of motion and full strength except for a slight weakness in his right supraspinatus muscle. *Id.* He had positive impingement signs and painful arc of motion between 70 and 140 degrees. *Id.* at 70. The assessment was superior glenoid labrum lesion and right shoulder pain. *Id.*

On October 7, 2016, Mr. Agate saw his PCP for complaints of lower back pain, and he also mentioned right shoulder pain with limited range of motion and weakness, and right lateral rib pain since being elbowed during a basketball game. Ex. 4 at 73. He had gone to an urgent care center for the rib pain and the x-rays were negative. *Id.* It is noted in the History of Present Illness, that Mr. Agate has "right shoulder pain since getting flu shot-limited ROM and weakness." *Id*. The review of systems portion of the report for this visit was positive for a left shoulder labral tear and upper extremity examination revealed "[f]ull ROM bilaterally." *Id.* at 74.

On October 25, 2016, Mr. Agate returned to his orthopedist at Buffalo Orthopaedic Group complaining of a "one-year history of right shoulder pain following a flu shot he received. He states since then he has had significant soreness about the right arm." Ex. 4 at 76. Mr. Agate stated that his pain severity was an 8 out of 10 and could increase to a 9/10 on some days. *Id*. He reported that "there is currently no legal action as a result of his concern[] that this developed following a flu shot." *Id*. On exam, Mr. Agate had positive results on several impingement tests. The note states, "Right shoulder has elevation to 150 degrees, external rotation to 55 degrees and internal rotation to T10… He has mild point tenderness over the a.c. joint with a negative cross body." *Id*. at 77. His provider recommended formal physical therapy, noting that it seemed that Petitioner "has straightforward impingement syndrome. I discussed with him, that I do not see the

connection of his symptoms and a flu injection. We'll plan to see him back in 4-6 weeks...." *Id*.

On November 15, 2016, Mr. Agate was seen for follow up of his left shoulder that was injured as a result of the 2010 motor vehicle accident. Ex. 4 at 84. The assessment was superior glenoid labrum lesion left shoulder and pain in the left shoulder, and physical therapy was again recommended. *Id.* There is no mention of *right* shoulder pain during this visit.

On December 5, 2016, Mr. Agate saw Dr. Michael Cicchetti at Buffalo Spine and Sports Medicine for a main complaint of right anterior lateral aspect shoulder pain, constant ache, pain refers into right trapezius. Ex. 9 at 1. The note lists onset of right shoulder pain as "last 9/15 no injuries." *Id*. Petitioner reported that his current pain level was a 4/10, that his pain was continuous, and worse with overhead reaching, end range shoulder abduction, internal and external rotation. *Id*. Upon exam, Mr. Agate had right shoulder range of motion within normal limits, some pain with restriction, and positive impingement signs. *Id.* at 3. Dr. Cicchetti also reviewed Petitioner's MRI results. The diagnoses were chronic right shoulder pain, osteoarthritis of the right acromioclavicular joint, subacromial bursitis, and superior glenoid labrum lesion of the right shoulder. *Id.* The plan was a diagnostic, anesthetic injection, which was administered. *Id.* Petitioner reported immediate improvement in right shoulder pain with all active range of motion. *Id*. Upon exam, impingement signs were improved, but a continued positive O'Brien's test was "suggestive of his labral pathology." *Id*.

Mr. Agate returned to Dr. Cicchetti in early 2017. Ex. 9-1 at 6. He reported right shoulder pain, improved since his last visit and anesthetic injection. *Id.* Dr. Cicchetti administered another injection with corticosteroid included "for a longer therapeutic effect." *Id*.

On March 6, 2017, Mr. Agate underwent spinal surgery (minimally invasive decompression laminectomy interbody fusion). Ex. 5 at 86. He was discharged on March 6, 2017, in good condition. *Id*. at 86-96.

Mr. Agate requested an online second orthopedic opinion from orthopedist Dr. Eric Ricchetti at Cleveland Clinic Consult on April 20, 2017, for complaints of pain in both shoulders, right greater than left. Ex. 4 at 87. The history section of the note stated that Petitioner had "complaints of bilateral shoulder pain since 2012" though he stated the right shoulder pain started after an influenza vaccine, and the left one after a motor vehicle accident. *Id.* Mr. Agate reported that "the right shoulder is the more symptomatic of the two currently." *Id.* He had pain with overhead activities, reaching, and lifting but not with

sports activities. *Id.* Mr. Agate was diagnosed with labral tears in both shoulders and conservative treatment was offered. *Id*.

After reviewing his imagining studies, Dr. Ricchetti noted:

> The MRIs of both shoulders show similar findings. There are changes around the labrum of both shoulders that may represent degenerative fraying, or wear and tear type changes from use over the years, or these changes may represent true tears of the labrum off the bony glenoid rim. The left shoulder shows a larger area of involvement. Although there is no significant cuff tear in either shoulder, there are also wear and tear type changes in the rotator cuff in both shoulders that could also contribute to [petitioner's] pain complaints. The symptoms in both shoulders may be from a combination of both the labrum and rotator cuff.

Ex. 4 at 87. Dr. Ricchetti recommended conservative treatment, cortisone injections, or arthroscopic surgery. *Id.* The diagnosis was left and right shoulder labral tears and rotator cuff tendinosis. *Id.*

On August 24, 2017, Mr. Agate returned to see Dr. Ricchetti, this time for an in-person consult for complaints of bilateral shoulder pain since 2012. Ex. 5 at 103. Petitioner again mentioned the motor vehicle accident and vaccination as the causes of both the left and right shoulder pain, respectively. *Id.* at 105. The note states that "[t]he right shoulder symptoms seemed to be precipitated by a flu shot 2 years ago. The right shoulder is the more symptomatic of the two currently." *Id*. Mr. Agate complained that he had difficulty with certain reaching, lifting, and overhead activities. *Id*. His active and passive range of motion mild limited in both shoulders, with normal strength bilaterally. *Id.* After review of imaging studies, Dr. Ricchetti's assessment was bilateral rotator cuff tendinosis, bilateral degenerative labral pathology, or tear. *Id.* at 106. Dr. Ricchetti recommended ongoing conservative treatment or arthroscopic surgery for subacromial decompression and possible labral tear repair. *Id.* The orthopedist noted "it does sound like [Petitioner] has also had discussion on potential distal clavicle excision in his right shoulder due acromioclavicular joint complaints on this side." *Id.*

On September 18, 2017, Mr. Agate returned to Buffalo Spine & Sports Medicine where he met with Dr. Cicchetti. *See* Ex. 9 at p. 9. At this appointment, Mr. Agate rated his pain at a 3/10 and stated that the pain was "constant." *Id*. He underwent an ultrasound injection of Depomedrol into his glenohumeral joint. *Id*. at p. 10. The report notes that there is "evidence of bursal fluid pooling lateral to the acromion at 90 degrees abduction in the impingement view." *Id.* The impression was: "1. Acromioclavicular joint degenerative changes. 2. Minimal subdeltoid-subacromial bursal thickening but without

definitive signs of bursitis. 3. All 4 rotator cuff tendons intact. 4. No evidence of the glenohumeral joint effusion or spinoglenoid notch cysts." *Id*. He was scheduled for a follow up in six to eight weeks. *Id.* at p. 11. It was also noted that "[a]t some point he may need to consider arthroscopic repair of the glenoid labrum. *Id*.

Mr. Agate has asserted in his witness statement that around this time, his father had a major stroke, and that he was heavily involved in the care of his father and subsequent extended hospitalization. Ex 1 at 2.

On February 12, 2018 (approximately five months later), Mr. Agate again saw Dr. Cicchetti at Buffalo Spine & Sports Medicine. *See* Ex. 9 at p. 12. It was noted that "[r]ight shoulder pain has exacerbated over the past several weeks. A prior acromioclavicular joint and subacromial bursa injection last January did really well for him. A more recent glenohumeral joint injection in Sept was ineffective … The patient rates the pain to be 5/10. The pain is intermittent." *Id*. Dr. Cicchetti at this time performed another ultrasound injection for Mr. Agate's acromioclavicular joint and a right subacromial bursa injection. *Id*. at 20.

On September 19, 2018, Mr. Agate was seen by Dr. Thaddeus Szarzanowicz, an orthopedic surgeon, for complaints of bilateral shoulder pain and left knee pain. Ex. 28 at 1-3. Mr. Agate stated that he wanted to shift the focus to his shoulders "now that the symptoms in the spine have been optimizing." *Id*. at 1. Petitioner reported that his right shoulder was more symptomatic than the left and that he was having difficulty with overhead lifting activities and reaching activities. *Id*. Pain, mechanical issues, and weakness were noted. Mr. Agate was assessed with pain and instability in his shoulders and the surgeon ordered a new MRI of his right shoulder only. *Id*. at 3.

On October 25, 2018, Mr. Agate underwent a physical therapy evaluation for his right shoulder pain and instability, which he reported began three years earlier after an influenza vaccine. Ex. 21 at 2. The assessment was probable right shoulder rotator cuff tear or impingement, and Mr. Agate was to attend physical therapy twice a week for two months. *Id.* On November 28, 2018, Mr. Agate had a whole-body evaluation at physical therapy for lower back pain and lumbar fusion and lower extremity weakness. *Id.* at 5. Petitioner attended one more physical therapy visit on November 31, 2018, for his right shoulder. *Id.* at 3. Visits on December 6, 2018, and December 12, 2018, only refer to the lower back pain. *Id.* at 6.

During the period from October 2015 through August 2020, Mr. Agate regularly attended massage and/or acupuncture sessions at Brain and Spine Medical Services, PLLC. *See generally* Ex. 24 (detailing approximately 109 visits). Aside from the visits on

October 6, October 31, and November 7, 2015, described above, Mr. Agate did not mention right shoulder pain or issues again until September 7, 2018, nearly three years later. *Id.* at 174. On that date, he complained of pain and stiffness in the neck, shoulders, and upper back, "L>R sided." *Id.* He also noted pain radiating into the right forearm and wrist. *Id.*

On December 3, 2019, Mr. Agate presented for an MRI of the right shoulder. Ex. 25 at 4-5. The impression was:

> 1. No rotator cuff tear is seen.
> 2. There is a posterior inferior labral tear with associated paralabral cystic change just inferior to 9 o'clock.
> 3. Also identified is subtle paralabral cystic change at 6 o'clock and anterior to 6 o'clock, and this may be due to occult labral tears at these additional locations which are not readily visible on this exam.
> 4. There is acromioclavicular spur formation, lateral acromial downsloping, and overall moderate subacromial narrowing.

Id.

On October 8, 2020, Mr. Agate had a telehealth consult with Marko Bodor, M.D. Ex. 25 at 2-3. Via Zoom, Mr. Agate complained of "[r]ight shoulder pain, low back pain, and right knee pain." *Id*. at 2. He reported the onset of his right shoulder pain as immediately following a flu vaccination in September 2015. Mr. Agate explained that he had been sitting while the pharmacist was standing and that he felt "intense" pain during the injection, which persisted days later. *Id*. Dr. Bodor performed a virtual physical exam, nothing that Mr. Agate had "not much" pain when he raised his arms over head but pain when reaching across his chest. *Id.* at 3.

Dr. Bodor reviewed the MRI report and noted no significant abnormalities to the infraspinatus tendon or teres minor tendon insertion. *Id.* He noted the report indicated an inferior labrum tear. *Id.* The assessment was right shoulder pain subsequent to vaccination in September 2015, immediate onset with persistence of pain, pain with cross arm abduction, lack of response to corticosteroid injections to AC joint, bursa, and labrum, and inferior labrum tear noted on MRI. *Id.* Dr. Bodor also assessed Mr. Agate with a left meniscus tear, lower back pain, and left shoulder pain. *Id.* Dr. Bodor discussed Mr. Agate's case with Dr. Cicchetti, and the plan was to conduct a Zoom call with both doctors to identify the location of a vaccine deposition and potentially perform a TenJet procedure. *Id.* Dr. Bodor noted, "I am happy to advise Dr. Cicchetti in doing this for the first time outside of our practice, or [Petitioner] can come here." *Id.*

On October 22, 2020, Mr. Agate presented to Dr. Cicchetti for a "a limited diagnostic evaluation of the posterior rotator cuff with attention to the infraspinatus/teres minor tendons." Ex. 26 at 1. Dr. Bodor was "available by FaceTime to assist with localizing the targeted lesion in the posterior rotator cuff for diagnostic local anesthetic injection." *Id.* Upon exam, Dr. Cichetti noted active range of motion within normal limits for the right shoulder, and mild pain with restriction. *Id.* An ultrasound was performed, and Dr. Cicchetti noted no focal partial thickness or full thickness tears in either tendon. *Id.* at 2. He noted a small cortical pit at the insertion of the infraspinatus tendon and the posterior aspect of the greater tuberosity. *Id.* His impression was that the location "correlates with the possible location of where the flu vaccine may have been administered." *Id.* Dr. Cicchetti performed an ultrasound-guided injection into the cortical defect. *Id.* Mr. Agate reported between 50% and 60% immediate pain relief, especially with cross-adduction. *Id.* The diagnosis was tendinitis of the right shoulder, and Mr. Agate was instructed to monitor his symptoms until the anesthetic wore off. *Id.* The plan was to follow up to discuss results and determine whether to proceed with a TenJet procedure. *Id.*

On October 28, 2020, Mr. Agate had a virtual telehealth consultation with Dr. Bodor. Ex. 25 at 1. He now reported a 50% improvement "by the time he got to his car following the procedure and it lasted for a couple hours." *Id.* Mr. Agate asked Dr. Bodor whether the defect in the bone was "definitive for a SIRVA injury and I told it that it was not and not specific for that, but the more specific finding is improvement with anesthetic injection." *Id.* The assessment was back pain, thigh pain, and right shoulder SIRVA injury. *Id.* The plan was to schedule an "ultrasound washout with the TenJet system." *Id.* Dr. Cicchetti was to perform the procedure, and Dr. Bodor told Mr. Agate he was "confident that Dr. Cicchetti was careful and able to identify the proper location." *Id.*

At his last appointment with Dr. Bodor on June 13, 2022, Mr. Agate confirmed the presence of ongoing shoulder pain, and it was noted that he was still considering surgery as well as additional injections and other medical management of his condition. *See* Ex. 29.

2. Affidavit Evidence

a. Mr. Agate

Mr. Agate submitted an affidavit, dated September 13, 2018, in support of his Petition, in which he stated that he recalled that the needle on the date of his September 15, 2015 vaccination "looked like a much larger gauge needle than I had seen on prior occasions." Ex. 1 at 2. He further stated that he was seated while the pharmacist was standing during vaccination administration, and that he noticed that the "shot went high

up into my shoulder." *Id.* Mr. Agate stated that he felt a sharp pain in his shoulder as soon as the vaccine was administered. *Id*. When the pain did not dissipate, Mr. Agate stated that he went back to Rite Aid to complain and to see what the response would be. Petitioner stated that he was told that the pain was "perfectly normal" and should subside. *Id*.

Regarding his delay in seeking treatment for his right shoulder pain, Mr. Agate explains that,

> [w]hen I was still having pain several weeks later, I told Dr. Hamill about my right shoulder. Dr. Hamill was an orthopedic doctor whom I had been treating with for injuries I sustained to my lower back in an automobile accident… My recollection is that I also saw Dr. Clerk during this time period for my right shoulder but I understand his office does not have any records of such a visit.
> …
> I remember talking to my doctors about my right shoulder and how it could affect the timing of surgery for my back if I ended up needing to get a procedure done for the shoulder. Since my back injuries were pretty significant and because I had already received recommendations to have surgery performed on my back, we made the decision to hold off on doing anything with the shoulder until I figured out how to proceed with my back.
> …

Id. at 3.

b. Renee Freda

Ms. Freda maintains that she has known Mr. Agate for approximately 13 years and has dated him for over eight and a half years. Ex. 3 at 1. She stated that she was living with Mr. Agate at the time of vaccination and recalled that when he returned home after receiving the vaccine on September 15, 2015, he complained that his arm was hurting him. *Id*. Ms. Freda also recalled that Mr. Agate noticed that the needle for the vaccine "appeared to be much larger than the ones he's seen used for flu shots in the past." *Id*. at 1-2. Ms. Freda averred that as time went on, Mr. Agate's shoulder pain did not subside, and she recalled that he returned to Rite Aid to complain about the pain. *Id*. at 2. She stated that around that time, Mr. Agate was also experiencing back issues and was undergoing back surgery, but that he still was suffering from right shoulder pain. *Id*. Ms. Freda stated that although Petitioner had suffered injuries in an automobile accident prior to receiving the flu shot, he never had any issues with his right shoulder or arm. She stated that as a result of the vaccine, Mr. Agate cannot do many things around the house

such as carry water, take out the garbage, or any other chores that require lifting. *Id*. at 3. Ms. Freda stated that Petitioner has been dealing with chronic pain every day. *Id*.

III. Expert Reports

a. Petitioner's Experts

A. Dr. Michael Cicchetti

Petitioner filed a statement from his treating physician, Dr. Michael Cichetti. Ex. 30. Dr. Cicchetti received his medical degree from the University of Virginia School of Medicine and completed his residency at the University of Virginia Department of Physical Medicine and Rehabilitation. *Id*. at 1. He is licensed to practice medicine in the State of New York and is board certified in Physical Medicine and Rehabilitation. *Id*. Dr. Cicchetti is also registered in Diagnostic Musculoskeletal Ultrasound by the American Registry for Diagnostic Medical Sonography (ARDMS). *Id*. He is currently associated with Buffalo Spine and Sports Medicine where he maintains a practice in Physical Medicine and Rehabilitation. *Id*.

Dr. Cicchetti first met Mr. Agate on December 5, 2016, for complaints of right shoulder pain that Petitioner reported he had been experiencing since receiving a flu shot in that arm on September 15, 2015. Ex. 30 at 1. Dr. Cicchetti reviewed Petitioner's treatment medical history with him, including the administration of a lidocaine injection into Petitioner's AC joint and subacromial bursa. *Id*. at 2.

In October 2020, Mr. Agate sought Dr. Cicchetti's opinion about whether the flu vaccine he received could have been the main source of his pain and symptomology. Ex. 30 at 3. Dr. Cicchetti stated, "I noted in my report that there is indeed some evidence from Dr. Marko Bodor (Napa, CA) that a shoulder injury resulting from vaccine administration ('SIRVA') may explain a rate subset of chronic shoulder pain in patients following vaccination." *Id*. With the assistance of Dr. Bodor via Facetime, Dr. Cicchetti stated that he administered a limited diagnostic local anesthetic injection to determine whether or not Petitioner's pain was SIRVA related. *Id*. Dr. Cicchetti noted "a small cortical pit noted at the insertion of the infraspinatus tendon and the posterior aspect of the greater tuberosity. This region is consistent and correlates with the possible location of where the flu vaccine may have been administered and as such was targeted for injection." *Id*. After injection, Petitioner reported a 50-60% relief in his pain which Dr. Cicchetti found to be "clinically and diagnostically significant as this is above placebo effects and is supportive of the conclusion that Mr. Agate's injury was likely a SIRVA injury." *Id*. at 4.

Dr. Cicchetti concluded that "[g]iven the temporal association reported by Mr. Agate between the flu shot and his symptoms, and when considering his history, complaints, examinations, and treatment and based upon the objective and subjective evidence I reviewed, as well as my treatment of him, it is my opinion that the influenza vaccination he received on September 15, 2015 was a substantial factor in causing a SIRVA injury to his right shoulder." Ex. 30 at 4. Dr. Cicchetti stated that he held this opinion "to a reasonable degree of medical certainty." *Id*.

B. Dr. Marko Bodor

Petitioner filed an expert report prepared by Dr. Marko Bodor. Ex. 31. Dr. Bodor obtained his Bachelor of Arts degree from Harvard University in 1982, and his M.D. from the University of Cincinnati Medical School in 1987. *See* CV, filed as Ex. 33 (ECF 61-2) at 1. He thereafter completed a residency in physical medicine and rehabilitation at the University of Michigan. *Id.* He is board certified in Physical Medicine and Rehabilitation (1994), Neuromuscular and Electrodiagnostic Medicine (1997), Pain Management (2004), and Sports Medicine (2010). *Id.* Since 1995, Dr. Bodor's primary practice has been treating patients "with a variety of neuromuscular, musculoskeletal, and pain problems. *Id.* at 2. Dr. Bodor's practice "has been an APPMR approved fellowship" taking on two fellows per year, whom he averages approximately 12 hours per week teaching and supervising. *Id.* at 7. Dr. Bodor has written several articles and given numerous presentations on varying neuromuscular and musculoskeletal issues, testing, and treatments. *Id.* at 3-5, 7-9. He has provided expert opinions in more than 50 SIRVA cases in the Program. Ex. 31 at 1.

Dr. Bodor begins his report by providing a chronological summary of Petitioner's medical records that have been filed in this case. Ex. 31 at 1-4. He emphasized that Mr. Agate, who had no prior history of right shoulder pain, experienced a "new onset of right shoulder pain immediately following a right shoulder vaccination on 9/15/15." Ex. 31 at 4. Dr. Bodor noted that Petitioner had a "good but temporary improvement" of his right shoulder pain after receiving several corticosteroid injections to his subacromial space, and a 50-80% improvement after a diagnostic anesthetic injection directed to the infraspinatus tendon insertion. *Id*. He stated that, "[t]his indicates that approximately 50-80% of his pain stems from a discrete location in his shoulder, consistent with our case series (Ref. 2) of patients who had chronic vaccination-related shoulder dysfunction and benefited from ultrasonic aspiration and debridement." *Id*.

Dr. Bodor also noted that Petitioner's 2016 MRI demonstrated edema in the subacromial bursa, "which has been demonstrated in cases of SIRVA, but is a nonspecific finding." Ex. 31 at 4. He admitted that specific MRI findings, such as edema at the infraspinatus and teres minor tendon insertions where not present in either of Petitioner's

2016 or 2019 MRIs. *Id*. However, Dr. Bodor stated that the absence of specific findings "are not necessarily exclusionary criteria." *Id*. He described a case report of a patient he treated who had been vaccinated with the COVId-19 vaccine and likewise, did not have specific abnormalities on MRI. *Id*. Ultrasonic aspiration and debridement treatment "was thought to work by removing vaccine antigens or antigen-antibody complexes (Ref. 3) from the rotator cuff, capsule and or adjacent bone." *Id*. Dr. Bodor concludes that "Mr. Agate's right shoulder pain appears to be more likely than not mostly attributable to the flu vaccination he had in September 2015." *Id*.

b. Respondent's Expert – Dr. Julie Bishop

A. Qualifications

Respondent submitted an expert report and curriculum vitae prepared by Dr. Julie Bishop. Dr. Julie Bishop received a B.S. in microbiology and a M.D. from Cornell University. Ex. B (hereinafter "Bishop CV") at 1. Dr. Bishop completed a general surgery internship and orthopaedic residency at George Washington University. Bishop CV at 1-2. Dr. Bishop also completed a shoulder surgery fellowship at Mt. Sinai Hospital and sports medicine visiting fellowship at the University of Pittsburgh. *Id.* at 2. Dr. Bishop is a professor of orthopaedics at the Ohio State University and serves as chief of the division of shoulder surgery, vice chair of finance of the department of orthopaedic surgery, and team physician for the Ohio State Department of Athletics. *Id.* at 1, 2. Dr. Bishop has won a number of awards including: OSU Faculty Teaching Award 2021, OSU Orthopaedic Educator of the Year 2019, Best Doctors in America 2010-21. *Id.* at 3-5. Dr. Bishop is on a number of national and OSU committees and editorial boards. *Id.* at 5-9. Dr. Bishop has authored approximately 87 peer-reviewed papers and 17 book chapters. *Id.* at 9-22.

B. Bishop Expert Opinion

Dr. Bishop's expert report begins with an overview of her medical background, followed by a detailed recitation of the medical records, and a discussion and summary of the medical records she reviewed. Ex. A at 1-10.

The next section of the report is dedicated to discussing the onset of Mr. Agate's shoulder pain. *Id*. at 10. Dr. Bishop noted that there "are no documented medical records of the petitioner seeking medical treatment shortly after his vaccination," other than the record from Rite Aid. *Id*. This record noted that Mr. Agate complained of pain after his flu shot, but he also stated that the pain was subsiding and almost gone. *Id*. Dr. Bishop also noted that while Petitioner stated that the needle used for vaccination was "larger than normal," there was no documentation to support this assertion. *Id*. She also noted that Petitioner's statements that he reported his right shoulder pain to his primary care

physician are not documented in any of the medical records. *Id*. Dr. Bishop concluded that there was no evidence to support a diagnosis of SIRVA as there was no factual medical documentation to support a 48-hour onset. *Id*. at 11.

The next section of Dr. Bishop's report discusses "Shoulder Diagnoses that support SIRVA." Ex. A. at 11. She noted that despite the fact that Mr. Agate saw "multiple physicians regarding his shoulder," "[n]one of these physicians provided the petitioner with a diagnosis consistent with SIRVA." *Id*. Dr. Bishop stated that no physician linked Petitioner's vaccination with his symptoms, and instead, diagnosed him with chronic degenerative pathologies of the shoulder, such as tendinosis, impingement, arthritis, and degenerative labral pathology. *Id*. She stated that none of these diagnoses are the acute inflammatory type diagnoses that are consistent with SIRVA. *Id*. Dr. Bishop also noted the statement from Dr. Mason, one of Mr. Agate's treating physicians, who felt that Petitioner had "straightforward impingement" and did not "see the connection of his symptoms and the flu injection." *Id*. at 12. She noted that although bursitis was mentioned one time in Petitioner's medical records, the diagnosis was not backed by any radiographic imaging. *Id*. Dr. Bishop explained that while SIRVA is not well known in the general medical community, in the orthopedic community, SIRVA is a well-recognized diagnosis that is recognized by any orthopedic surgeon that treats a shoulder injury. *Id*. She stated that Dr. Eric Richetti, who treated Petitioner and whom she knows personally, is well-versed in all shoulder injuries, including SIRVA, but still felt that Petitioner's injury was due to chronic degeneration, not an acute inflammatory process. *Id*. Dr. Bishop also noted that Petitioner was a "retired hockey player" and stated that it was likely that this sport caused wear and tear to the shoulder. *Id*. She stated that "[a]ll of the documented right shoulder examinations, testing, and diagnoses are consistent with degenerative wear and tear in the right shoulder…" *Id*.

Dr. Bishop next discussed the imaging studies in the record. Ex. A at 12. She noted that Mr. Agate underwent radiographs, two MRIs, and one ultrasound prior to October of 2020, and no acute inflammatory findings were noted. *Id*. Dr. Bishop stated that all of the findings supported a chronic, degenerative pathology. *Id*. She noted that the edema seen in the first MRI was "within physiologic limits" and no edema was mentioned in the second MRI. *Id*. Dr. Bishop stated that, "[i]f the needle from the vaccination caused a direct impact, the sequela of this would be edema in the soft tissue and osseous (bone) edema in the humeral head that would have been seen initially." *Id*. She also noted that the "cortical pit" that Dr. Bodor identified was detected five years post vaccination and was never seen on any prior imaging. *Id*. Thus, Dr. Bishop concluded that there were no imaging findings to support a SIRVA diagnosis. *Id*.

Finally, Dr. Bishop explained that the physical examination findings are not consistent with SIRVA. Ex. A at 13. She noted that there was never a deficit with Petitioner's range of motion. *Id*. In fact, she noted, that when range of motion was noted in any physical exam, it was noted to be "full, intact, symmetric…" *Id*. Dr. Bishop noted that while Mr. Agate complained of weakness, there is no documentation of a loss of range of motion. *Id*. She also noted that "multiple examinations of [Petitioner's] left shoulder were always very similar to the right shoulder and really there were no differentiating factors between the 2 sides." *Id*. Dr. Bishop also noted that Dr. Bodor described in his paper that, in his experience, patients with SIRVA had posterior pain, often relieved with anesthetic injection, and Petitioner never had any pain described as posterior pain. *Id*. at 13-14. She noted that Mr. Agate's pain "was never localized or characterized as being primarily posterior/posterolateral shoulder pain until the initial encounter with Dr. Bodor, 5 years after the vaccination." *Id*. at 14. Dr. Bishop opined that any pain Petitioner reported in this area was unrelated to vaccination and consistent with symptoms related to degeneration as documented over the years. *Id*.

In conclusion, Dr. Bishop opined that Mr. Agate's symptoms do not meet the SIRVA criteria, because (1) there is no medical documentation to support the onset of pain within 48 hours of vaccination, (2) there is no documented loss of mobility and range of motion, and (3) that there is "an abundance of evidence from different imaging sources, and multiple physical examinations… that the petitioner clearly had many other abnormalities in his shoulder clearly related to wear and tear and degenerative causes, that clearly explained his symptoms, and therefore, SIRVA is not the only plausible diagnosis for his symptomology." *Id*. She concluded "with a reasonable degree of medical certainty that there is no objective evidence or documentation to support the shoulder symptoms of Mr. Agate were caused by his flu vaccination on September 15, 2015." *Id*. Instead, Dr. Bishop stated that there is evidence that his right shoulder symptoms were due to "chronic, degenerative, wear and tear types of pathology." *Id*.

IV. Parties' Respective Arguments

Petitioner argues that the medical records, affidavit, and Drs. Cicchetti's and Bodor's expert reports all clearly demonstrate that he suffered a SIRVA injury following receipt of the flu vaccine on September 15, 2015. Mot. at 1-2. Respondent argues that Petitioner's SIRVA claim fails because the onset of his shoulder pain did not occur within 48 hours of vaccination, and that "there are additional explanations for petitioner's right shoulder pain which preclude a finding of SIRVA as a Table injury." Thus, two Table SIRVA injury requirements cannot be met. Opp. at 1; 14. Respondent also argues that Petitioner has not established a cause-in-fact claim. *Id*. at 23.

V. Applicable Law

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). 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." *Cucuras v. Sec'y of Health & Hum. 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 & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has 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 & Hum. 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 v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined.

Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

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 & Hum. 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).

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

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially

thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)); *see also Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed,* No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner

must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at

742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). 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").

Consideration of Medical Literature

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles (if any) that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

Analysis

I. Interplay Between Table and Non-Table Claims Based on Same Facts

It is not uncommon for the same facts relevant to an alleged vaccine injury to be the basis for both a Table and non-Table claim, such that the latter can viable even if the former is not. Indeed, in the SIRVA context in particular, I have routinely found (as here) that a Table element cannot be met, but then transfer the case out of SPU for resolution as a non-Table claim. At that point, however, the context for analysis changes substantively. The nature of the specific showing that must be met to obtain entitlement for a non-Table claim is quite different.

Causation is presumed for Table claims—meaning the Government has already made a determination, when announcing the existence of a Table claim, that sufficient scientific and medical evidence exists to allow Program claimants to seek damages without also requiring them to prove, for example, that a particular vaccine "can cause" an injury. In addition, Table claimants need only prove facts sufficient to meet certain elements of the claim at issue. *See* 42 C.F.R. § 100.3(b)(10). Most of the time, this obligates a petitioner to prove that (a) he received a covered vaccine, (b) he suffered a specific injury (consistent with the Table's "qualifications and aids to interpretation," which provide detailed definitions), and (c) the injury occurred in a defined timeframe measured from the time/date of vaccination. *Germaine v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 226, 227 (2021) (discussing the elements needed for compensation of a Table injury compared to those of a non-Table injury); *Spaans v. Sec'y of Dep't of Health & Hum. Servs.*, No. 12-585V, 2012 WL 5928730, at *1 (Fed. Cl. Spec. Mstr. Nov. 6, 2012) (dismissing a claim involving a non-covered vaccine).[3]

The specific Table elements relevant to a defined injury tend to be synergistically related, based on medical science about how (and when) a putative vaccine injury is *most likely* to occur. SIRVA provides an excellent example. SIRVA is believed to occur almost *immediately* after the improper administration of a vaccine. G. Cross et al., *Don't Aim Too High: Avoiding Shoulder Injury Related to Vaccine Administration*, 45 Australian Family Physician 303, 303 (2016), filed as Ex. 9(c) (ECF No. 31-3). Thus, a Table SIRVA is only viable if preponderant evidence exists establishing pain very close in time to vaccination. However, while more often than not Table claimants allege immediate pain, a Table SIRVA can also succeed even if the pain does not manifest until up to 48 hours post-vaccination. The claim's most likely temporal "target" for occurrence, for purposes of the claim, has thus been widened somewhat. *See, e.g.*, National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 FR 45132-01 ("[i]n

[3] Sometimes expert input is required to adjudicate Table claims (for example, when a diagnosis is disputed), although it is not common.

order to capture the broader array of potential injuries, the Secretary proposes to add SIRVA for all tetanus toxoid-containing vaccines that are administered intramuscularly through percutaneous injection into the upper arm. The interval of onset will be less than or equal to 48 hours").

Unsuccessful Table claims are not automatically dismissed in their entirety, even if it is determined that one or more Table elements cannot be met. Nevertheless, thereafter the "road to entitlement" becomes more difficult (although the preponderant burden of proof is consistent) once the claim becomes subject to the non-Table, causation in fact analysis. Although non-Table claimants may often be able to take advantage of the evidence that resulted in the Table presumption in their effort to satisfy the first, "can cause" *Althen* prong, they cannot rely on how close they came to meeting the Table requirements. *See, e.g.*, *Fantini v. Sec'y of Health & Hum. Servs.*, No. 15-1332V, 2022 WL 1760730, at *22 (Fed. Cl. Spec. Mstr. May 2, 2022) (". . . Program claimants cannot "piggyback" on the Table requirements when attempting to prove a non-Table claim."); *Greene v. Sec'y of Health & Hum. Servs.*, No. 11-631V, 2018 WL 3238611, at *9 (Fed. Cl. Spec. Mstr. May 7, 2018) (noting that an expert's opinion on the timing issue of a brachial neuritis claim relied on conclusory determinations that the "Table time periods were not that far off the time period in question (something Program law says is not permitted)"). Rather, they must support each prong with sufficient preponderant evidence.

II. Petitioner Cannot Establish All SIRVA Table Claim Elements

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[4] a petitioner must establish that he suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A

[4] In summary, a petitioner must establish that he 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 his 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* § 11(c)(1)(A)(B)(D)(E).

vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following (set forth in the Table's Qualifications and Aids to Interpretation ("QAI")):

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

42 C.F.R. § 100.3(c)(10).

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." *Cucuras v. Sec'y of Health & Hum. 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 & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381 at 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. 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 & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

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 Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184 at 204 (2013) (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. 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).

A. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner cannot satisfy all of the QAI requirements for a Table SIRVA. I will address each QAI below.

1. No Prior Right Shoulder Condition or Injury

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). The specific language of the relevant QAI portion states that there must be "[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection." 42 C.F.R. § 100.3(c)(10)(i). Mr. Agate's medical history does not evidence pre-

vaccination explanatory "pain, inflammation or dysfunction" of his right shoulder. Thus, the first SIRVA criterion is met.

2. Pain Occurring Within the Specified Timeframe (Onset)

A petitioner alleging a SIRVA must also show that his pain occurred within two days, or 48 hours, of vaccination. (42 C.F.R. § 100.3(c)(10)(ii) (QAI criteria)).

Respondent has argued that the first mention of right shoulder pain post-vaccination in the medical records is simply a passing reference to right deltoid tension, which Mr. Agate conveyed to his massage therapist on October 6, 2015. Opp. at 24. Petitioner did not relate the "tension" to his September vaccination at that time, however, and there is no other discussion of the right shoulder symptoms contained in that record. *Id.* However, on October 27, 2015—now six weeks after vaccination—Petitioner is recorded to have returned to the pharmacy to complain about pain from the flu shot. *Id*. citing Ex. 22 at 1. Respondent nevertheless argues that it was not until eight months after vaccination that a medical provider treating petitioner noted his alleged right shoulder injury. *Id*. In addition, Respondent noted that Mr. Agate had earlier visits with his PCP at which he discussed other diagnoses but failed to mention right shoulder issues. *Id*. And although Petitioner alleged in his affidavit that he felt pain immediately after vaccination, the court cannot find that a vaccine-related injury occurred based solely on the claims of petitioner alone. *Id*.

The totality of the evidence preponderantly supports the conclusion that Mr. Agate's shoulder pain occurred within 48 hours of his vaccination. Approximately one month after vaccination, the records show that Mr. Agate returned to Rite Aid Pharmacy to complain of right shoulder pain after his flu vaccination. Ex. 23 at 2. The record states that Mr. Agate, "stopped in 10/27/15 to talk about pain from flu shot- recommended ice/motrin and to follow up. Pain has been subsiding and is almost gone he said (sic)." *Id*. While not completely dispositive, I find that this record alone preponderates in Petitioner's favor demonstrating that he experienced right shoulder pain immediately after vaccination. Thus, Petitioner has fulfilled this criterion as well.

3. Petitioner's Pain and Limited Range of Motion was Limited to his Right Shoulder

The specific language of a SIRVA injury contained in the QAI of the Vaccine Injury Table is that "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii) (QAI criteria)). Respondent has argued that Mr. Agate never experienced any documented reduced

range of motion in his vaccination arm, and thus cannot fulfill this criterion. Opp. at 15. In support of this argument, Respondent notes that Petitioner's citation to the record for evidence of reduced range of motion "inaccurately reflects subjective portions of the medical records as if they were objective findings." *Id*. But objective findings memorialized in the record "consistently demonstrate normal, full, symmetric range of motion each time tested." *Id*.

Whether Petitioner suffered ROM issues sufficient to meet the claim's requirements presents a closer question - although one I find can be resolved in Petitioner's favor. Petitioner's Reply brief cites to numerous references in the medical records that purport to demonstrate a reduced range of motion. Reply at 5-6.[5] In reviewing these references to the medical records, it does appear that Mr. Agate displayed objective limitations in his range of motion that would satisfy the QAI criteria for a "reduced range of motion." And a petitioner alleging a Table SIRVA need not establish ROM limitation *beginning* within 48 hours of vaccination (as he must with pain),[6] so the timing of this symptom need not occur at a specific post-vaccination moment. I thus find that Petitioner, more likely than not, has fulfilled this criterion.

4. There is No Evidence of Another Condition or Abnormality

The last criterion for a Table SIRVA states that there must be no other condition or abnormality which would explain Petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent has argued that Petitioner's own treaters concluded that his right shoulder pain is unrelated to vaccination and likely caused by the same wear and

[5] *See*, e.g., Ex. 5 at 105 (range of motion testing conducted at the Cleveland Clinic showed decreased range of motion for both passive and active elevation and external rotation as well as pain, tenderness to palpation, and positive orthopedic testing); Ex. 21 at 2 (range of motion testing performed at Buffalo Physical Therapy & Sports Rehabilitation, P.C. showed decreased range of motion on flexion, extension, abduction, and internal rotation); Ex. 4 at 73 (on October 7, 2016, Mr. Agate returned to see Dr. Clerk, where it was noted: "R shoulder pain since getting flu shot – limited rom and weakness"); Ex. 7 at 1 (MRI report for his right shoulder from Great Lakes Imaging noted "Deltoid muscle pain at site of flu shot injection. Limited ROM"); Ex. 4 at 49, 66-83 (on May 9, 2016, his PCP after doing x-rays and diagnosing him with pain in his right shoulder, ordered Mr. Agate physical therapy for "Active Assistive ROM," which is when the joint receives partial assistance from an outside force because of pain and limited range of motion in the extremity); Ex. 4 at 49, 66, 67, 73, and 83.

[6] Indeed, the claim's QAIs do not specify *any* particular timeframe in which ROM limits must manifest. And I do not otherwise find that a failure to show ROM manifesting within six months of onset implicates the Act's "severity requirement." *See* Section 11(c)(1)(D)(i). The Act only obligates a claimant to show that *sequelae* of the injury persisted more than six months from onset—and here that is easily demonstrated. It does not specify severity to mean that *all* manifestations of an injury, as defined by the QAIs, must fully be evident *within* six months of the onset. This is also not a case where no evidence of ROM issues is to be found (even if that is not the predominant character of Petitioner's SIRVA—something relevant to damages).

tear that caused similar pain in his left shoulder. Thus, Respondent claims that Petitioner has failed to establish a Table claim.

This is the sole QAI Petitioner cannot preponderantly meet. For there *is* ample evidence of another "condition or abnormality" that would explain Petitioner's symptoms. Dr. Bishop's expert report persuasively interprets the record to allow for the possibility that the significant degenerative pathologies of Petitioner's right shoulder likely explain his symptoms. Bishop Report, Ex. A at 11-15.

Importantly, because of the Table's wording, I can find as a fact matter that Petitioner did not rebut this "possibility"—even though in the causation-in-fact setting, the construction of the Petitioner's burden generally would not require him to eliminate a "factor unrelated" in his *prima facie* case. Here, to obtain the causality presumption, Petitioner (not Respondent) must *affirmatively* satisfy each Table element—and this one clearly requires him to *rule out* other explanations for his pain and related deficiencies. *See* 42 C.F.R. § 100.3(c)(10)(iv) ("[n]o other condition or abnormality is present that *would explain* the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)" (emphasis added). But as discussed above, and as not persuasively undermined by Petitioner's treaters or experts, ample record evidence exists – as reflected in MRI findings and amplified by Dr. Bishop—that *other things could explain* the shoulder pain Petitioner clearly experienced. This is enough to defeat his Table showing.

II. Petitioner Has Not Shown Entitlement to Damages Under a Causation-in-Fact Claim

As noted, I have already determined that a Table SIRVA claim was unsuccessful in this case because I found that there *was* another condition or abnormality present that would explain Petitioner's symptoms. This does, however, allow for the possibility that Petitioner could rebut the "condition or abnormality" evident from the record, by satisfying the *Althen* prongs in a SIRVA context – including that the flu vaccine likely "did cause" a SIRVA, as opposed to some preexisting condition.

However, the record establishes that Petitioner cannot preponderantly satisfy the second *Althen*[7] prong. Because it has not been preponderantly established that Mr.

[7] Since all three *Althen* prongs must be met, I need not discuss Petitioner's success on establishing the other three prongs – although I do note that (relying on the same medical science that resulted in creation of the Table SIRVA) it would be fair to conclude that vaccines "can cause" SIRVAs, even if in certain non-Table contexts a petitioner cannot show that happened *to him.*

Agate's vaccination likely caused his shoulder injury. Rather, the record evidence reveals other causes for Petitioner's injury that are more likely.

The evidence shows that on October 27, 2015 (just over a month after vaccination), Mr. Agate went to the Rite Aid Pharmacy where he received the flu vaccine to complain of right shoulder pain. Ex. 23 at 2. The record from this visit states ""stopped in 10/27/15 to talk about pain from flu shot- recommended ice/motrin and to follow up. Pain has been subsiding and is almost gone he said (sic)." Then, there is no mention of right shoulder pain in Petitioner's medical records for more than six months. The next mention of right shoulder pain occurred on May 9, 2016, when Petitioner was primarily seen for treatment of his lower back pain after surgery and the diagnoses included right shoulder pain. That same month, Petitioner also complained of *left* shoulder pain as a result of his 2010 motor vehicle accident. Ex. 4 at 52-54. During the physical examination of that visit, Mr. Agate exhibited normal strength in both upper extremities and experienced no pain with range of motion of either shoulder. *Id*. Then, there is another gap of more than two months where there is no mention of right shoulder pain. Finally, on August 6, 2016, 10 months and 22 days after vaccination, Mr. Agate was seen for complaints of right shoulder pain that he purported was due to his September 2015 flu vaccination. Ex. 6 at 2.

As Dr. Bishop explained in her expert report, when Mr. Agate's right shoulder was examined by multiple medical providers contemporaneous to his complaints from 2016 to 2020, *none* linked Petitioner's right shoulder symptoms to his vaccination, despite Petitioner's belief that the flu vaccination caused his injuries. In fact, Petitioner's treating orthopedist opined that he did not think the vaccination was the cause of his injury, stating it seemed that Petitioner "has straightforward impingement syndrome. I discussed with him, that I do not see the connection of his symptoms and a flu injection...." Ex. 4 at 76-77. Dr. Bishop also noted that one of Petitioner's treating providers, Dr. Ricchetti, who is "an internationally known shoulder surgeon," and who is very familiar with the SIRVA diagnosis, did not feel that Petitioner's presentation was consistent with SIRVA, instead finding that both Mr. Agate's right and left shoulder symptoms were very similar and were consistent with chronic degeneration, not an acute inflammatory reaction to a vaccination. Ex. A at 12.

Even Dr. Cicchetti, who provided an affirmative statement of causation in this case, did not initially link the vaccination with Petitioner's right shoulder symptoms. It was only after consulting with Dr. Bodor did he state that, "there is indeed some evidence from Dr. Marko Bodor (Napa, CA) that a shoulder injury resulting from vaccine administration ('SIRVA') may explain a rate subset of chronic shoulder pain in patients following vaccination." Ex. 30 at 3.

Dr. Bishop further explained in her report that all the diagnoses Mr. Agate received were "chronic degenerative pathologies of the shoulder, such as tendinosis, impingement, AC arthritis, degenerative labral pathology; none were acute inflammatory type diagnoses that are considered consistent with SIRVA as SIRVA is thought to be due to unintended injection of the vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction." Ex. A at 11. She explained that,

> The most common diagnoses with SIRVA are inflammatory (words ending in 'itis' which means 'forming names of inflammatory diseases') (Ex.11, 12, 13,19). Thus, commonly seen are adhesive capsulitis, bursitis, tendonitis, fluid collections from bursitis, etc. Chronic pathologies such as degenerative labral tears, osteoarthritis, tendinosis (the 'osis' means chronic tendon issue) are not thought to be consistent with SIRVA.

Ex. A at 11-12. She noted that the only time the term "bursitis" was used in the records was by Dr. Cicchetti on December 5, 2016 (a condition noted to have improved by September 18, 2017). *Id*. at 12. But this finding of "bursitis" was not supported by the diagnostic imaging, as there were no acute inflammatory findings on any of the imaging. *Id*.

In reviewing the numerous radiographs, two MRI studies, and one ultrasound study performed by Dr. Cicchetti, Dr. Bishop found that all of the readings supported a chronic, degenerative pathology of Mr. Agate's right shoulder. Ex. A at 12. Dr. Bishop noted that the edema seen on the first MRI "was read as 'within physiologic limits' and none was mentioned at all on the second MRI." *Id*. She noted that there were no definitive signs of bursitis on the ultrasound performed by Dr. Cicchetti in 2020. *Id*. Dr. Bishop explained that with a diagnosis of SIRVA, there would be evidence of edema in the soft tissue and osseous bone edema in the humeral head, and none was seen on any of the MRIs. *Id*. She also explained that the "cortical pit" that Drs. Cicchetti and Bodor found in October 2020 on ultrasound was found five years post vaccination, but had not been present on the earlier performed MRIs. *Id*. She explained that an MRI study was "exceedingly more sensitive to detect bone changes and bone erosions and bone edema than US [ultrasound]," and none were found in the 2016 or in the 2019 MRIs. *Id*. Thus, if a "cortical pit" was seen in an ultrasound five years later, Dr. Bishop opined that it likely developed well after the 2019 MRI, and had no relationship to the September 2015 flu vaccination. *Id*.

Dr. Bishop also found compelling the fact that Mr. Agate was a "retired hockey player (Ex. 5; 1), and certainly hockey is a sport that causes wear and tear in the shoulder,

and other body parts which is supported by the many bodily complaints of the petitioner to massage PT [physical therapist]." Ex. A at 12. She concluded that,

> [a]ll of the documented right shoulder examinations, testing and diagnoses are consistent with degenerative wear and tear in the right shoulder and the nature of degenerative/wear and tear issues in the shoulder is that the pain has an insidious onset, due to the buildup of wear and tear over the years.

Ex. A at 12.

I find Dr. Bishop's opinion to be highly persuasive, and it compellingly established that Petitioner's injury was not likely vaccine-related. Although Mr. Agate did experience *some* right shoulder pain shortly after vaccination, by the end of October (as he told a staff member at Rite Aid) that pain was "subsiding and almost gone." Then, for more than six months, Mr. Agate did not complain of, and was not seen for, right shoulder pain. That right shoulder pain, more likely than not, mostly resolved during that period of time.[8] His later complaints of *both* right and left shoulder pain were likely due to chronic, degenerative changes, as was seen on radiographic imaging and in his medical examination, since the symptomology of both shoulders was very similar. Dr. Cicchetti's and Dr. Bodor's opinions simply did not adequately explain these findings.

This is not a case in which one side's expert possessed superior knowledge of the relevant injury. All experts were well-qualified, and proved knowledgeable about the topics at issue. However, Dr. Bishop more persuasively interpreted Petitioner's record, and in doing so effectively explained why Petitioner's presentation of symptoms undercut the determination that his vaccination was causal.

In making this determination, I am not finding that an alternative cause *has* been established to any degree of certainty. But the mix of facts presented by this case (no preponderant showing of a Table SIRVA injury, and evidence of confounding factors that prevent the satisfaction of the "did cause" *Althen* prong) do not support the claim. This does not mean that *all* non-Table SIRVAs will fail, or should. But a more robust showing must be made than was offered in this case if they are going to succeed. *Compare L.J. v. Sec'y of Health & Hum. Servs.*, No. 17-0059V, 2021 WL 6845593, at *15–17 (Fed. Cl.

[8] I do find, however, that the Vaccine Act's severity requirement is met, because despite the more than six-month gap in focus on shoulder pain issues (from late October 2015 to May 2016), Petitioner did begin complaining specifically about shoulder pain he felt was associated with vaccination in August 2016.

Spec. Mstr. Dec. 2, 2021) (noting that petitioner provided preponderant evidence to prevail under the *Althen* test).[9]

Conclusion

Based on the entire record in this case, I find that Petitioner has not carried his burden of proof, whether the claim sounds as a Table or causation-in-fact claim. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[10]

IT IS SO ORDERED.

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

[9] Although *L.J.* stands as an example of a successful non-Table SIRVA claim, the facts and circumstances posed therein are distinguishable (and highlight why the present case could not similarly succeed). For starters, the *L.J.* Petition was filed *prior* to the time when SIRVA was added to the Vaccine Table (although I looked to the Table elements for guidance). *L.J.*, 2021 WL 6845593, at *8. Otherwise, *L.J.* turned on different fact questions involving pain experienced elsewhere in the body.

[10] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.